NSAID regulation in vulture range states: A review and analysis of European and South Asian policies regulating the licensing and banning of vulture-toxic drugs.

Master Thesis

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NSAID regulation in vulture range states:
A review and analysis of European and South Asian policies regulating the licensing and banning of vulture-toxic drugs.

Master’s Thesis
Environmental Sciences
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Abstract

Within a decade (1994-2004), the nephrotoxic effects of the non-steroidal anti-inflammatory drug (NSAID) diclofenac reduced South Asia’s once abundant endemic vulture species to one of the most threatened groups of birds in the world. After a suite of bans on the veterinary use of diclofenac across the Indian Subcontinent in the late-2000s, vulture populations in some areas are thought to be stabilising although numbers remain critically low. Further regulatory progress on banning other NSAIDs also known to be vulture-toxic has been slow and a mosaic of inconsistent licensing decisions exists across the range states of these obligate scavengers. This thesis documents the workings of existing drug licensing procedures for the authorisation and banning of veterinary NSAIDs across key vulture range states in Europe and South Asia, before analysing these procedures through the lens of various policy legitimacy indicators. While contextual factors limit direct comparisons between certain case studies, all are facing similar challenges that restrict legitimate and evidence-based veterinary NSAID regulation: (i) decisions on NSAID licensing have been made without regards to safety testing in non-target species including vultures, (ii), the limited bindingness of national and international vulture conservation commitments is impeding evidence-based decision-making, (iii), policy variation across the Indian subcontinent has engendered incoherence and ambiguity, while the transparency and enforcement of measures remains a challenge and (iv), the precautionary approach applied to the regulation of other diffuse ecotoxic chemicals in the European Union has not been afforded to the use of veterinary NSAIDs.

Acknowledgements

I would like to thank my supervisors, Eva Lieberherr and Rhys Green, for their continued support and feedback throughout this project. To Rhys, for proposing such an interesting project and providing the wealth of contacts and expertise necessary to conduct this work, and to Eva for her guidance on policy analysis and discussion.

I would also like to thank all of my interviewees, without whom this thesis would not have been possible. The kindness, generosity and guidance I received from the community of researchers and individuals working in this space has been incredible. Special mention must go to Chris Bowden, Abhishek Ghoshal and Antoni Margalida for their extensive support, feedback and provision of information.
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<th>Full Form</th>
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<tr>
<td>AEMPS</td>
<td>Spanish Agency of Medicines and Sanitary Products</td>
</tr>
<tr>
<td>BCN</td>
<td>Bird Conservation Nepal</td>
</tr>
<tr>
<td>BFD</td>
<td>Bangladesh Forest Department</td>
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<tr>
<td>BNHS</td>
<td>Bombay Natural History Society</td>
</tr>
<tr>
<td>BNVRC</td>
<td>Bangladesh National Vulture Recovery Committee</td>
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<tr>
<td>BSE</td>
<td>Bovine spongiform encephalopathy</td>
</tr>
<tr>
<td>BV</td>
<td>Bearded vulture, <em>Gypaetus barbatus</em></td>
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<td>CDSCO</td>
<td>Central Drugs Standard Control Organisation (India)</td>
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<tr>
<td>CMS</td>
<td>Convention on the Conservation of Migratory Species of Wild Animals</td>
</tr>
<tr>
<td>CR</td>
<td>Critically Endangered (IUCN Red List category of threat)</td>
</tr>
<tr>
<td>CV</td>
<td>Cinereous vulture, <em>Aegypius monachus</em></td>
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<td>CVMP</td>
<td>Committee for Veterinary Medicinal Products (EMA)</td>
</tr>
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<td>CVWG</td>
<td>Cambodia Vulture Working Group</td>
</tr>
<tr>
<td>DCGI</td>
<td>Drug Controller General of India</td>
</tr>
<tr>
<td>DDA</td>
<td>Department of Drug Administration (Nepal)</td>
</tr>
<tr>
<td>DGDA</td>
<td>Directorate General of Drug Administration (Bangladesh)</td>
</tr>
<tr>
<td>DLS</td>
<td>Department of Livestock Services (Bangladesh, Nepal)</td>
</tr>
<tr>
<td>DNPWC</td>
<td>Department of National Parks and Wildlife Conservation (Nepal)</td>
</tr>
<tr>
<td>DRAP</td>
<td>Drug Regulatory Authority of Pakistan</td>
</tr>
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<td>DTAB</td>
<td>Drugs Technical Advisory Board (India)</td>
</tr>
<tr>
<td>ECAH</td>
<td>Empowered Committee for Animal Health (India)</td>
</tr>
<tr>
<td>EFSA</td>
<td>European Food Safety Authority</td>
</tr>
<tr>
<td>EGV</td>
<td>Eurasian griffon vulture, <em>Gyps fulvus</em></td>
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<td>EMA</td>
<td>European Medicines Agency</td>
</tr>
<tr>
<td>EN</td>
<td>Endangered (IUCN Red List category of threat)</td>
</tr>
<tr>
<td>EU</td>
<td>European Union</td>
</tr>
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<td>EV</td>
<td>Egyptian vulture, <em>Neophron percnopterus</em></td>
</tr>
<tr>
<td>FACCC</td>
<td>Fundraising, Advocacy and Communications Committee (of SAVE)</td>
</tr>
<tr>
<td>GDAHHP</td>
<td>General Directorate of Animal Health and Production (Cambodia)</td>
</tr>
<tr>
<td>HGV</td>
<td>Himalayan griffon vulture, <em>Gyps himalayensis</em></td>
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<td>INFAH</td>
<td>Indian Federation of Animal Health Companies</td>
</tr>
<tr>
<td>IVR</td>
<td>Indian Veterinary Research Institute</td>
</tr>
<tr>
<td>IUCN</td>
<td>International Union for the Conservation of Nature</td>
</tr>
<tr>
<td>IUCN SSC VSG</td>
<td>IUCN Species Survival Commission: Vulture Specialist Group</td>
</tr>
<tr>
<td>IVRI</td>
<td>Indian Veterinary Research Institute</td>
</tr>
<tr>
<td>LBV</td>
<td>Long-billed vulture, <em>Gyps indicus</em></td>
</tr>
<tr>
<td>MAFF</td>
<td>Ministry of Agriculture, Forests and Fisheries (Cambodia)</td>
</tr>
<tr>
<td>MITECO</td>
<td>Ministry for the Ecological Transition and Demographic Challenge (Spain)</td>
</tr>
<tr>
<td>MLE</td>
<td>Maximum level of exposure</td>
</tr>
<tr>
<td>MoAFF</td>
<td>Ministry of Agriculture, Fisheries and Food (Spain)</td>
</tr>
<tr>
<td>MoCC</td>
<td>Ministry of Climate Change (Pakistan)</td>
</tr>
<tr>
<td>MoE</td>
<td>Ministry of Environment (Cambodia)</td>
</tr>
<tr>
<td>Acronym</td>
<td>Description</td>
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<tr>
<td>---------</td>
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</tr>
<tr>
<td>MoEFCC</td>
<td>Ministry of the Environment, Forestry and Climate Change (India)</td>
</tr>
<tr>
<td>MoFAHD</td>
<td>Ministry of Fisheries, Animal Husbandry and Dairying (India)</td>
</tr>
<tr>
<td>MoNHSRC</td>
<td>Ministry of National Health Services, Regulation and Coordination (Pakistan)</td>
</tr>
<tr>
<td>MoU</td>
<td>Memorandum of Understanding</td>
</tr>
<tr>
<td>MsAP</td>
<td>Multi-species Action Plan</td>
</tr>
<tr>
<td>NGO</td>
<td>Non-governmental organisation</td>
</tr>
<tr>
<td>NSAID</td>
<td>Non-steroidal anti-inflammatory drug</td>
</tr>
<tr>
<td>NVCAP</td>
<td>National Vulture Conservation Action Plan</td>
</tr>
<tr>
<td>NVRC</td>
<td>National Vulture Recovery Committee</td>
</tr>
<tr>
<td>OWRV</td>
<td>Oriental white-rumped vulture, <em>Gyps bengalensis</em></td>
</tr>
<tr>
<td>PhACs</td>
<td>Pharmaceutically active compounds</td>
</tr>
<tr>
<td>PP</td>
<td>Precautionary Principle</td>
</tr>
<tr>
<td>PVRP</td>
<td>Pakistan Vulture Restoration Project</td>
</tr>
<tr>
<td>PWG</td>
<td>Pharma Working Group</td>
</tr>
<tr>
<td>NT</td>
<td>Near Threatened (IUCN Red List category of threat)</td>
</tr>
<tr>
<td>RHV</td>
<td>Red-headed vulture, <em>Sarcogyps calvus</em></td>
</tr>
<tr>
<td>RSC</td>
<td>Regional Steering Committee (of South Asian Governments)</td>
</tr>
<tr>
<td>RSPB</td>
<td>Royal Society for the Protection of Birds (UK)</td>
</tr>
<tr>
<td>SAVE</td>
<td>Saving Asia’s Vultures from Extinction</td>
</tr>
<tr>
<td>SBV</td>
<td>Slender-billed vulture, <em>Gyps tenuirostris</em></td>
</tr>
<tr>
<td>TEEB</td>
<td>The Economics of Ecosystems &amp; Biodiversity</td>
</tr>
<tr>
<td>TDRC</td>
<td>Technical Drugs Regulation Review Committee (India)</td>
</tr>
<tr>
<td>VCF</td>
<td>Vulture Conservation Foundation</td>
</tr>
<tr>
<td>VMPs</td>
<td>Veterinary Medicinal Products (EU)</td>
</tr>
<tr>
<td>VPC</td>
<td>Veterinary Pharmaceutical Committee (EU Commission)</td>
</tr>
<tr>
<td>VSFS</td>
<td>Vulture Safe Feeding Site</td>
</tr>
<tr>
<td>VSZ</td>
<td>Vulture Safe Zone</td>
</tr>
<tr>
<td>VU</td>
<td>Vulnerable (IUCN Red List category of threat)</td>
</tr>
<tr>
<td>MsAP</td>
<td>Multi-species Action Plan to Conserve African-Eurasian Vultures (CMS)</td>
</tr>
<tr>
<td>WI</td>
<td>Wildlife Institute of India</td>
</tr>
<tr>
<td>WWF</td>
<td>World Wildlife Fund</td>
</tr>
<tr>
<td>ZSL</td>
<td>Zoological Society of London (UK)</td>
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</table>
INTRODUCTION

In the early 2000s, the unprecedented and previously unexplained decline of Gyps vulture populations across the Indian subcontinent was linked to the widespread veterinary use of the non-steroidal anti-inflammatory drug (NSAID) diclofenac in cattle (Oaks et al., 2004). Diclofenac was initially developed and marketed for human medicine but was later identified as a profitable veterinary drug by pharmaceutical companies in Asia after its patent lapsed. Administered to cheaply alleviate inflammation, pain and fever in cattle across South Asia, diclofenac was first licensed for veterinary use in India in 1993 and began to be widely dispensed in 1994 (Cuthbert et al., 2014a; IUCN, 2004). However, consumption of contaminated carrion led to scores of vultures dying within days of exposure from kidney failure due to the accumulation and precipitation of uric acid in their blood and internal organs (Oaks et al., 2004; Swan et al., 2006). Once thought to be the world’s most abundant large raptor, there were likely tens of millions of oriental white-rumped vultures [OWRV; Gyps bengalensis] roaming the skies of the Indian subcontinent in the 1980s (Houston, 1985). Today, only around 5,000 mature individuals of this species remain (Prakash et al., 2019). Together with two other Gyps species – the long-billed and slender-billed vultures [LBV; Gyps indicus, SBV; Gyps tenuirostris] – all three were listed as ‘Critically Endangered’ on the International Union for the Conservation of Nature’s (IUCN) Red List in 2000, having up to then been considered as ‘Least Concern’ (IUCN, 2022). Cattle carcass contamination with diclofenac in India was shown to be high enough to conclude that diclofenac alone was sufficient to have caused the observed declines (Green et al., 2004, 2007).

Within barely a decade after 1994, the widespread use and nephrotoxic effects of diclofenac saw the collapse of vulture populations across South Asia. In response to the crisis, governments across the Indian subcontinent banned its veterinary use and embarked on concerted efforts to promote population recovery (Delhi, 2012). Since the first bans in 2006, enforcement has remained a challenge in several vulture range states (Galligan et al., 2021), although vulture recovery has begun in Nepal where measures to discourage veterinary use of diclofenac have been particularly effective (Galligan et al., 2020). Furthermore, other veterinary NSAIDs also known to cause harm to vultures remain largely unregulated: only two of the eleven in use have so far been confirmed as vulture safe (Chandramohan et al., 2022; Cuthbert et al., 2011b). Besides diclofenac, there is evidence that four others (aceclofenac, ketoprofen, flunixin, nimesulide) cause similar nephrotoxic effects in Gyps vultures at doses likely to be encountered in the wild (Chandramohan et al., 2022 Cuthbert et al., 2016; Galligan et al., 2016; Naidoo et al., 2010; Zorilla et al., 2015). The discovery of these other vulture-toxic NSAIDs poses a continued threat to the remaining critically low South Asian vulture populations. Regulatory action is starting to be taken against a few of these other drugs, and more diclofenac bans have been introduced in other vulture range states including Cambodia, Oman and Iran. Meanwhile, the European Union’s decision not to ban the veterinary use of diclofenac in vulture range Member States has drawn widespread criticism. In particular, the recent marketing authorisation of diclofenac in Spain, which is home to over 90% of Europe’s vultures, has raised concern over the risk to future population stability (Green et al., 2016; Margalida and Oliva-Vidal, 2017).

Although several countries have now taken regulatory action against diclofenac, efforts to ensure the banning of other vulture-toxic NSAIDs differ hugely among states and regions and occur on a case-by-case, ad hoc basis. At present, ‘no specific policy instrument exists to ensure that the development of future NSAIDs, nor the retrospective assessment of existing products, is wildlife friendly’ (Botha et al., 2017, p.82). The goal to establish such an instrument is one repeated in both
international and national action plans and frameworks (Botha et al., 2017). However, there is little existing literature exploring the current process by which veterinary NSAID licensing and banning is achieved, nor about the actors, agencies and decision-making processes involved.

Through qualitative interviews with regional experts and comprehensive literature analysis, this thesis aims to provide the first detailed documentation of the workings of existing licensing and banning procedures. I will then assess their legitimacy – that is, the quality of governance processes and their performance in regulating the veterinary use of vulture-toxic pharmaceutical drugs in a timely, appropriate and effective way – through the lens of various policy indicators. The regional experts consulted have been drawn from a diverse array of fields across Europe and South Asia, with the help of the broad network of partners involved in the international vulture conservation consortium SAVE (Saving Asia's Vultures from Extinction). Interviewees include those from government ministries, pharmaceutical companies manufacturing veterinary NSAIDs, and local, national and international NGOs working in vulture conservation. Furthermore, the hurdles facing the development of a more robust future policy framework will be discussed in light of the challenges encountered by current approaches. Hence this thesis asks: in vulture range states with existing procedures for regulating veterinary NSAIDs, how do these procedures work and are they reducing the risk posed to vultures through legitimate and evidence-based regulation of drugs known to be vulture-toxic?

Beyond white-rumped, long-billed and slender-billed vultures, some other species of Old World vultures – those found across Eurasia and Africa, belonging to the family Accipitridae – are also being shown to be vulnerable to the fatal effects of certain NSAIDs. The New World vultures of the Americas (family Cathartidae) are less susceptible (Rattner et al., 2008). Despite being similarly affected by these drugs, it is important to remember throughout this thesis that Old World vultures in different geographic regions face a distinct portfolio of threats, each with varying gravity (Botha et al., 2017). This distinction can in part explain the variation in strategies employed to protect remaining vulture populations, but also makes direct comparison across vulture range states difficult and in some cases unhelpful. For example, African and European vultures are at greater risk of death through the consumption of deliberately-set poisoned baits, whereas the threat of veterinary NSAIDs is more pronounced in South Asia (Botha et al., 2017). Among others, the variety in animal husbandry practices, preferred veterinary NSAIDs, cultural constraints on human consumption of beef, carcass management strategies and societal perceptions of vultures, all vary spatially, meaning NSAID policies cannot be considered in a vacuum without appreciation of social context. These other factors will therefore also be drawn upon to contextualise the problem regionally, while hopefully allowing conclusions to be reached regarding the efficacy of existing and future regulatory procedures.

This thesis is based on case studies from European and Asian countries who have taken an active role in regulating the use of veterinary NSAIDs with a view to protecting vultures, or whose policy frameworks have at least considered the impact on vultures. The initial focus will be on the four parties to the Regional Declaration on the Conservation of South Asia's Critically Endangered Vulture Species: India, Pakistan, Nepal and Bangladesh, whose partnership in 2012 spearheaded international vulture conservation efforts (Delhi, 2012). Other countries across South Asia – Cambodia in the Southeast and Oman and Saudi Arabia in the Middle East – will then be used to illustrate more recent regulatory moves taken utilising the knowledge and evidence gained from work done on the Indian subcontinent. Finally, Spain will serve as the European case study to assess how the problem is being handled by the European Union (EU) and by the few Member States who have authorised the use of veterinary diclofenac. Africa will not be discussed as no country is yet
to take regulatory action against veterinary NSAIDs, and the apparent prevalence and threat of these drugs remains dwarfed by other intentional, unintentional and sentinel poisoning incidents (Botha et al., 2017). Analysis of these case studies will include the application of policy indicators to assess the legitimacy of existing procedures, including analysis of policy coherence, ambiguity, transparency and bindingness. This analysis aims to reveal the lessons that can be or have been learned from past NSAID regulation, and how these lessons can be applied to the creation of a more robust policy instrument. The fundamental challenges to further NSAID regulation will be considered, as well as an investigation of the policy levers best suited to the management of this problem long-term.

BACKGROUND & CONTEXT

NSAIDs

One of the most prescribed class of drugs in the world, non-steroidal anti-inflammatory drugs (NSAIDs) are widely used for their analgesic, antipyretic and anti-inflammatory properties in both human and veterinary medicine (Ghlichloo and Gerriets, 2022). Since the discovery of salicylates – the active ingredient in the first naturally-occurring NSAIDs – in the mid-19th century (Rainsford, 2007), NSAIDs now number over fifty different drugs including aspirin, ibuprofen, diclofenac and ketoprofen (Vonkeman and van de Laar, 2010).

Despite their structural diversity, NSAIDs share a common mechanism of action. Since the discovery of this mechanism by Sir John Vane in the 1970s, great progress has been made in explaining how NSAIDs block the biosynthesis of prostaglandins via the inhibition of cyclooxygenase (‘COX’) enzymes (Rao and Knaus, 2008; Vane, 2000). Vast pharmaceutical and financial resources have been devoted to understanding their common side effects in humans (Davis and Robson, 2016), as well as their effect on other medical conditions including COVID-19 (Abu Esba et al., 2021), Alzheimer’s (Zhang et al., 2018) and colon cancer (Vonkeman and van de Laar, 2010). Yet research into the environmental chemistry and ecotoxicology of NSAIDs is primitive by comparison, despite them quickly emerging as global contaminants of concern (Rasheed et al., 2019). While environmental exposure to NSAIDs via wastewater treatment plants or as leachate from landfills is increasingly studied (Rastogi et al., 2021), the veterinary use of NSAID pharmaceuticals as a source of environmental exposure remains largely undocumented (Lonappan et al., 2016). However, one such risk that is now well understood is their impact on some obligate and facultative avian scavengers (Oaks et al., 2004). Carcass contamination with NSAIDs can put these birds at risk of toxic levels of exposure, often at doses far higher than those recommended in veterinary practice (Taggart et al., 2009).
Veterinary NSAIDs in South Asia

The precipitous declines of Old World vultures across South Asia was first reported by Dr Vibhu Prakash, Principal Scientist at the Bombay Natural History Society (BNHS). Dr Prakash observed that in the decade between 1988 and 1999, vulture populations in Keoladeo National Park (Rajasthan, India) declined rapidly at approximately 50% per year, leading to extinction of the colony by 2003 (Prakash, 1999). The declines were linked to mass mortality also seen across the wider Indian subcontinent, with some vultures exhibiting abnormal behaviour, most notably ‘neck drooping’ (Prakash et al., 2003). Blamed on everything from American pesticides, a lack of food, heavy metals, to a viral infectious disease (Cunningham et al., 2003), the true cause of decline was discovered by a US-based raptor conservation NGO, The Peregrine Fund, working with partners in Pakistan (Oaks et al., 2004). Post-mortem analysis revealed that most dead wild vultures in India, Pakistan and Nepal were suffering from extensive visceral gout perfectly associated with the presence of diclofenac (Oaks et al., 2004; Shultz et al., 2004). Histopathological examination of kidney tissue from experimentally treated birds showed that they had characteristic necrotic lesions of the kidney tubules (Meteyer et al., 2005). The same post-mortem signs and pathology as that seen in experimentally treated birds were also seen in most vultures found dead in the wild during the decline (Oaks et al., 2004; Shultz et al., 2004). A consortium of national and international organisations (including BNHS, Bird Conservation Nepal (BCN), Royal Society for the Protection of Birds (RSPB), and Zoological Society of London (ZSL)) confirmed and extended these findings (Pain et al., 2008).

By 2007, the population of OWRV in India had fallen to 0.1% of their numbers in the early 1990s, and the population of LBV and SBV combined had fallen to 3.2% (Prakash et al., 2007). South Asian vultures face a multitude of threats including poison baits, loss of nesting habitat, declines in wild ungulate populations and collision with human infrastructure (Botha et al., 2017). However, it was shown that less than 0.8% of domesticated ungulate carcasses would need to have been lethally contaminated with diclofenac to cause the observed rate of population decline in India and Pakistan (Green et al., 2004). Subsequent measurements of actual diclofenac concentrations in cattle carcasses in India showed that the level of real-world contamination was more than sufficient to produce these declines (Green et al., 2007). This evidence demonstrated that the nephrotoxic effects of diclofenac alone were responsible for the population crash, without invoking a role for any other environmental drivers.

The fatal poisoning of OWRV, LBV and SBV populations through their consumption of diclofenac contaminated carrion has been shown to affect some other Accipitriformes, with nine Eurasian vulture species now confirmed or suspected to be susceptible to diclofenac poisoning (Table 1). Besides *Gyps* vultures, other obligate and facultative scavengers in the same family (*Accipitridae*) including Egyptian vultures [*Neophron percnopterus*], red-headed vultures [*Sarcogyps calvus*] and steppe eagles [*Aquila nipalensis*] may also be at risk (Galligan et al., 2014; Sharma et al., 2014). However, the New World vultures of the Americas (family *Cathartidae*, which is not closely related to the *Accipitridae*) have been found to tolerate over 100 times more diclofenac than is lethal to these Old World vultures (Rattner et al., 2008). The toxicity of diclofenac to even less closely related bird species, such as domestic fowl and pigeons, is also low.
Table 1: Vulture species found in Asia and Europe confirmed or suspected to be susceptible to diclofenac poisoning. Data from: Botha et al., 2017; Galligan et al., 2014; IUCN, 2022; SAVE, 2020.

<table>
<thead>
<tr>
<th>Species, abbreviation</th>
<th>Scientific name</th>
<th>Range</th>
<th>Est. global population</th>
<th>Global IUCN threat level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oriental white-rumped vulture, OWRV</td>
<td>Gyps bengalensis</td>
<td>South &amp; SE Asia</td>
<td>4,000-6,000</td>
<td>Critically Endangered, CR</td>
</tr>
<tr>
<td>Long-billed vulture, LBV</td>
<td>Gyps indicus</td>
<td>South Asia</td>
<td>5,000-15,000</td>
<td></td>
</tr>
<tr>
<td>Slender-billed vulture, SBV</td>
<td>Gyps tenuirostris</td>
<td>South &amp; SE Asia</td>
<td>730-870</td>
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<td>Red-headed vulture, RHV</td>
<td>Sarcogyps calvus</td>
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<td>2,500-9,999</td>
<td></td>
</tr>
<tr>
<td>Egyptian vulture, EV</td>
<td>Neophron percnopterus</td>
<td>Africa, Asia, Europe</td>
<td>12,400-36,000</td>
<td>Endangered, EN</td>
</tr>
<tr>
<td>Himalayan griffon vulture, HGV</td>
<td>Gyps himalayensis</td>
<td>Asia</td>
<td>66,000-334,000</td>
<td>Near Threatened, NT</td>
</tr>
<tr>
<td>Bearded vulture, BV</td>
<td>Gypaetus barbatus</td>
<td>Africa, Asia, Europe</td>
<td>1,675-6,700</td>
<td></td>
</tr>
<tr>
<td>Cinereous vulture, CV</td>
<td>Aegypius monachus</td>
<td>Europe, Asia</td>
<td>16,800-22,800</td>
<td></td>
</tr>
<tr>
<td>Eurasian griffon vulture, EGV</td>
<td>Gyps fulvus</td>
<td>Africa, Asia, Europe</td>
<td>80,000-900,000</td>
<td>Least Concern, LC</td>
</tr>
</tbody>
</table>

The life-history characteristics of vultures and other large-bodies scavenging raptors – namely their long lifespans, slow maturation and low fecundity – make their population size and trend especially sensitive to additional adult mortality and hence they are especially vulnerable to dramatic population declines (Green et al., 2016, 2022). The estimated doubling time for a wild vulture population is at least ten years under optimum conditions, so the road to recovery will be long (MoEFCC, 2020). This reproductive strategy, combined with the devastating effects of diclofenac and other causes of additional anthropogenic mortality, have rendered Old World Vultures the most threatened group of birds in the world (Figure 1) (Buechley and Şekercioğlu, 2016). As yet, no other bird species is known to have undergone such declines in such a short period and still survived extinction (Botha et al., 2017).

Figure 1: Red List index for Old World vultures compared to all birds. Figure taken from: Safford et al., 2019.
As well as life-history traits, the susceptibility of Old World vulture species to the effects of diclofenac is also a result of feeding hierarchies and diet specialisations (Botha et al., 2017). White-rumped, long-billed and slender-billed vultures are resident in the lowlands of South Asia and specialise on eating soft tissues, mostly of domestic cattle and water buffaloes in whose carcasses lethal levels of NSAIDs are typically found. This year-round exposure makes these species especially sensitive to a given level of contamination. However, there is growing concern that migratory scavengers who breed in areas where few NSAIDs are used but migrate to lowland South Asia may also suffer significant exposure. These species include Himalayan griffon vultures [HGV; Gyps himalayensis] which breed at high altitudes but whose pre-breeding immatures migrate to the lowlands, and steppe eagles which breed in Central Asia and migrate to winter in South Asia. The abrupt vacation of the scavenging niche by the resident vultures may have increased the proportion of these species scavenging on contaminated carcasses of domestic cattle in the lowlands, thereby increasing their risk of exposure. Furthermore, species which have historically specialised in the consumption of other tissues such as bones (e.g., bearded vultures [BV; Gypaetus barbatus]), may also be at higher risk as competition for soft-tissues (where NSAIDs are found in their highest concentration) is reduced (Acharya et al., 2009; Botha et al., 2017; Das et al., 2011).

Vultures are a group of keystone species and contribute to a multitude of ecosystem services, mainly stemming from their removal of carrion. They are masterfully adapted for detoxification: their low stomach pH kills bacteria and resistant spores (Houston and Cooper, 1975), and they kill bacteria on their legs after feeding through urination (Ilyas, 2014). In addition to serving as vital pest and disease control agents (Markandya et al., 2008), they have been shown to contribute to the reduction of greenhouse gas emissions (Morales-Reyes et al., 2015), as well as the fundamental task of efficiently removing vast quantities of organic waste from our landscapes free of charge. A study by IUCN Pakistan estimated the monetary value of a single vulture at between $10,400-23,800 (Karkaria, 2015). Furthermore, they have significant spiritual and existence values to people across South Asia. The Hindu demi-god brothers, Jatayu and Sampati, take the form of vultures and are thought to represent courage and self-sacrifice. Vultures are believed by some to be the spy of the god Sani (Saturn) and they continue to be relied upon in traditional burial rituals ('sky burials' and 'towers of silence') by Himalayan and Tibetan Buddhists, as well as by Parsi Zoroastrians (Bhusal et al., 2020; Karkaria, 2015).

The extraordinary declines of Asian vulture populations have important implications for human health. The dwindling numbers of scavenging Gyps vultures has led to a massive rise in feral dogs filling this vacant niche: between 1992 and 2006, their numbers in India increased by over 5.5 million, resulting in 38.5 million additional dog bites (Markandya et al., 2008). At one carcass dump site alone, dog numbers rose from 60 to 1200 between 1992-2001 (Prakash et al., 2003). This increase has, in turn, led to a rise in rabies incidence which caused an estimated 50,000 additional human casualties in India between 1992-2006 (Swan et al., 2006). Together with the increased incidence of other pests and diseases (including anthrax, rats and bubonic plague), the total costs of vulture losses on human health in India over the same period was estimated at $34 billion (Markandya et al., 2008). More recent studies have estimated that all-cause human mortality increased by over 4% between 2000 and 2005 in Indian districts formerly home to large populations of vultures (Frank and Sudarshan, 2023). The same study estimated the cost of operating a network of carrion incinerators to replace the ecosystem services provided by vultures would exceed US $750 million each year (without accounting for the cost of air pollution generated or transportation of carrion required) (Frank and Sudarshan, 2023). Similarly in Spain, the waste disposal services provided by vultures are worth an estimated US $50 million annually and avoid the emission of 77,000 metric tons of carbon dioxide (Morales-Reyes et al., 2015). Population recovery is therefore of significant value to human health and economic welfare.
Historically, vultures relied on the carcasses of wild ungulates as their primary food source (MoEFCC, 2020). However, since the industrialisation and expansion of livestock farming, the availability of wild food sources has dwindled and been replaced by an abundant supply of carrion derived from domesticated ungulates. Until the early 1990s, cultural reasons meant that this presented a stable and safe food supply for South Asian vultures, particularly in India. In Hinduism, the prohibition on the killing of cattle and consumption of beef means that cattle are primarily farmed for milk, leather and labour. There are serious legal implications associated with harming a cow: in 20 of the 28 Indian states, the slaughter of cattle is regulated or prohibited and in extreme cases carries a punishment of life imprisonment (Gujarat Animal Preservation (Amendment) Act, 2011). These cultural norms mean large numbers of ageing and infirm cattle are cared for and routinely dosed with drugs prior to their natural death by cattle welfare charities. In areas where Islam is prevalent, cattle which die from disease or are not slaughtered in the permissible (‘halal’) way are usually not consumed by humans. Hence, when diclofenac was first licensed for veterinary use in India and Pakistan in the 1990s, this plentiful supply of cattle carrion was no longer safe for vultures (IUCN, 2004). Furthermore, the shift in vulture diets from wild to domesticated ungulate carrion has increasingly brought them into conflict with humans. They are at greater risk of (accidental or deliberate) exposure to poison baits set to kill carnivores and have been the target of growing community animosity amid reports of attacks on livestock in Spain (Duriez et al., 2019; Margalida et al., 2014).

The IUCN called for urgent action to be taken to conserve Gyps species in 2004 (IUCN, 2004). In response, the Governments of India, Nepal and Pakistan banned the veterinary use of diclofenac in 2006, followed by Bangladesh in 2010. Moreover, the four governments reached a united political agreement in 2012 to coordinate their response; the actions agreed upon included establishing ‘vulture safe zones’ (VSZ) and conservation breeding centres (VCBC), while upholding diclofenac bans and promoting research and monitoring (Delhi, 2012). Since this Regional Declaration, a Regional Steering Committee (RSC) has met biannually to assess, discuss and consolidate national progress (Delhi, 2012; Interview 17). Other vulture range states across Asia have also moved to ban veterinary diclofenac, including Iran (2015), Cambodia (2019) and Oman (2020) (SAVE, 2015, 2019, 2020). Saudi Arabia may become the latest country to do so, with a decision expected soon.

Figure 2: Change in all-cause human mortality between 1988 and 2005 in Indian districts with high or low suitability for vulture habitation. Figure demonstrates the divergence of all-cause mortality after the approval of veterinary diclofenac and increased human death rates in districts home to declining populations of vultures. Figure taken from: Frank and Sudarshan, 2023.
Since introduction of the first diclofenac bans, several studies have tracked levels of compliance with regulations and vulture population recovery across South Asia. Although results have shown imperfect enforcement and awareness of the bans, there is evidence that populations are stabilising and, in some areas, beginning to recover (Chaudhry et al., 2012; Galligan et al., 2019, 2014). However, even in these cases, numbers remain critically low (Galligan et al., 2019; Prakash et al., 2019). Moreover, evidence for the illegal use of diclofenac persists, including via the veterinary use of human formulations of the drug (Cuthbert et al., 2011a; Galligan et al., 2021).

In surveys of cattle carcasses available to vultures in India, 16.2% contained detectable NSAID residues of some kind (Galligan et al., 2022). Despite the relatively fast international clamp-down on diclofenac, at least eleven other veterinary NSAIDs remain available across South Asia and are increasing in popularity to fill the vacant niche in the market left by the once ubiquitous diclofenac (Galligan et al., 2016). Among these, several have now also been shown to also cause nephrotoxic effects in vultures (Table 2) and their continued use is likely stalling further population recovery (Nambirajan et al., 2021). However, knowledge or at least suspicion of the toxicity of other veterinary NSAIDs is not new: both ketoprofen and aceclofenac were mentioned in the 2012 Regional Declaration as ‘drugs with similar toxicity to diclofenac’ (Delhi, 2012). Although Bangladesh recently became the first nation to ban veterinary ketoprofen, other NSAIDs have yet to receive the same stringent and coordinated regulatory attention despite an increasingly strong evidence-base for their toxicity to vultures (Bowden, 2020). Aceclofenac, for example, has been shown to be a pro-drug of diclofenac that rapidly metabolises to the banned NSAID on ingestion by cattle (Galligan et al., 2016). Again, this is not new knowledge: it was described as such in the 2012 Regional Declaration, but the drug is yet to be widely regulated in any vulture range state (Delhi, 2012).

**Table 2**: Threat of different NSAIDs to Old World Gyps vultures. Table adapted from: Bowden, 2020.

<table>
<thead>
<tr>
<th>NSAID</th>
<th>Vulture threat</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diclofenac</td>
<td>Toxic</td>
<td>(Oaks et al., 2004; Shultz et al., 2004; Swan et al., 2006)</td>
</tr>
<tr>
<td>Ketoprofen</td>
<td></td>
<td>(Naidoo et al., 2010a, 2010b)</td>
</tr>
<tr>
<td>Aceclofenac</td>
<td>ToxG</td>
<td>(Galligan et al., 2016; Sharma, 2012)</td>
</tr>
<tr>
<td>Nimesulide</td>
<td></td>
<td>(Cuthbert et al., 2016; Galligan et al., 2022; Nambirajan et al., 2021)</td>
</tr>
<tr>
<td>Flunixin</td>
<td></td>
<td>(Cuthbert et al., 2007; Herrero-Villar et al., 2020; Zorrilla et al., 2015)</td>
</tr>
<tr>
<td>Carprofen</td>
<td>Toxic at high doses</td>
<td>(Cuthbert et al., 2007; Naidoo et al., 2018)</td>
</tr>
<tr>
<td>Meloxicam</td>
<td>Safe</td>
<td>(Naidoo et al., 2008; Swan et al., 2006; Swarup et al., 2007)</td>
</tr>
<tr>
<td>Tolfenamic acid</td>
<td></td>
<td>(Chandramohan et al., 2022)</td>
</tr>
</tbody>
</table>
Only two NSAIDs have been confirmed as vulture-safe at doses likely to be encountered by wild vultures – meloxicam and tolfenamic acid (Chandramohan et al., 2022; Swan et al., 2006). Meloxicam is not as fast acting or antipyretic as diclofenac, and poor formulations with high pH and high osmolarity cause pain in livestock on injection (Cuthbert et al., 2014b). Although this (and its higher price) initially slowed public uptake, improvement in formulations available have increased consumer acceptance and evidence shows it is now widely used (Galligan et al., 2021). Variation among Indian regions in the reduction of the prevalence of diclofenac in samples of cattle carcases since the diclofenac ban was shown to correlate with changes in the prevalence of meloxicam: diclofenac prevalence decreased most where meloxicam prevalence increased most (Cuthbert et al., 2014b). The more recent safety clearance of tolfenamic acid also holds promise as it has more comparable pharmaceutical performance to the historically favoured veterinary NSAIDs (Chandramohan et al., 2022). Yet regional acceptance of these safe alternatives by veterinarians and pharmaceutical companies remains a challenge. Other veterinary NSAIDs sold in South Asia whose effects on vultures remain poorly understood include metamizole, piroxicam, mefenamic acid and phenylbutazone (Galligan et al., 2021).

Veterinary diclofenac in the EU

Despite a wealth of ecotoxicological evidence from South Asia and Southern Africa, and acknowledgement from the European Medicines Agency (EMA) of the risk to vultures (CVMP, 2014), diclofenac was first authorised for veterinary use in Italy in 2009 and is now marketed in five EU Member States: Spain, Italy, Estonia, Latvia and the Czech Republic (Becker, 2016). The marketing authorisation of veterinary diclofenac in Spain is particularly concerning given the country is home to over 90% of vultures found in the Western Palearctic (Margalida and Oliva-Vidal, 2017).

![Figure 3: Positive population trends of four vulture species found in Spain between 1975-2020. Figure taken from: (Moreno-Opo et al., 2021).](image)

Conservation efforts over recent decades have seen the increase of all four vulture species found on the Iberian Peninsula (EGV, CV, EV and BV) (Figure 3). Eurasian griffon vultures [EGV; *Gyps fulvus*] in particular have increased by over 200% in 20 years, with the Spanish EGV population now representing over 95% of those found in the EU (Margalida et al., 2014). However, the concentration of European vultures in Spain together with the increasing annual use of veterinary diclofenac and...
other nephrotoxic NSAIDs could pose a serious threat to the stability of future populations (Moreno-Opo et al., 2021). The first NSAID-related vulture death was recorded in 2012 when an EGV died of flunixin poisoning in Andalusia (Zorrilla et al., 2015). The first diclofenac-related vulture death was then confirmed in a cinereous vulture in Catalonia [CV; *Aegypius monachus*] (Herrero-Villar et al., 2021). Depending on details of exposure, the continued use of veterinary diclofenac in Spain could see the currently increasing EGV populations declining by up to 1-8% annually (Green et al., 2016).

However, the balance of threats facing vultures in Europe and South Asia is significantly different. While vulture populations on the Indian subcontinent collapsed because by the use of veterinary diclofenac, vultures in Spain are currently at much greater risk from the illegal use of poison baits and collision with human infrastructure (Botha et al., 2017). Deliberate setting of poison baits remains the leading threat to several Annex I species of the EU Birds’ Directive, including Eurasian griffon, Egyptian, cinereous, and bearded vultures (Directive 2009/147/EC), and also to wild carnivores. Vultures are increasingly among the host of carnivorous ‘pests’ targeted with such baits. Although the use of poison baits is also a cause of vulture mortality in South Asia, these are usually ‘bycatch’ poisoning incidents in which the target was a ‘pest’ carnivore and not vultures themselves (DNPWC and DoFSC, 2022). This differential balance of threats in part explains why vultures in Spain have not (yet) undergone the same devastating declines as those seen in South Asia.

The Spanish Government’s case in support of the marketing authorisation of veterinary diclofenac hinges on the argument that sufficient risk mitigation measures have been put in place to ensure that the chance of vulture exposure to diclofenac is low (Moreno-Opo et al., 2021). This is based on Spain’s sanitary regulations which prevent carcasses of domesticated ungulates from being dumped at registered vulture feeding stations. However, sampling evidence has revealed that these precautions are not working perfectly (Herrero-Villar et al., 2017; IREC-Tragsatec, 2017), and an EU-authored report concluded that veterinary diclofenac poses a risk to European vultures (CVMP, 2014).

The potential impact of veterinary diclofenac on European vultures has been taken more seriously by other Member States. The Portuguese Parliament recently passed a motion recommending that the marketing authorisation of veterinary diclofenac in Portugal be prevented. Home to the third largest vulture stronghold in Europe and significantly overlapping with Spanish populations, this decision is significant (CVMP, 2014; VCF, 2018).

**Cultural perceptions of vultures**

Alongside varying threats across geographic regions, cultural perceptions of vultures also vary between vulture range states, resulting in differing levels of public engagement and enthusiasm for the introduction of vulture conservation policies by national governments. As discussed above, vultures in South Asia are widely valued for the use and non-use value of the ecosystem services they provide.

However, the cultural perceptions of vultures in Spain since the population rebound of EGVs has taken a more negative turn: they are being accused of a change in feeding behaviour whereby they actively attack livestock (Margalida et al., 2011). The rising number of such complaints from farmers has not been helped by increasingly sensationalist coverage and the proliferation of fake news on social media (Lambertucci et al., 2021; Margalida et al., 2014). This conflict between farmers and vultures is particularly pronounced during the spring birthing season and in areas recently
recolonised by vultures (Margalida et al., 2014; Oliva-Vidal et al., 2022a). Successful complaints lead to farmers receiving compensation, which cost the Spanish Government EUR 278,590 between 2004-2008 (Margalida et al., 2014). Of 1,793 complaints filed in Spain between 1996-2010, 69% were rejected due to the lack of evidence that the animal had been attacked by a vulture while still alive (Margalida et al., 2014). Similarly, a review in Catalonia found only a 22% compensation rate (Oliva-Vidal et al., 2022a). Other studies have also concluded that the perception of this conflict is often blown out of proportion and does not correlate to actual evidence of such behaviour (Duriez et al., 2019). This issue of biased perception, together with community transmission of misinformation, is not exclusive to vultures and is increasingly common in human-wildlife conflict worldwide (Cavalcanti et al., 2010; Moleón et al., 2011).

As a result of these heightened tensions, vultures are becoming a target of illegal poison baits set by farmers to kill pests and carnivores. The recent increase in the abundance and distribution of the grey wolf (*Canis lupus*) in Spain and other EU countries as a result of more effective wildlife protection is also contributing to the increased use of deliberately set poison baits. This killing method has a long history in Spain, with hunters financially compensated for killing certain wild carnivores including vultures, eagles and Iberian lynx since 1903 (Bodega Zugasti, 2014). However, after decades of institutionalised persecution, the use of poison baits is now outlawed under EU law (Decision 82/72/EEC), Spanish national law (Law 4/1989 on the Conservation of Natural Areas and of Wild Flora and Fauna) and Spanish regional law (Law 8/2003 on the Flora and Fauna of Andalucía). Yet illegal use persists, and baits are often laced with banned toxins including aldicarb and carbofuran (Bodega Zugasti, 2014). More than 8,000 such poisoning cases were reported in Spain between 1990-2010, of which over 4,000 involved the killing of vultures (Margalida, 2012). Farmers are dissatisfied with existing policies to deal with the perceived vulture problem and 88% say the incidence of vulture attacks on livestock has increased in recent years, owing to the increase in vulture populations and a decline in food availability (Oliva-Vidal et al., 2022a). This conflict presents additional challenges to organisations advocating for vulture conservation in Spain, including efforts to ban veterinary diclofenac.

**Actors in Vulture Conservation Policy**

Vulture conservation is represented at an international level under which several regional, national and provincial actors function independently or to coordinate the actions and communication of other actors (Figure 4). In 2017, parties to the Convention on the Conservation of Migratory Species of Wild Animals (CMS) adopted the Vulture Multi-Species Action Plan (MsAP) which set out a conservation action plan covering the range of all 15 Old World vulture species (Botha et al., 2017). This was followed in 2020 when Raptors MoU (the CMS Memorandum of Understanding on the Conservation of Migratory Birds of Prey in Africa and Eurasia) published the first strategic implementation plan for the MsAP (Pritchard, 2020). This plan summarised efforts to date and set out a roadmap for the delivery of the MsAP by 2029.

These global-level efforts are regionally facilitated by various organisations including NGOs, committees and legislative bodies. The two most prominent regional NGOs are Saving Asia’s Vultures from Extinction (SAVE) and the Vulture Conservation Foundation (VCF). The former is an international consortium of 25 organisations, founded in 2011, which engages with governments and partners across South Asia to facilitate vulture conservation and cooperation between range states (SAVE, n.d.). The VCF, on the other hand, chiefly operates to further European vulture conservation (VCF, n.d.). Other influential regional actors include the Regional Steering Committee (RSC): a biannual meeting of government officials established in the wake of the 2012 Regional
Declaration between India, Nepal, Pakistan and Bangladesh to coordinate and inform future conservation efforts (IUCN, 2012). RSC members include the government chairs of National Vulture Recovery Committees (NVRCs), representatives from national NGOs, and other organisations including IUCN and BirdLife International. In addition to the four countries originally party to the Regional Declaration, Cambodia has also joined the RSC (Interview 17). The RSC’s early work included the creation of a Global Environment Facility (GEF) proposal to fund South Asian vulture conservation (Interview 17). This proposal included goals for the establishment of VSZs, captive breeding facilities, awareness raising, and an economic valuation of the ecosystem services provided by vultures (‘TEEB’). Unfortunately, this GEF project fell through and since then, the power of the RSC has been in decline (Interview 17). However, the increasing engagement of SAVE with national governments means the ambition for collaboration has not been lost, and the RSC continues to meet.

The recent creation of SAVE’s FACC Pharma Working Group is also paving the way for further regional collaboration. Yet to be fully established, the goal is to form national pharma working groups (PWGs) under NVRCs (Interview 6). Members will include representatives from pharmaceutical companies, government officials, environmental lawyers and NVRCs. National PWGs will present evidence on NSAID safety to NVRCs who will then submit ban requests to national governments where needed. National PWGs will also communicate with each other across South Asia to expedite and coordinate regional action (Interview 6). Furthermore, the use of existing collaborative frameworks could be exercised to encourage the diffusion of vulture conservation messaging through national institutions. The Indian Federation of Animal Health Companies (INFAH) for example, has been tabled as a potential avenue for eliciting widespread change through India’s extensive pharmaceutical industry (Interview 2). A consortium of 52 companies in India’s animal husbandry industry, engagement with this body could increase awareness and action for vulture conservation in India.

![Figure 4: Actors involved in the international, regional, national and provincial vulture conservation discussed in this thesis. Source: own representation.](image-url)
Below these international and regional-level actors, a series of national actors work to achieve and coordinate in-country vulture conservation initiatives (Figure 4). Government-led National Vulture Recovery Committees (NVRCs), for example, include representatives from a variety of fields and have been involved in seeking national bans on vulture-toxic NSAIDs (Interview 6). State-level iterations of these committees also exist in certain places like Tamil Nadu (Interview 10). Provincial initiatives operate in countries including Bangladesh, where Vulture Conservation Teams (VCTs) organise and facilitate local engagement (MoEF, 2016). Besides the actors actively involved in vulture conservation, others also play an important role in steering the fate of this debate. International bodies including the European Medicines Agency (EMA), and national government ministries responsible for drug licensing, animal husbandry and the environment, all hold sway. Industry actors like pharmaceutical companies who manufacture veterinary NSAIDs are another important player and when these industry players band together (e.g., INFAH), their respective lobbying power increases significantly. Aside from the actors outlined above, further detail, definitions and background on the actors shown in Figure 4 is provided in Appendix 2.

Regulatory Ambitions in Vulture Conservation Action Plans

The establishment of a more robust regulatory framework for the licensing and banning of veterinary NSAIDs in vulture range states is discussed in both international and national frameworks. Resolution 11.15 on Preventing Poisoning of Migratory Birds, adopted by Parties to the Convention on the Conservation of Migratory Species of Wild Animals (CMS) in 2014 recommends that countries ‘prohibit the use of veterinary diclofenac’, ‘substitute with readily available safe alternatives’, and ‘introduce mandatory safety-testing of NSAIDs, […] including multi-species testing, […] with burden of proof on the [licence] applicant’ (Botha et al., 2017, p. 82; CMS, 2014). CMS Parties also adopted the Vulture Multi-species Action Plan (MsAP) in 2017, covering 128 countries where the 15 species of Old-World vultures are found. The MsAP aims to ‘promote concerted, collaborative and coordinated international actions towards the recovery of these populations to acceptable levels by 2029’ and its implementation is overseen by the Coordinating Unit of the CMS Raptors Memorandum of Understanding (MoU) (Botha et al., 2017, p.9). Nepal and Pakistan became MoU signatories in 2008, Spain in 2015, India 2016 and Saudi Arabia in 2017. Bangladesh and Oman are not signatories to this non-binding instrument, and Cambodia is not an included range state (CMS, 2020).

Covering the broad spectrum of threats facing Old World vultures across Eurasia and Africa, the MsAP’s second objective is to eliminate the availability of vulture-toxic veterinary NSAIDs and to see the introduction and widespread use of safe alternatives (Botha et al., 2017). Recommended actions include the establishment of a ‘formalised approval process before market authorisation is granted for all veterinary NSAIDs’, ‘robust and mandatory safety testing on vultures’, and a ‘government-backed alert system across the Vulture MsAP range to identify potentially dangerous veterinary drugs already in use’ (Botha et al., 2017, p.106). Those advocating for further regulation hope that such measures will establish consideration for ‘vulture-relevant safety parameters in parallel with existing human parameters’, for example through the study of withdrawal times from various edible tissues in livestock (Botha et al., 2017, p.83). The Coordinating Unit of the Raptors MoU published the first Strategic Implementation Plan for the MsAP in 2020 (Pritchard, 2020). This plan set out detail as to current progress and future tasks relating to the goals outlined in the MsAP. Among eleven ‘flagship projects’, the eighth aims to conduct safety testing on all veterinary NSAIDs currently used in Eurasia and Africa as a steppingstone for withdrawal of those found to be vulture-toxic (Pritchard, 2020). The organisations appointed to lead this initiative are IVRI and BNHS, and it is estimated to cost $20,000 USD per drug and take 2-4 years (Pritchard, 2020).
To date, only four of the fourteen NSAIDs on the market in India have been safety tested on vultures (MoEFCC, 2020). Instead, clinical trials continue to involve other avian test subjects with incomparable susceptibilities. Domestic chickens, for example, can tolerate doses 50-100 times larger than Gyps vultures before they suffer similar nephrotoxic effects (Naidoo et al., 2007). Of course, in vivo clinical trials of a potentially lethal substance on critically endangered species remains challenging to perform with a sufficiently large sample size. CMS argue the development of an accurate in vitro and read-across method holds potential to allow the routine safety-testing of critically endangered vulture species to ascertain their susceptibility to both existing and future drugs (Botha et al., 2017; CMS, 2014).

Many of the goals outlined in the MsAP are also articulated in the national vulture conservation action plans (NVCAPs) set out by countries in South Asia. All four countries party to the Regional Declaration (2012) have formulated at least one NVCAP since their banning of veterinary diclofenac, with Nepal about to publish their third (DNPWC & DoFSC, 2022). These NVCAPs vary in duration but all aim to set out a roadmap for future vulture conservation efforts including the recommended roles of different actors. NVCAPs are prepared by a single government ministry (or NGO in the case of Pakistan). Despite detailing plans for their implementation by various ministries and actors, they have no legal clout or power to bind other stakeholders (Interview 5). India’s NVCAP, for example, is set out by the Ministry of Environment, Forestry and Climate Change (MoEFCC); although in reality there is very little that this ministry can do alone for the conservation of vultures (Interview 4): the licensing and distribution of veterinary drugs is the responsibility of the Central Drugs Standard Control Organisation (CDSCO) under the Ministry of Health and Family Welfare (MoHFW), while dispensing and administration is the responsibility of the Animal Husbandry Commissioner under the Ministry of Fisheries, Animal Husbandry and Dairying (MoFAHD) (MoEFCC, 2020). As a result, although comprehensive and ambitious, the actual implementation of NVCAPs has so far been limited and their subsequent iterations are often repetitive.

The NVCAPs contain many goals for enabling the restoration of healthy vulture populations, including several relevant to the procedures regulating the use of NSAIDs. All four countries aim to create some form of regulatory mechanism to facilitate pre-emptive banning of veterinary NSAIDs proven to be harmful to vultures. India’s NVCAP states that ‘if a drug is found to be toxic by a scientific study and it is published in a high impact factor international journal, it should be automatically removed from the veterinary market once the paper is reviewed by the technical committee of DCGI. A mechanism should be developed to automatically ban a drug if it is found toxic to vultures or other scavenging birds’ (MoEFCC, 2020, p.36). In Bangladesh, the NVCAP aims to establish a ‘ban on ketoprofen and other harmful drugs’ and to ‘develop clear guidelines on the manufacture and use of veterinary NSAIDs’ (MoEF, 2016, p.25). Nepal aims to ‘advocate a regulatory mechanism to ban other NSAIDs shown to be vulture-toxic.’ (DNPWC, 2015, p.14) and this goal was repeated in their most recent action plan (DNPWC & DoFSC, 2022). Pakistan sets out a goal to establish ‘an effective system of regulation of veterinary drugs […] based on safety-testing on vultures for all current painkillers (NSAIDs) and for all potential new ones entering veterinary practice’ (Karki & Mirbahar, 2016, p.23). Despite progress made to ban or restrict certain NSAIDS, the creation of this general regulatory procedure incorporating risk to vultures has yet to be achieved by any range state.
Theoretical Background

In order to help explain the licensing status of veterinary NSAIDs in key vulture range states, the legitimacy of policies and procedures will be analysed. Legitimacy, in general terms, can be thought of as the degree to which those governed by a policy deem it ‘appropriate, proper, and just’ (Tyler, 2006, p.375). It can be further split into three veins: input, throughput and output legitimacy (Scharpf, 1999; Schmidt, 2006). Input legitimacy is concerned with the level of participation in a policy process, which can be affected by the involvement of and communication between actors, as well as the distribution of power and resources among them (Scharpf, 1999). For example, a democracy would be considered to have greater input legitimacy than autocratic or oligarchic forms of government. On the other side, output legitimacy examines the ability of policies to solve a given problem: their ‘effectiveness’ or real-world outcome (Scharpf, 1999). Throughput legitimacy sits between political input and policy output and is instead concerned with the quality of governance processes that go on in the ‘black box’ linking together this systems approach to policy legitimisation (Schmidt, 2013, p.5).

While factors relevant to input and output legitimacy will not form the central part of this analysis, some remain relevant in helping to explain policy formation and outcomes. Elements of input and output legitimacy have considerable overlap with indicators relating to that of throughput (Schmidt, 2013). These three veins of legitimacy are not mutually exclusive and, in many cases, can be compensatory or complementary (Lieberherr and Thomann, 2020). Factors relating to input legitimacy, such as the action resources of actors involved (i.e., both the tangible and intangible assets at an actors’ disposal to influence the policy process) can explain the power balance at play in governance processes and thus subsequent outcomes (Knoepfel et al., 2011). These resources may include the financial means at actors’ disposal, the organisation and size of their workforce, or their level of political support. Participation and inclusiveness across actor groups in policy input also speaks to the fundamental quality of governance processes and hence throughput legitimacy (Newig et al., 2018).

No matter the arsenal of their action resources, actors must concurrently navigate the accountability dilemmas they face between the multiple demands and agendas of other actors (Thomann et al., 2016). These dilemmas of accountability have in the past been discussed in the context of policy implementation (Lieberherr and Thomann, 2020). However, in this thesis they will be considered as an input to contrast an actor’s available action resources: that is, as the flipside to the endowments of actors – a representation of the conflicting pressures they find themselves under. When combined as input factors, balancing of the two may shed further light on the output achieved and intervening throughput legitimacy.

Actors in mediating roles such as governments are under particular pressure to balance these accountability dilemmas. The conflict may be between incentive, vocational or societal pressures – all exerted due to the varying needs and wants of private actors which must be managed and balanced by the state (Lieberherr and Thomann, 2020). While these three categories were used by Lieberherr and Thomann to describe conflicting pressures faced by an actor in policy implementation, they will be adapted here to explain the input pressures a government actor must consider in the policy formation process. Incentive pressures may come from private actors with significant financial lobbying power to further their commercial interests (such as those from the pharmaceutical industry), while vocational pressures might concern citizen livelihoods which could be adversely affected by the prospective policy. Societal pressures may come from a broader array of sources, for instance the protection of national interests overseas or the maintenance of a safe
and healthy environment. These three angles will exert varying amounts of pressure on a policy-making body and hence affect the eventual form that policy will take, including its throughput legitimacy.

Discussion of these two input indicators – action resources and accountability dilemmas – will therefore be used to contextualise the throughput legitimacy of governance processes and subsequent policy formation achieved. In contrast, discussion of output legitimacy (i.e., the licensing status of veterinary NSAIDs) will be limited to its use as the dependent variable to be explained through analysis of throughput legitimacy (Figure 5).

**Figure 5:** Schematic summarising the analytic trajectory of this thesis. Source: own representation.

Policy analysis in this thesis will centre around the weighing of throughput legitimacy indicators including coherence, ambiguity, transparency and bindingness (E. Lieberherr, pers. comm., 2022). When discussed together, these normative criteria can aid in understanding both input and output policy legitimacy (Schmidt and Wood, 2019). Coherence and ambiguity can be taken together as a measure of the ‘adequacy’ of the policy in question. The former is a measure of policy completeness, consistency and compatibility with existing actions to address a problem or target-group (Knoepfel et al., 2011; May, 2015). Two elements of coherence will be discussed: internal and
external. Internal and external coherence have in the past been used to either distinguish between policies taken within/between sectors (Lieberherr and Thomann, 2020), or those taken by the same/different actors (OECD, 2021). This thesis will take the latter approach whereby internal coherence will consider policy compatibility with wider policy frameworks introduced by the same actor, as well as consistency with the norms and standards to which that actor adheres. For instance, the degree of alignment between policies and respected legal principles. External coherence, on the other hand, will consider compatibility with external policy commitments implemented by other actors or those in international law (OECD, 2021). The use of internal and external coherence to compare policies between actors rather than between sectors has been chosen due to the national case study approach of this thesis, whereby the policies of state actors will be compared across countries.

Policy coherence may be harder to obtain in a system where various ‘misfits’ exist (Ingold et al., 2018), and this can affect the output legitimacy achieved. Such misfits present mismatches in either a transboundary, vertical, horizontal, or temporal plane, and may require additional actions to rectify their impact on policy coherence and downstream effectiveness (Ingold et al., 2018). Transboundary misfits arise spatially and are often present when environmental issues involve multiple jurisdictions, such as those sharing a common river basin or in this case, overlapping vulture populations. Vertical misfits arise in multi-level governance, often where there is an ambiguous division of power or competencies ranging from the local to international level. Misfits that occur on a horizontal plane involve multiple sectors, whereby the environmental issue in question may be at odds with policy objectives or agendas in other fields. Finally, temporal misfits occur when issues of timescale between an environmental issue and the policy intervention required differ. Climate change, for example, is an environmental problem in which all four of these misfits arise: it must be managed by many countries (i.e., transboundary), it causes impacts at the local to global level thus requiring multi-level governance interventions which may be at odds with each other (i.e., vertical), certain sectors have a commercial interest to delay action while others are ready to act (i.e., horizontal), and the real-world impacts of climate change are temporally uncertain (i.e., temporal). The presence of some or all of these misfits in environmental problem-solving efforts can undermine a policy’s coherence and thus throughput legitimacy, especially when multiple jurisdictions are involved (Ingold et al., 2018).

While internal and external coherence will consider the degree to which policies are compatible with each other, the extent to which policies are compatible with established scientific literature will also be considered (Head, 2013). So-called ‘evidence-based’ or ‘evidence-informed’ policymaking considers the degree of ‘mismatch between government expectations and actual, on-the-ground conditions’ (Howlett, 2009, p.153). Used as another branch of policy analysis, the inclusion of ‘theoretically informed empirical analysis’ in public policymaking is believed by many to greatly enhance the effectiveness and suitability of policies and their outcomes (Howlett, 2009, p.154). The growing field of science communication aims to do just that: to communicate emerging science effectively and actionably, preventing applicable knowledge getting stuck in silos (Fischhoff, 2013). However, it is also acknowledged that policymaking is not a ‘purely rational affair but an exercise in pragmatic judgement’ where non-evidence-based factors also shape governance processes (Howlett, 2009, p.156; Oliver et al., 2014). Relevant to this thesis will be the degree to which NSAID licensing policies are consistent with the scientific data collected on vulture populations and drug toxicology, as well as the appropriate use of these studies to confirm or refute licensing arguments. This will be viewed as a third arm of coherence: the degree to which policies are coherent with the existing knowledge base. In relation to action resources, as discussed above, it is also important to consider whether government actors are equipped with the tools
necessary to enable evidence-based policymaking, or whether barriers to this exist (Oliver et al., 2014).

Closely linked to coherence, policy ambiguity is another throughput legitimacy indicator which deals with the degree of clarity of the policy goals and procedures (Matland, 1995). As pointed out by Matland (1995: 157-158), policy ambiguity can often be to blame for implementation failure, although it is also a critical tool in avoiding conflict between actors (especially when roles are poorly defined). The role of ambiguity in the former or latter sense within NSAID policies will therefore be highly relevant to the efficacy of such procedures. Matland makes the distinction between ambiguity in policy goals and policy means. While goal ambiguity is often at fault in implementation failure, ambiguity in means can arise in many forms: most relevant to this thesis are (i) lack of clarity on the roles of different actors in the implementation process, and (ii) uncertainty over the tools best suited to solving the environmental problem (Matland, 1995; Lieberherr and Thomann, 2020).

In addition to the clarity of policies themselves, it is a marker of throughput legitimacy that policies are made clear and accessible to those governed by them. Policy transparency is concerned with the dissemination of information and communicability of measures and means to the governed (Héritier, 2003). This goes beyond the accessibility of policy decisions, but also includes that of governance processes; closely linked to other indicators including inclusiveness and openness (Schmidt, 2019). Further, both policy transparency and ambiguity may affect the bindingness of a policy – that is, its potential or actual enforcement and compliance mechanisms. Although an increase in the amount of ‘leeway for interpretation’ may increase policy coherence, it will swiftly diminish the clarity and precision of goals, and with it hopes of effective enforcement (Thomann et al., 2016).

The above throughput indicators will therefore be considered with reference to relevant input legitimacy indicators, system misfits and degree of policy compatibility with the existing evidence base, as shown in Figure 5. The output achieved – namely, the licensing status of veterinary NSAIDs – will be treated as the dependent variable to be rationalised through analysis of these indicators.
METHODS

As stated in the introduction, this thesis seeks to answer the following questions: in the vulture range states with existing procedures for regulating exposure to veterinary NSAIDs, (i) how do these procedures work, and (ii) are they reducing the risk posed to vultures through legitimate and evidence-based regulation of known vulture-toxic drugs? To answer these two questions, a case study approach covering the most salient examples is used to investigate how this problem is being managed across Europe and South Asia. First and foremost, it is important to elucidate the exact workings of the licensing and banning procedures in use before any policy analysis can begin. Such analysis will then be brought in to complement the empirical evidence collected and help rationalise policy output.

Case study approach

Old World vultures, on which this thesis is based, are found in 128 different countries across Africa and Eurasia (Botha et al., 2017). It was therefore necessary to significantly refine the case studies to be considered (Yin, 2018). This was done through selection of countries which met some or all of the following criteria:

(i) Countries with existing policies regulating the use, sale, or manufacture of veterinary NSAIDs which were formulated with some consideration for their impact on vultures.
(ii) Countries where future regulatory action on veterinary NSAIDs is being considered for the benefit of vultures.
(iii) Vulture populations found in the country represent a significant proportion of regional totals.
(iv) Veterinary NSAIDs pose a significant risk to the country’s vulture population.

Figure 6: Map indicating the leading threats facing Old World vulture populations across Africa and Eurasia. Figure taken from: Botha et al., 2017.
Vulture populations in all range states are facing a plethora of threats and most have undergone significant declines (IUCN, 2022). These threats vary enormously among range states and include a general decline in food availability, increase in human disturbance, habitat loss, direct persecution, secondary poisoning (poison baits, lead, NSAIDs) and collisions with human (energy) infrastructure (Botha et al., 2017). However, the use of vulture-toxic veterinary NSAIDs is of particular concern on the Indian subcontinent and continues to be the main threat facing vultures in this region (Figure 6). The regulation of veterinary NSAIDs to protect South Asian vultures began in 2006 and the four countries at the forefront of these efforts were India, Pakistan, Nepal and Bangladesh (Delhi, 2012). As the subject of the vast majority of existing literature and arguably the most salient cases, these four countries form the principal basis of this analysis (Yin, 2018). In no other region is the issue of NSAIDs’ impact on vultures more evident, interconnected or widely monitored. Case studies from neighbouring vulture range areas including Southeast Asia (Cambodia) and the Middle East (Oman and Saudi Arabia) will then be drawn upon to illustrate how more recent pre-emptive action is being taken utilising the knowledge and evidence acquired from work done on the Indian subcontinent. While evidence for NSAID-related vulture decline in these regions remains limited, they are good examples of where a precautionary approach is being taken. Furthermore, although European vultures are primarily at risk from (intentional or unintentional) poisoning incidents involving deliberately-set poison baits, it is predicted that the more recent licensing of vulture-toxic NSAIDs by certain EU Member States could pose a future threat (Green et al., 2016). Spain, which is home to the majority of Western Palearctic vultures, will therefore be used as a case study to illustrate how the problem is being handled by the EU and its Member States. The EU’s approach is an example where risk mitigation strategies rather than precautionary action is currently favoured. Meanwhile, although Old World vulture populations in Africa are also declining, this thesis will focus only on the situation in Europe and Asia. The use, impact, and regulation of veterinary NSAIDs in Africa remains less certain and secondary to other more prominent threats (including direct, indirect and sentinel poisoning) which are addressed in other available literature (Botha et al., 2017).

The eight case studies presented differ sufficiently in nature and context to make consideration of each of them relevant to this discussion. Among others, the variation in approach to animal husbandry, carcass management and veterinary drug use, present unique challenges to vultures in different nations. Furthermore, considering the broader regional approach is important given that ranges of individual vultures and vulture populations do not conform to national borders. Social context and belief-based nuances are also relevant; in India, for example, religious objections to cattle slaughter help explain the scale of the problem, while growing community animosity towards vultures in Spain highlights the challenge of local engagement. Appreciation of each case’s defining features quickly dispels the notion that a ‘one-size-fits-all’ approach is appropriate and only once these distinctions are understood can the efficacy of vulture conservation efforts be contextualised.

Data Sources & Collection

The process of data collection began with a comprehensive review of the existing literature. Since discovery of the cause of vulture declines across the Indian subcontinent in the early 2000s, a huge amount of quantitative research has gone into assessing the scale of the problem. This has involved extensive survey work monitoring vulture populations as well as the environmental and retail prevalence of veterinary NSAIDs. Safety testing and toxicity studies have also been performed to ascertain which of these drugs presents a threat, and to which species of avian scavenger that threat exists (Table 2). This work has helped elucidate the output effectiveness (i.e., result) of NSAID
bans and restrictions introduced thus far, including compliance patterns and population response (Galligan et al., 2021). Furthermore, several countries have published action plans or risk mitigation strategies to guide future conservation.

However, in order to ascertain and analyse the current picture of efforts to regulate veterinary NSAIDs in vulture range states, more qualitative data was collected. The exact workings of the licensing and banning procedures in these countries have not yet been widely or clearly described; it was therefore important to first establish what these processes involve as well as who participates in them. Moreover, the relevant legal documents were often difficult to find or in inaccessible forms. To answer these outstanding questions and fill gaps identified during the literature analysis, interviews were held with nineteen experts across South Asia and Europe (Mieg & Näf, 2005). Most of these contacts came about thanks to the broad network of partners involved in the international consortium SAVE. In reaching out to interviewees, it was important to achieve a broad range of perspectives and expertise with representation at each level from local to international, hence many are representatives of key actors outlined in Figure 4. Interviewees included those from a range of fields: local, regional and international NGOs, research institutes, government ministries and pharmaceutical companies (Table 3). The unique problem framing and regulatory history of the vulture-NSAID debate across range states meant these interviews could not be standardised, and instead were tailored to the country in question and expertise of the interviewee. The generalised interview template which was used is provided in Appendix 1. Where interviews were not possible, two respondents answered questions via email. Another invaluable source of information and discussion was my supervisor and the Chairman of SAVE, Professor Rhys Green.

<table>
<thead>
<tr>
<th>Interviewee</th>
<th>Affiliation</th>
<th>Actor Level</th>
<th>Region of Expertise</th>
<th>Interview Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Spanish National Research Council (IREC-CSIC)</td>
<td>National</td>
<td>Spain</td>
<td>19.9.22; 8.11.22</td>
</tr>
<tr>
<td>2</td>
<td>SAVE, RSPB</td>
<td>Regional, International</td>
<td>South Asia</td>
<td>20.9.22; 7.12.22</td>
</tr>
<tr>
<td>3</td>
<td>ClientEarth</td>
<td>International</td>
<td>Europe</td>
<td>20.9.22</td>
</tr>
<tr>
<td>4</td>
<td>Bombay Natural History Society (BNHS)</td>
<td>National</td>
<td>India</td>
<td>26.10.22</td>
</tr>
<tr>
<td>5</td>
<td>Bombay Natural History Society (BNHS)</td>
<td>National</td>
<td>India</td>
<td>1.11.22; 14.12.22</td>
</tr>
<tr>
<td>6</td>
<td>IUCN Bangladesh</td>
<td>National</td>
<td>Bangladesh</td>
<td>2.11.22</td>
</tr>
<tr>
<td>7</td>
<td>Bird Conservation Nepal (BCN)</td>
<td>National</td>
<td>Nepal</td>
<td>8.11.22</td>
</tr>
<tr>
<td>8</td>
<td>WWF Pakistan</td>
<td>National</td>
<td>Pakistan</td>
<td>14.11.22</td>
</tr>
<tr>
<td>9</td>
<td>Ministry for the Ecological Transition and Demographic Change (MITECO)</td>
<td>National</td>
<td>Spain</td>
<td>17.11.22</td>
</tr>
<tr>
<td>10</td>
<td>Arulagam</td>
<td>Provincial</td>
<td>Tamil Nadu, India</td>
<td>19.11.22</td>
</tr>
<tr>
<td>11</td>
<td>NatureLife Cambodia</td>
<td>National</td>
<td>Cambodia</td>
<td>24.11.22</td>
</tr>
<tr>
<td>12</td>
<td>NatureLife Cambodia</td>
<td>National</td>
<td>Cambodia</td>
<td>24.11.22</td>
</tr>
</tbody>
</table>
While there is a growing body of literature on the output legitimacy of NSAID policies (often framed as policy effectiveness), little work has been done to assess the throughput legitimacy of these licensing procedures, and in doing so helping to explain that output. Consideration of throughput legitimacy is important as assessment of policy effectiveness alone does not consider the drug types which did not complete early phases of the regulatory process, got stuck in the middle, or never even entered it. This thesis aims to analyse throughput legitimacy through the lens of different policy indicators (as outlined in ‘Theoretical Background’) with reference to relevant input legitimacy indicators, system misfits and degree of policy compatibility with the existing evidence base. The licensing status of different veterinary NSAIDs (i.e., the output of licensing policies) will be used as the dependent variable to be explained through analysis of these throughput indicators. Such an analysis may shed light on why some known vulture-toxins have been successfully banned in certain countries, while others have not.

Assessing the throughput legitimacy of policies and procedures will be dealt with by first analysing their internal and external coherence (OECD, 2021; Schmidt, 2013). For internal coherence, the degree of compatibility between NSAID licensing policies and other relevant regulatory frameworks under the jurisdiction of a certain actor will be explored: for instance, the use of NSAIDs for human consumption or wider trace-pharmaceutical legislation. Specifically in discussion of the EU’s handling of the problem, comparisons will be made with their regulatory approach to other diffuse ecotoxic chemicals including neonicotinoids and antibiotic growth promoters (Dibner and Richards, 2005; McGrath, 2014). This will allow conclusions to be drawn on the internal coherence of EU policies regulating veterinary NSAIDs in light of overarching European legal principles and frameworks, such as the precautionary principle (TFEU, 2016). Discussion of external coherence, on the other hand, will consider alignment with policies made by other actors in the same context (OECD, 2021). This will include comparison of NSAID policies across vulture range states, particularly in areas where vulture populations overlap, or where veterinary NSAIDs are traded across borders. Closely linked to analysis of coherence will be an investigation of the degree to which NSAID licensing policies are evidence-based, and the degree of compatibility with existing scientific literature. This will be analysed in the context of whether decisions to ban or license drugs has been made with heed to sampling and toxicology studies, and whether evidence from these studies has been used appropriately to support or refute such decisions.
Amid discussion of coherence, and in particular regards to policy compatibility, the success of policies in dealing with various ‘misfits’ in this problem will also be analysed (Folke et al., 2007). There are two pertinent transboundary issues which challenge the effectiveness of national NSAID regulations: first, neither vulture populations nor individuals conform to national borders; and second, nationally manufactured vulture-toxic NSAIDs are (il)legally traded between vulture range states. In addition, the horizontal misfit between sectors promoting vulture conservation and those of livestock health must be reconciled. The significant regional and community variation in awareness of NSAID policies is also a vertical misfit between levels of government which challenges successful policy implementation (Galligan et al., 2021). These transboundary, horizontal and vertical misfits will need to be considered alongside analysis of external coherence. Lastly, the doubling time of vulture populations presents a temporal misfit, whereby the outcomes and impacts of policies will not be realised for at least a decade after their introduction (MoEFCC, 2016). This long doubling contrasts with the ‘halving-time’ for vulture populations affected by regulatory failure: the populations of OWRV in both India and Pakistan fell by half in every successive year of the decline when veterinary diclofenac use was unregulated. Such rapid declines could happen again and persist given the long periods required for some regulatory decision-making to reach a conclusion (R. Green, pers. comm., 2023). Given these challenges, NSAID policies must be dealt with to some extent at both a supranational and local level, demanding both internal and external policy coherence.

Closely linked to coherence, analysis of policy ambiguity will be concerned with the degree of clarity of goals and procedures (Matland, 1995). This will be further subdivided into discussion of the ambiguity of both goals and means. For the former, it will be asked whether existing policies go far enough or if sufficient efforts have been made to collaborate with neighbouring range states on common goals (such as the improvement of meloxicam formulations or understanding of vulture ecology). While it is known that an increase in policy ambiguity can pacify opposition, it can also lead to dilution of policy ambition and hence suboptimal output (Matland, 1995). Conversely, ambiguity of policy means will be discussed as it arises from two sources (Lieberherr and Thomann, 2020; Matland, 1995): (i) lack of clarity on the roles of different actors in NSAID policy implementation (MoEFCC, 2020), and (ii) uncertainty over the tools best suited to solving the vulture crisis (CVMP, 2014). For instance, the former will include comparisons between the actor roles proposed in national conservation action plans against the real-world implementation dynamics (MoEFCC, 2020). A lack of clarity on such role delegation could easily lead to misinterpretation, unnecessary duplication of effort, or problem avoidance. Ambiguity in the understanding of appropriateness and effectiveness of vulture conservation tools also threatens the success and ambition of policy outputs (CVMP, 2014).

In addition to discussion of policy ambiguity, the degree of clarity in disseminating NSAID licensing information to the public will also be considered through analysis of policy transparency. The discussion of transparency will consider efforts to communicate measures taken to citizens and veterinarians, including the introduction of education programmes, awareness campaigns and pharmaceutical labelling (Héritier, 2003). In addition, the transparency of policies between vulture range states is important to assess in terms of regional efficacy and coordination, involving the work of multinational actors like SAVE and the Regional Steering Committee (RSC). An important downstream indicator linked to policy transparency and ambiguity is policy bindingness, which will be assessed through discussion of policies’ legal clout and enforcement histories. The differing power of national action plans and drug licensing decisions to bind other stakeholders will be
examined; although whether such power is actually upheld will depend on the amount of leeway afforded by such policies, as well as their level of accessibility (Thomann et al., 2016).

As mentioned above, certain input legitimacy indicators are also highly relevant to understanding the power balance between actors, as well as the context of governance processes and their subsequent outputs (Knoepfel et al., 2011). Two such input indicators, namely action resources and accountability dilemmas, will be discussed and weighed against each other to form a balanced understanding of actor dynamics throughout the governance process. For the former, the most influential of these resources in this case include the financial and legal means at actors’ disposal. Furthermore, whether actors are sufficiently equipped to navigate and balance the demands of accountability dilemmas using their respective resources is also informative on the balance of power at play (Thomann et al., 2018). Government actors in particular must balance incentive pressures (such as those from pharmaceutical lobbying), vocational pressures (including the protection of farmer livelihoods) and societal pressures (including the maintenance of ecosystem services), all while striving to maintain impartiality and adherence to obligations made under international treaties. These conflicting pressures will inevitably affect the makeup and implementation of chosen policy measures, as well as their transparency, ambiguity and bindingness (Lieberherr and Thomann, 2020; Thomann et al., 2018).

Analysis of these indicators together aims to create a balanced and nuanced picture of what is unavoidably a political issue, while accounting for the inherent differences in individual country case studies.
RESULTS

In order to begin assessing the legitimacy of policies regulating the licensing and banning of veterinary NSAIDs in vulture range states, it is first important to establish the status quo – that is, which drugs are currently licensed, restricted or banned in key range states (i.e., policy output). This information is summarised for countries on the Indian subcontinent in Table 4. The procedures involved in NSAID licensing and banning in key vulture range states will then be presented and described as national case studies. These descriptive case studies are based on information gathered from interviews with regional and country experts as well as the existing literature. A comparative regional analysis will then be undertaken between the four central case studies in South Asia (those in Table 4 below), as well as in Spain and the wider EU. Through discussion and analysis of various policy indicators outlined previously, such an analysis aims to rationalise policy output as well as shedding light on the legitimacy of procedures involved in NSAID licensing.

<table>
<thead>
<tr>
<th>NSAID</th>
<th>India</th>
<th>Pakistan</th>
<th>Nepal</th>
<th>Bangladesh</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aceclofenac</td>
<td>Licensed in certain states</td>
<td>Licensed</td>
<td>Not in use</td>
<td>Not in use</td>
</tr>
<tr>
<td>Nimesulide</td>
<td>Licensed</td>
<td>Not in use</td>
<td>Licensed</td>
<td>Banned (for unrelated reason)</td>
</tr>
<tr>
<td>Flunixin</td>
<td>Licensed</td>
<td>Restricted in Tamil Nadu (2019)</td>
<td>Licensed</td>
<td>Not in use</td>
</tr>
</tbody>
</table>

Table 4: Vulture-toxic veterinary NSAIDs currently banned, restricted or licensed for veterinary use in South Asian vulture range states (Interview 4, 5, 6, 7, 8, 10, 15, 18, 19). ‘Banned’ refers to NSAIDs whose licences have been rescinded and their manufacture, sale and/or use disallowed. ‘Not in use’ refers to drugs which are not domestically manufactured, imported or registered. Some drugs are nationally licensed, but their use is ‘restricted’ in certain areas e.g., ketoprofen in India.
National Case Studies

India

The size of India compared to neighbouring vulture range states and the devolved powers of state governments present additional challenges to the regulation of vulture-toxic NSAIDs. Vultures are protected under Schedule I of the Wildlife (Protection) Act (1972), representing the highest possible level of protection under Indian law. They are culturally respected and described as ‘the most efficient soldiers’ in the Government of India’s nationwide sanitation campaign (MoEFCC, 2020).

In response to the vulture crisis, India’s National Board for Wildlife recommended a veterinary diclofenac ban in 2005. This led to a country-wide ban in 2006 under Section 26A of the Drugs and Cosmetics Act (1940), with the Drug Controller General of India (DCGI) requiring a ban on the use, sale and manufacture of veterinary diclofenac within three months (MoEFCC, 2020, p90). Section 26A gives the Government of India powers to ‘regulate, restrict or prohibit the manufacture, sale or distribution of such drug or cosmetic […] in the public interest’ (The Drugs and Cosmetics Act, 1940). In addition, the ban notification highlighted that meloxicam was a vulture-safe alternative (MoEFCC, 2020). The ban became an official law on gazettement two years later in 2008 (Gazette of India Notification No. GSR449(E)).

In surveys taken in India 7-31 months after the ban, the proportion of carcasses contaminated with diclofenac fell from 10.8% to 6.5% (Cuthbert et al., 2011a). Furthermore, the populations of OWRV, LBV and SBV were stable in India between 2007 and 2011, albeit at a fraction of their former numbers (Balmford, 2013; Prakash et al., 2012). In surveys of drugs offered for veterinary use across 11 states between 2007-2010, meloxicam was the most commonly encountered drug (sold in 70% of pharmacies) (Cuthbert et al., 2011b). However, by 2012 diclofenac still made up the largest share of NSAIDs offered for sale in India (44%) (Galligan et al., 2021), with scientists suspicious that the ban was being circumvented through the illegal sale of diclofenac manufactured for human use as a veterinary drug (Cuthbert et al., 2011b).

To tackle this loophole, a restriction on the vial size of human formulations was passed in 2015 and immediately gazetted into law (MoEFCC, 2020, p91). The restriction meant no vial exceeding 3ml of diclofenac could be sold anywhere in India, regardless of its intended recipient. Despite this, some Indian pharmaceutical companies continued to illegally produce large vials of diclofenac post-2015 (Galligan et al., 2021). Diclofenac remained on sale in 10-46% of Indian pharmacies in 2017 with significant regional variation, suggesting imperfect regional enforcement and awareness of the ban and vial size restriction (Galligan et al., 2021). Indeed, only 22% of pharmacies in India’s southern states were found to be aware of the diclofenac ban, while 71% of pharmacies in the state of Jharkhand were fully aware (Galligan et al., 2021). Yet there is evidence that the use of human formulations is decreasing, with no large vials of diclofenac found in pharmacy surveys across eight Indian states in 2019-2020 (SAVE, 2021).

Despite the rapid regulatory response to the discovery of diclofenac as the cause of vulture declines, not all actors in India have supported the policies fielded to tackle the issue. In 2016, two Indian pharmaceutical companies (Laborate Pharmaceuticals and Alpa Laboratories) launched a legal case to challenge the restriction on vial sizes of diclofenac. After two years in court, the Madras High Court upheld the ban on multi-dose vials of diclofenac to discourage its illegal veterinary use (Laborate Pharmaceutical India… vs Union of India, 2017). The Court appointed a panel of experts to review the evidence: the Honourable Judge concluded the Court was ‘accepting the
precautionary principle’ and that the argument presented by the petitioners about the ‘lack of decline in vulture populations post 2012 [...] pales into insignificance.’ Used as a lobbying tool by pharmaceutical companies to negate further action, this pervasive argument that the perceived stabilisation of vulture populations is a great achievement endangers the ambition of further action. In reality, vulture populations remain critically low (Interview 5).

Other industry actors have not taken such a combative approach: Intas Pharmaceuticals has been proactive in dealing with vulture-toxic NSAIDs and receptive to new evidence. In communication with SAVE, they voluntarily withdrew production of both veterinary diclofenac and multi-dose vials prior to their respective bans (Interview 15). Intas was the first Indian pharmaceutical company to work on vulture-safe meloxicam and is now the country’s largest producer of meloxicam and tolfenamic acid (Interview 15).

The procedure for licensing a new veterinary NSAID like tolfenamic acid in India involves both central and state government actors (Figure 7). A pharmaceutical company applies for a licence to manufacture or import a drug from the Central Drugs Standard Control Organisation (CDSCO). This application must be accompanied by a dossier containing all the required evidence including safety testing performed in the recipient species (e.g., cattle). No environmental toxicity tests are required to be performed on secondary or tertiary species like vultures (Interview 15). The CDSCO will consult the Ministry of Fisheries, Animal Husbandry and Dairying (MoFAHD) who will review the evidence. If no further evidence is required nor other issues raised, the MoFADH will submit a ‘no objection certificate’ (NOC) back to the CDSCO. After final review by the CDSCO and Drugs Controller General of India (DCGI), the drug can be centrally licensed. This process of central licensing typically takes one to two years (Interview 15). The matter is then passed to state drug departments, who must separately issue regional licences. Once a pharmaceutical company has received central licensing and the drug has been on the market for four years, other companies can directly approach state governments for regional licences (Interview 15). While most drug licensing occurs centrally before being passed to state departments, loopholes in this procedure exist and veterinary aceclofenac is one such exception: it is not centrally approved by CDSCO but has been licensed for veterinary use in several Indian states (Interview 15). The central government holds the power to request that these state licences be rescinded but so far, no such challenge has arisen (Interview 15).

Conversely, the procedure for banning a veterinary NSAID in India can take significantly longer and must usually be shown to ‘serve a larger purpose’ (Interview 15). Any organisation or individual may write to the DCGI requesting a ban, and such a request must be accompanied by a dossier of relevant evidence. Reports from international peer-reviewed scientific publications are likely to be considered more seriously, and a minimum of two are required (Interview 4). It is at the discretion of the DCGI whether an application is passed on for review by further committees (Figure 8). Such a review will be conducted by either the Technical Drugs Regulation Review Committee (TDRRC) or Drugs Technical Advisory Board (DTAB), who examine requests and the validity of the accompanying evidence base (Interview 19). The TDRRC are consulted on matters involving human medicines, so they were the committee involved in the restriction of multi-dose vials of diclofenac (SAVE, n.d.). DTAB, on the other hand, would be the body consulted on veterinary drugs (Interview 15). The DCGI will concurrently consult the MoFAHD’s Empowered Committee for Animal Health (EHAC), whose input is included in the review process (Interview 19). After deliberation by these committees, which may require subsequent meetings or the collection of further information, their recommendation for approval or rejection of the ban request is passed to the DCGI. If the recommendation is approval, the DCGI will usually endorse this and pass it to the Secretary of the
Ministry of Health, who in turn approves and passes the matter to the Law Ministry for legal approval. The Law Ministry will publish the signed decision into law, at which point it becomes binding, before final gazettement (Interview 4; SAVE, n.d.).

Figure 7: schematic of procedure to achieve the central and state licensing of a veterinary NSAID in India (Interview 15).

Since the ban on veterinary diclofenac in 2006, BNHS has submitted requests for the banning of three more vulture-toxic NSAIDs: ketoprofen, aceclofenac and nimesulide (Interview 5). Despite an increasingly robust evidence-base for the nephrotoxic effect of these drugs on vultures, little regulatory progress has been made. The original request for the banning of veterinary ketoprofen
was filed by BNHS in 2009, but the case has not been progressed by the DCGI. The request for a ban on aceclofenac was submitted in 2019 but remains under review (Interview 4; SAVE, n.d.).

The lack of progress in regulating these other known vulture-toxic drugs has now been challenged in court. A petition filed by the Delhi-based lawyer Gaurav Bansal has demanded the DCGI enacts national bans on veterinary aceclofenac, ketoprofen and nimesulide (Gaurav Kumal Bansal vs Union of India and ors., 2022). The case is currently being heard in the Delhi High Court and respondents involved include BNHS, the Wildlife Institute of India (WII) and the Indian Veterinary Research Institute (IVRI). In their arguments, BNHS draws attention to India's own National Vulture Conservation Action Plan (NVCAP) which sets out the role of the DCGI in facilitating vulture recovery. Meanwhile the WII stresses that two vulture-safe alternative drugs exist, meaning a ban will have 'little or no impact on the availability of drugs for the treatment of livestock in India' (BNHS and WII, 2022, as cited in Kaur, 2022a).

Gaurav Bansal (the original petitioner) filed a Right to Information application with the CDSCO (of which the DCGI is the head) to enquire about efforts made to implement the NVCAP. The intended roles of the DCGI and CDSCO (which operate under the Ministry of Health and Family Welfare, MoHFW) are clearly laid out in the NVCAP and include them helping 'in getting a ban or restricting the use of vulture toxic drugs for veterinary use once the results are published in scientific journals’ (MoEFCC, 2020, p. 46). In the most recent hearing (December 2022), the Court directed the CDSCO to file a report on the steps it had taken to protect India's vultures (Kaur, 2022b). However, the CDSCO stated in an affidavit that they could not ban the drugs without consensus from the MoFAHD. This directly contradicts the proposed roles of the MoFAHD outlined in the NVCAP, which only include tasks related to implementation (MoEFCC, 2020). While this development is promising and shows intent from the Court to pursue the matter, it is no guarantee that national bans on these drugs will materialise without further legal challenges (Interview 5). Furthermore, the procedure involved in achieving these potential bans would involve India’s judiciary and therefore differ from the process outlined above in Figure 8.

Despite slow progress at the national level, more progress has been made by individual states. In 2015, Tamil Nadu restricted the government supply of ketoprofen across three state districts home to vultures: Nilgiri, Erode and Coimbatore (Interview 10). The government supply of flunixin was subsequently similarly restricted in 2019 (Interview 10). This decision involved Tamil Nadu’s vulture conservation committee, animal husbandry department, the state drug controller and the forestry department. Compared to the lengthy processes to achieve bans at national level, the restriction on ketoprofen was organised within 3 months of application, and within 4 months for flunixin (Interview 10). The evidence presented in these requests required at least one study conducted in Tamil Nadu itself, as well as other studies performed in India. In general, studies performed in India are preferred to those done in other countries or continents (Interview 10).

Although this move prevents the government distribution of the drugs in these districts, their wider manufacture, sale and use are not affected. My interviews yielded conflicting information on whether Indian states have the explicit power to enact state-wide bans on veterinary NSAIDs independent of the central government: some interviewees are of the opinion that they do (Interview 5) while others believe they do not (Interview 4, 10, 19). Regardless, none have exercised such power and banning decisions have so far only been taken by the central government. Given that India’s largest state is over two times the size of neighbouring vulture range countries, Bangladesh and Nepal, this is a significant factor impeding the regional banning of vulture-toxic NSAIDs. However, as exercised by Tamil Nadu, state drug controllers have been more active in controlling the types of drugs purchased by government agencies for use by state veterinarians or
distribution to livestock-keepers in the local area (Interview 5). The CDSCO has no jurisdiction in this regard and the NSAIDs purchased under such schemes therefore vary spatially (Interview 15). Similar restrictions on government supply are thought to have occurred in other states including Uttar Pradesh and Haryana, although this has only been achieved informally at the request of SAVE (Interview 2). There is currently no legal mechanism to ensure the purchase of vulture-safe drugs by these local ministries (Interview 5).

Furthermore, the purchase of NSAIDs by livestock owners or their ‘quacks’ is poorly monitored. ['Quack' is the term used regionally to describe an unlicensed medical practitioner]. Technically, veterinary NSAIDs are in ‘Schedule-H’ of the Drug and Cosmetics Act (1940), meaning they should only be obtainable on prescription. However, in reality they are readily available over the counter country-wide (Interview 4, 5). In 1,452 covert pharmacy visits in India between 2012 and 2017, only 35 pharmacies refused to sell an NSAID due to a lack of prescription (Galligan et al., 2021). India’s NVCAP aims to get veterinary NSAIDs onto ‘Schedule-X’, meaning not only would a chemist have to sell them on prescription, but they would also have to retain a copy of said prescription which could be produced on inspection of sales records. Unfortunately, no progress has yet been made on this front and veterinary NSAIDs continue to be purchased over the counter with neither prescription nor record (Interview 4).

Just as NSAID purchase patterns vary across India, carcass disposal methods also vary spatially. Before the start of the vulture crisis, carcasses were almost exclusively dumped in open areas with easy access to scavengers. These dumps were often administered by local municipal agencies, with local businesses benefitting from taking cattle hides and the recovery and use of cattle bones rapidly made available by the vultures feeding. While this practice is still commonplace in less populated areas of northern India, livestock carcasses in southern states like Tamil Nadu are now mostly buried or burnt (Interview 10). In some areas, this shift in practice has legal standing and state governments actively discourage carcass dumping (Interview 10). While this reduces the risk and nuisance posed by rabid feral dogs, it also greatly reduces the food available for vulture populations, further stifling their chances of recovery. In some states including Tamil Nadu, advocacy efforts towards state authorities to allow open carcass dumping in forested areas are attempting to increase the food available to vultures (Interview 10).

In addition to the pursuit of further bans on vulture-toxic veterinary NSAIDs, the illegal use of diclofenac remains a problem. This was emphasised by IVRI in their letter to the environment ministry in relation to the Delhi High Court case, explaining how diclofenac is still ‘easily available in multi-dose vials for use in human practice which is in turn being used in animals by quacks’ (IVRI, 2022, as cited in Kaur, 2022a). Such illegal use is rarely prosecuted, with a recent crackdown in Tamil Nadu serving as one of the few instances where NSAID policies have been enforced by local governments (Interview 10). In the last two years, the Director of Drugs Control in Tamil Nadu has registered over 100 cases against actors at all levels of the supply chain: suppliers, distributors, manufacturers and retailers of diclofenac (Premkumar, 2022). Indeed, this is the first such instance that SAVE are aware of prosecutions being taken against illegal use since the ban in 2006 (SAVE, 2022). While overall use of diclofenac is on the decline, availability and use of other veterinary NSAIDs were shown to vary regionally in surveys taken near vulture colonies by BNHS: in Assam and Tamil Nadu, meloxicam is the dominant drug, whereas in Uttar Pradesh and Madhya Pradesh, the use of diclofenac, aceclofenac and nimesulide remain commonplace (Interview 5). Unlike in smaller neighbouring countries, the role of Indian states in this problem alongside the actions of the central government cannot be overlooked.
Pakistan

Pakistan banned the veterinary use of diclofenac in 2006, alongside India and Nepal (Karki & Mirbahar, 2016, Annex III). Unlike other range states, this ban did not extend to the manufacture of diclofenac altogether, only the cancellation of its domestic registration. Veterinary drugs containing diclofenac could continue to be manufactured if ‘registered exclusively for export purpose’ (Karki & Mirbahar, 2016, Annex III). Despite the ban on domestic use, six of Pakistan’s eight vulture species showed negative population trends in 2015, including the critically endangered OWRV, LBV and RHV (Karki & Mirbahar, 2016).

Pakistan’s provinces do not have the power to ban or license drugs: this can only be done at the federal level (Interview 18). However, as in Tamil Nadu (India), there has been some success in regionally restricting the use of other NSAIDs. Although licensed country-wide, the veterinary use of ketoprofen and aceclofenac were ‘restricted’ in Sindh province (the location of Pakistan’s VSZ) on the orders of Sindh’s Chief Drug Inspector in 2018 (SAVE, 2018). It is thought this decision was driven by the advocacy activities of WWF-Pakistan and the Hawk Conservancy Trust (HCT) who lead the Pakistan Vulture Restoration Project (PVRP). This provincial restriction does not extend to the registration or manufacture of the drugs in Sindh but simply to their sale and use (Interview 8). Moreover, the vulture colonies in Sindh are found in remote areas where livestock are farmed extensively and thus veterinary drugs are not widely used (Interview 8). The restriction can therefore be seen as more of a declaration of commitment to vulture conservation (Interview 18).

Limited monitoring has led to weak enforcement of the restriction and the two drugs continue to be sold in the province, albeit at a lower level in the VSZ itself (Interview 8). Undercover surveys of 12 pharmacies within the VSZ found no ketoprofen or aceclofenac available, with the majority of pharmacies (8/12) offering meloxicam (SAVE, 2021). However, ketoprofen and aceclofenac were found in 8 and 5 out of 10 pharmacies respectively in Mithi, Tharparkar, a city bordering the VSZ (SAVE, 2021). From surveys of 350 pharmacies in Punjab (the province to the north of Sindh), ketoprofen was an active ingredient in 4 of the 33 NSAIDs on offer in 2019-20, while aceclofenac was in 2 and flunixin in 6 (SAVE, 2021). Meloxicam was the active ingredient found in the majority of these NSAIDs products (20/33). Nimesulide, on the other hand, is not registered for veterinary use in Pakistan (Interview 8).

Unlike in India, there is no government distribution of veterinary NSAIDs in Pakistan (Interview 8). Although their procurement legally requires a prescription, this is poorly enforced and in reality, the drugs are widely available and often administered by unqualified ‘quacks’ (Interview 8). Yet the threat from multi-dose vials in Pakistan is less than that found across the border: the Drugs Regulatory Authority of Pakistan (DRAP) confirmed in 2017 that ‘multi-dose vials of all human NSAIDs are banned in Pakistan and only 3ml vials are registered and available. There are no plans for such a licence to be issued’ (SAVE, 2021). In undercover surveys covering all 36 provinces in Punjab in 2019-20, no NSAIDs in excess of 3ml were found (SAVE, 2021). However, the use of human formulations of diclofenac in veterinary medicine still occurs (Interview 18). Such formulations were found in 5 out of 10 pharmacies outside Pakistan’s VSZ in Mithi, Tharparkar in 2019-20 (SAVE, 2021). The other vulture-toxic NSAIDs still widely used include ketoprofen, aceclofenac, flunixin and phenylbutazone (Interview 8).

For the wider banning of these NSAIDs, DRAP has agreed to cooperate on provision of sufficient scientific evidence in the form of dossiers. Any individual or organisation can submit such dossiers and the actors actively involved in their preparation include WWF Pakistan, IUCN Pakistan,
Pakistan’s NVRC, SAVE and the RSPB (Karki & Mirbahar, 2016). In October 2022, two dossiers were submitted to DRAP requesting the wider banning of aceclofenac and ketoprofen and they remain in the earliest stages of consideration (Interview 8).

**Figure 9**: schematic of procedure to achieve the banning or licensing of a veterinary drug in Pakistan (DRAP, 2022; Interview 8, 18).

DRAP is an autonomous body under Pakistan’s Ministry of National Health Services, Regulation and Coordination (MoNHSRC). Composed of around 20 members, the DRAP Registration Board meets monthly and decides on the licensing or withdrawal of pharmaceuticals in Pakistan (both human and veterinary). Established under the Drugs Act (1976), DRAP’s Registration Board includes representatives from various DRAP departments as well as directors from provincial drug testing laboratories. Members also include those with expertise in law, intellectual property, pharmacology and physiology (DRAP, 2022). In addition, representatives from the pharmaceutical industry are permitted to attend the meetings as observers (Interview 8). The DRAP Policy Board reviews applications and evidence on different drugs before deciding whether to grant, rescind or ban the drug in question (Figure 9). There is no concrete threshold for the type or volume of evidence considered, and peer-reviewed studies conducted outside of Pakistan are considered (Interview 8). The committee will also occasionally consult an existing licence holder of the drug before a decision is made but no other government ministries are typically involved in this process (Interview 8).

**Nepal**

Nepal’s National Drug Policy (1995) states that ‘drug registration will be based on scientific facts’ and that the ‘distribution of ineffective, harmful, toxic as well as irrationally combined formulations will be banned.’ This bodes well for vulture conservation and Nepal is in many ways leading the way in protecting vultures from toxic veterinary NSAIDs at a local level. Nepal pioneered the introduction of Vulture Safe Zones (VSZs), led by Bird Conservation Nepal (BCN), which are now a widely accepted in-situ conservation strategy across neighbouring range states and endorsed by SAVE (DNPWC, 2015). There is increasing evidence in support of the VSZ approach, with vulture populations in Nepal among those thought to be partially recovering (Galligan et al., 2019; Prakash et al., 2012). Nepal has also spearheaded the introduction of community-based vulture-safe feeding sites (VSFS), of which there are now seven, overseen by BCN, the RSPB and Himalayan
Nature. These areas surround a breeding colony of vultures and the birds are provided with diclofenac-free carcasses within their mean feeding range (DNPWC, 2015). VSFS are important given the shifting carcass disposal practices in Nepal (and neighbouring countries) in favour of burial over open carcass dumps. Nearly 92% of carcasses are now buried soon after death, significantly reducing the food available for vultures (Dhakal et al., 2022). Unlike neighbouring range states, vultures in Nepal are not yet nationally protected species (DNPWC and DoFSC, 2022); although there is seemingly limited evidence from other states on the benefit of such legal protection in reality.

Alongside India and Pakistan, Nepal banned the veterinary use of diclofenac in 2006 (DNPWC, 2015). By comparison with other range states, Nepal has arguably done the best job in eliminating the presence of veterinary diclofenac: 76 out of Nepal’s 77 districts have been declared diclofenac-free, representing over 98% of the country’s area (DNPWC and DoFSC, 2022). There was also zero record of diclofenac discovered in both undercover and general pharmacy surveys conducted in 2020 (SAVE, 2021). Together, advocacy and education campaigns, government support, and the fact that most diclofenac in Nepal was manufactured in India, have all helped in eliminating diclofenac from vulture food chains (Galligan et al., 2021). However, as in other range states, the use of human formulations of diclofenac remains a threat. A request for a national restriction on vial size was recently sought by BCN, although the only Nepalese pharmaceutical company manufacturing multi-dose vials has voluntarily ceased production after being asked to do so by conservationists (Interview 7). Any human formulations of diclofenac now found in Nepal are therefore of Indian origin and must be addressed through stricter border controls (DNPWC, 2015). As further evidence of the importance of drug imports from India, sales of diclofenac in ‘human’ pharmacies in Nepal fell from 22.5% in 2013 to 0.5% in 2017 following the ban on multi-dose vials in India in 2015 (Galligan et al., 2021).

Efforts to encourage the substitution of diclofenac with meloxicam have been particularly successful in Nepal, with initiatives including the government’s ‘diclofenac-for-meloxicam’ exchange programme introduced in 2010 (Interview 7). Although meloxicam now holds a large share of the veterinary NSAID market in Nepal (89.9% in 2017 (Galligan et al., 2021)), other vulture-toxic NSAIDs including ketoprofen and nimesulide also hold sway (DNPWC, 2015). Nimesulide, in particular, is emerging as a popular replacement for diclofenac and regulatory action is needed to prevent further population decline (Interview 7). Sales of nimesulide were shown to increase between 2012-2017, particularly in the Western Terai region (Galligan et al., 2021). Furthermore, the legal requirement to purchase veterinary NSAIDs on prescription is poorly enforced and over-the-counter purchasing remains commonplace (Interview 7). As in India, Nepal’s NVCAP aims to ‘enforce prescription-only and recorded sales of NSAIDs’ but this has yet to materialise (DNPWC, 2015, p.14).

The process to achieve a ban on a veterinary NSAID in Nepal involves Nepal’s National Vulture Recovery Committee (NVRC), the Department of National Parks and Wildlife Conservation (DNPWC) and the Department of Drug Administration (DDA) (Figure 10). Nepal’s NVRC has written to the DDA requesting a ban on veterinary ketoprofen and aceclofenac (SAVE, 2021). While the DDA are continuing to review a ketoprofen ban, they have stated that aceclofenac is not licensed in Nepal and will not be licensed in future for production or sale (Interview 7; SAVE, 2021). As in previously discussed range states, no regulatory mechanism exists in Nepal to pre-emptively ban NSAIDs shown to be toxic to vultures (DNPWC and DoFSC, 2022).
Nepal’s success can largely be attributed to the efficacy of advocacy work engaging the general public, veterinarians and local communities (Interview 7). In addition, the significant national media attention garnered by Nepal’s ‘vulture restaurants’ and the ‘diclofenac-for-meloxicam’ scheme has fostered community understanding of vulture conservation efforts and motivation for its success. However, populations of most of Nepal’s nine vulture species remain critically low. Besides the well-documented declines of OWRV, LBV and SBV across South Asia, monitoring of other vulture species also took place in the Upper Mustang region between 2002-2008. Over this period, populations of BV and HGV declined by 80% and 70% respectively (Acharya et al., 2010, 2009). Hence going forward, establishing bans on ketoprofen, nimesulide and aceclofenac are priorities for ensuring long-term safety for vultures from the effects of toxic NSAIDs (Interview 7).

Bangladesh

Connecting the vulture populations of South and Southeast Asia, Bangladesh’s small but diverse vulture population holds seven of the nine vulture species found in South Asia (MoEF, 2016). Vultures are protected under Schedule III of Bangladesh’s Wildlife (Preservation) (Amendment) Act, (1974) and Wildlife (Conservation and Security) Act, (2012). The loss of vultures is predicted to cost Bangladesh $5.5 million over the next 50 years to deal with the management of excess carrion in one of the world’s most densely populated countries (MoEF, 2016).

Bangladesh banned the production, distribution and sale of veterinary diclofenac in 2010, becoming the fourth South Asian country to do so (MoEF, 2016). In addition, Bangladesh took further steps to legitimately enshrine vulture conservation in national legal frameworks: the Bangladesh National Vulture Recovery Committee (BNVRC) was established by gazette notification in 2013 (MoEF, 2016, Annex I), followed by the establishment of two Vulture Safe Zones (VSZs) bordering India in 2014 (MoEF, 2016, Annex II). Unlike other vulture range states, the VSZs have legal standing and are protected as ‘landscape zones’ under the Wildlife (Conservation and Security) Act, (2012). They are the only government-declared safe zones in the world and a three-tier institutional mechanism has been set up to manage and further guarantee their integrity (MoEF, 2016, Annex III). However, between 2008 and 2012, the OWRV population in Bangladesh declined from 1,972 to 816 individuals (Khan, 2013), with a further reduction to just 260 spanning only 12 of the country’s 26 districts by 2015 (MoEF, 2016).

The use of diclofenac is still a concern in areas near the Indian border as diclofenac is often illegally imported into Bangladesh. As much as 50% of remaining diclofenac found in Bangladesh in 2015 was Indian-made (Sarowar et al., 2016) and multi-dose vials of diclofenac are not domestically
produced (Karki & Mirbahar, 2016; SAVE 2021). The authorities are aware of this border issue and BNVRC sent a letter to the Ministry of Home Affairs requesting action be taken against banned veterinary drugs crossing the border into Bangladesh (Interview 6; Karki & Mirbahar, 2016). Unfortunately, the permeability of the border to the drugs themselves is not the only concern: around 2 million cattle are smuggled into Bangladesh annually to escape Indian laws that prevent cow slaughter (Nair and Paul, 2015). A flourishing trade worth $600 million a year and considered legal by Dhaka, the practice could be exposing vultures in Bangladesh to NSAID-contaminated carrion if these cattle die soon after their last treatment and their carcasses are not properly managed (Interview 6).

In the years after the diclofenac ban, continued monitoring found that ketoprofen was quickly replacing diclofenac as the preferred veterinary NSAID in Bangladesh (Galligan et al., 2020; MoEF, 2016). Market surveys conducted in 2015 across 235 pharmacies found that 40% of veterinary NSAIDs offered contained ketoprofen as their active ingredient, while 24% each contained diclofenac or meloxicam. A parallel undercover study in the two VSZs found a 56% share of ketoprofen, 7% share of diclofenac, and 19% of meloxicam (MoEF, 2016; Sarowar et al., 2016).

To tackle the growing popularity of this proven vulture-toxin, the BNVRC proposed that ketoprofen should be banned in the VSZs (SAVE, n.d.). A national workshop of government ministries and was held in 2016 at which a prominent ZSL veterinarian, Dr. Nic Masters, gave a presentation on the harmful effects of ketoprofen and the acceptable performance of meloxicam for the treatment of cattle, in efforts to persuade the reluctant Department of Livestock Services (DLS) that a ban was necessary and would not be harmful to livestock husbandry (SAVE, n.d.). This workshop included representatives from the Ministry of Environment, Forest and Climate Change (MoEFCC), Bangladesh Forest Department (BFD), the DLS, IUCN Bangladesh and other participants from veterinary and conservation bodies. The MoEFCC sent two letters to the Ministry of Health and Family Welfare (MoHFW) to initiate the ban, who then sent a letter to the Directorate General of Drug Administration (DGDA). In 2017, the DGDA issued a ‘government order restricting the sale, distribution, storage, preservation and exhibition of ketoprofen in any form’ in the VSZs (SAVE, n.d.). However, the ban was difficult to implement while the drug remained legally available elsewhere and an unsubstantiated rumour that meloxicam was unsafe to administer to pregnant animals did not help: ketoprofen maintained a 62% share within the VSZs in 2018 (Galligan et al., 2021; SAVE, 2021).

In 2020, BNVRC chaired a meeting discussing the country-wide banning of ketoprofen, to which all stakeholders agreed (including 13 pharmaceutical companies, the DGDA, DLS and BFD). A country-wide ban was then enacted in 2021 by MoEFCC (Figure 11), making Bangladesh the first country to ban a second vulture-toxic NSAID. In the most recent undercover pharmacy surveys conducted in the VSZs in 2020: no diclofenac was found, the share of ketoprofen fell to 51%, the share of meloxicam remained at 25% and the share of tolfenamic acid rose to 21% (from 5% in previous surveys) (Interview 6). The increase in market share of tolfenamic acid is encouraging but these figures mean the majority share of veterinary NSAIDs in the VSZs remain vulture-toxic (Interview 6). The use of nimesulide, however, was banned in Bangladesh on human health grounds and no pharmaceutical company currently produces aceclofenac (Interview 6).
Figure 11: schematic of procedure to achieve the banning or restriction of a veterinary NSAID in Bangladesh (Interview 6; SAVE, n.d.)

Also of note in Bangladesh are the examples of positive collaboration with national pharmaceutical companies on efforts to save vultures (Interview 6). Including their involvement in the country-wide banning of veterinary ketoprofen mentioned above, two of the largest pharmaceutical companies in Bangladesh – Renata and Acme – have voiced enthusiasm for encouraging the use of vulture-safe NSAIDs. Both manufacture and promote the use of meloxicam and were early adopters of the improved meloxicam formulations (neutral pH/low osmolarity) which do not cause pain on injection (Cuthbert et al., 2014a). Their products were tested by an independent laboratory in the UK and found to be satisfactory in this regard. Their products also include the addition of vulture-awareness labelling (SAVE, 2021). Acme’s label translates to: ‘Vultures play an important part in maintaining the balance of the environment. The use of meloxicam in domestic animals is safe for the vultures’ (MoEF, 2016). Renata’s director of animal health also delivered a presentation on the importance of meloxicam at an International Vulture Awareness Day webinar in 2020 (SAVE, 2021). In a country with a relatively concentrated pharmaceutical industry, (59% of NSAIDs surveyed are manufactured by a single company, and 89% by just six companies, (Galligan et al., 2021)), the potential impact of actions taken by single pharmaceutical companies to conserve vultures is significant.

Finally, Bangladesh’s majority Muslim population are not opposed to eating beef and thus there is not a large population of ageing or infirm cattle. There is therefore not the same pressure on carcass disposal as is found across the border in India, although approved (‘halal’) methods of slaughter are required and animals dying from ill-health are unlikely to be eaten by humans. Carcasses are mainly left where they fall for scavengers or buried (Interview 6). Similarly, there is no government distribution programme for veterinary NSAIDs, and hence the institutionalised distribution of vulture-toxic drugs is not a concern in Bangladesh. Instead, vulture-safe meloxicam is provided to pharmacists and veterinarians free of charge under a scheme led by IUCN Bangladesh (Interview 6).
Cambodia

Cambodia is home to three resident species of Old World vulture: OWRV, SBV and RHV (Loveridge and Phearun, 2016). Unlike vultures on the Indian subcontinent, whose main risk of non-natural mortality continues to be the use of veterinary NSAIDs, Cambodian vultures are primarily at risk from intentional or secondary poisoning incidents involving deliberate setting of baits (not involving NSAIDs) (Loveridge and Phearun, 2016). These poisonings are estimated to have accounted for 73% of vulture mortality between 2004-2011, and remaining populations number as few as 153 individuals restricted to the north and northeast of the country (Clements et al., 2012; Loveridge and Phearun, 2016).

A 2015 study of 1,450 households and 74 pharmacies in these vulture range provinces found only 27% of households were giving drugs of any description to their livestock, and no veterinary diclofenac was found on sale in pharmacies (Loveridge and Phearun, 2016). Furthermore, the issue of multi-dose vials was not present as the only ‘human’ diclofenac found was in pill form (Interview 11, 12). It was therefore concluded that veterinary diclofenac did not pose a threat to Cambodian vultures, although a pre-emptive ban was nevertheless recommended in Cambodia’s 2016 Vulture Action Plan (Loveridge and Phearun, 2016).

This recommendation was expedited after a single point of sale was discovered at a pharmacy in Siem Reap in 2018 (Interview 11, 12). Although this is not a vulture range province, it served as the alarm bell required and Cambodia’s Vulture Working Group (CVWG) wrote to the Ministry of Agriculture, Forests and Fisheries (MAFF) expressing their concern (Figure 12). After a year of further letters, submission of evidence and enlisting the support of the Ministry of Environment (MoE), the ban was issued by the General Directorate of Animal Health and Production (GDAHP, which functions under MAF) in 2019 (Interview 11, 12). The high degree of cooperation between NGOs and the Cambodian Government, together with the central role of NGOs in national conservation facilitated the speed at which this was achieved (Interview 11, 12).

No other veterinary NSAIDs have yet been banned in Cambodia, nor has the presence of any vulture-safe NSAIDs been found in survey work (Interview 11, 12). The situation in unique to that on the Indian subcontinent as there is no domestic production of veterinary drugs in Cambodia: all drugs are imported from neighbouring countries. Indeed, the one instance of veterinary diclofenac discovered for sale in 2018 was manufactured in Vietnam (Interview 11, 12). This presents different challenges to the regulation of veterinary NSAIDs as the fate of the ban relies heavily on the permeability of the border. Due to Cambodia’s reliance on veterinary drug imports,
it is normal for drug licensing (or banning) to occur only after an imported drug has already arrived on the domestic market (Interview 11, 12). Secondly, animal husbandry practices differ significantly from those employed on the Indian subcontinent: livestock are primarily kept as a means of storing capital and are often left to wander for 4-5 months of the year unsupervised (and hence unmedicated) in the forest. Since the decline in wild ungulate populations, this practice provides a vital food resource for Cambodia’s remaining vultures (Interview 11, 12).

Oman

Oman is home to resident populations of Egyptian and Nubian vultures as well as several migratory raptor species (Interview 13). The Arab country has also recently taken regulatory action against diclofenac, with its import, trade and use prohibited in 2020 (Interview 13). The Ministry of Agriculture was alerted to the dangers of veterinary diclofenac in 2018: it drafted a dossier describing what was needed which was then sent to the Ministry of Legal Affairs, who approved and prepared the legal document required. The ban on veterinary diclofenac came into force after being signed by the Minister of Agriculture (Ministerial decree No. 81/2020) and published in the Official Gazette (No. 1338) in April 2020 (Interview 13). The Director General of Animal Health said in a press release that this step had been taken ‘based on the overwhelming evidence’ of the risk of diclofenac and the ‘availability of safe alternatives.’ He added that ‘by moving fast, it means that Oman has not had to face the consequences’ faced in vulture range states across the Indian subcontinent (Interview 13).

Saudi Arabia

In neighbouring Saudi Arabia, progress is being made towards a country-wide ban on diclofenac. A workshop held with the Ministry of Environment, Water and Agriculture, together with representatives from pharmaceutical companies and agencies, led to consensus on the withdrawal of further prescriptions of veterinary diclofenac (Interview 14). However, in reality diclofenac remains available over the counter without prescription to local people and a country-wide ban has not yet been established. Diclofenac remains significantly cheaper than vulture-safe alternatives in this region and is a widely trusted veterinary drug (Interview 14). Scepticism exists over whether Saudi vulture populations are actually at risk from veterinary NSAIDs, with questions raised to this effect at the recent workshop. The main threat to vultures in Saudi Arabia, as in other regions, is indirect poisoning via poison baits deliberately set to kill carnivores (Interview 14). Nevertheless, evidence and actions from other vulture range states (including neighbouring Oman) are encouraging pre-emptive measures against veterinary diclofenac to be considered. However, the authorisation of the drug in the European Union is hampering efforts by conservation organisations to recommend a ban to the Saudi government (Interview 14).
The concentration of European vulture species on the Iberian Peninsula makes policy decisions taken by the Spanish Government critical to the fate of the EU’s vulture populations. However, the veterinary use of eleven NSAIDs are currently authorised in Spain: diclofenac, ketoprofen, flunixin, carprofen, meloxicam, tolfenamic acid, acetylsalicylic acid, phenylbutazone, sodium salicylate, metamizole, and suxibuzone (CIMAVET, 2020). Of these, diclofenac, ketoprofen, flunixin and carprofen are known to be nephrotoxic to Gyps vultures. In 2013, despite the well documented collapse of South Asian vultures, the pharmaceutical company Fatro Ibérica S.L. was granted marketing authorisation for two drugs containing diclofenac – Diclovet and Dolofenac – for the treatment of pigs, cattle and horses not intended for human consumption (AEMPS et al., 2020; Margalida et al., 2014). This marketing authorisation was then renewed in 2018, in accordance with Spanish Royal Decree 1246/2008.

Veterinary medicinal products (VMPs) containing diclofenac do not have central marketing approval from the European Medicines Agency (EMA). Instead, they must be authorised independently by EU Member States (Botha et al., 2017). Such authorisation has been granted by five Member States: Estonia, Czech Republic, Latvia, Italy and Spain (CVMP, 2014). In all of these five countries, the marketing authorisation holder is the same company: Fatro S.p.A. (or its affiliate Fatro Ibérica S.L. in Spain). Of the veterinary diclofenac sold in the EU, the majority is for use in cattle (60%) and pigs (30%), 90% of which is used in intensive farming (CVMP, 2014). Since the marketing authorisation in Spain in 2013, sales volumes of diclofenac in the EU have tripled and its use in Spanish livestock continues to increase (Figure 13) (CVMP, 2014; Moreno-Opo et al., 2021).

![Figure 13: The estimated number of livestock treated with diclofenac in Spain between 2013 and 2019. Figure taken from: Moreno-Opo et al., 2021.](image)

Although the decision to authorise veterinary diclofenac is arguably ‘not a good message’ to be sending out to other vulture range states (Interview 9), the Spanish Government’s justification for their decision hinges on two arguments: (i) that all legal requirements to approve the drug have been fulfilled, and (ii) that the risk of vulture exposure to veterinary diclofenac is low (Interview 1).

For the first of these arguments, the authorisation of veterinary diclofenac is indeed at the behest of the Spanish authorities and has been approved in accordance with EU law. Under Directive
92/18/EEC, the safety testing required for the environmental risk assessment of a veterinary drug does not include its potential impact on scavenging birds and therefore does not require specific analysis of the drug’s impact on vultures (Moreno-Opo et al., 2021). Furthermore, injectable NSAIDs fall under the list of VMPs exempt from assessments beyond ‘Phase I’ as they are considered to be used for ‘a small number of animals in a flock or herd’ (EMA, 2008, p.9). Hence, although NSAIDs are known to pose a risk to non-target species, they are exempt from the most rigorous environmental impact assessment requirements. Even if this were not the case, their effects on vultures would still not form part of that assessment: the consumption of carrion treated with VMPs is not listed as a risk of exposure to the terrestrial environment (EMA, 2008).

The second argument fielded by the Spanish authorities stems from their belief that sufficient risk mitigation measures have been put in place to prevent significant exposure (Moreno-Opo et al., 2021). A government-led risk assessment estimated diclofenac may cause the deaths of 15-39 EGVs in Spain each year (AEMPS et al., 2014). This was in stark contrast to Green et al.’s (2016) estimate of 715-6389 deaths per year, with a projected annual population decline of 0.9-7.7%. Both assessments were based on the same data and estimates of diclofenac sales volumes and vulture populations (Moreno-Opo et al., 2021). The most recent estimate using in situ sampling predicted an intermediate rate of 78-600 EGV deaths per year (Herrero-Villar et al., 2020).

To date only one diclofenac-related and four flunixin-related vulture deaths have been confirmed in Spain (Herrero-Villar et al., 2021, 2020; Zorrilla et al., 2015). However, past experience in India during a period when tens of millions of vultures were killed by diclofenac showed that only a very small proportion of dead birds were recovered for determination of the cause of death. There is conflicting evidence from field surveys about the true prevalence and potential impact of vulture-toxic NSAIDs on vultures. Some studies have found, as the Spanish authorities suggest, that the risk of exposure is very low:

- Between 2013-2019, the causes of death of 389 vultures were analysed: 16.7% were found to have died as a result of poisoning. None had been poisoned by diclofenac, although three EGVs had died from flunixin poisoning (Herrero-Villar et al., 2020).
- In 2013-2020, none of the 5,333 vultures admitted to official rescue centres across 14 Spanish autonomous communities were deemed poisoned by diclofenac (although only 955 vultures had a full necropsy or clinical check) (Moreno-Opo et al., 2021).
- Of 1,231 targeted NSAID controls carried out in slaughterhouses as part of the National Residue Research Plan (PNIR), no carcasses tested positive for diclofenac (AEMPS et al., 2020).

However, the results of other field surveys suggest that the presence of vulture-toxic NSAIDs may be higher than current evidence suggests (Interview 1):

- In recent blood samples taken from 350 Pyrenean obligate and facultative scavengers, flunixin residues were detected in five EGVs (Oliva-Vidal et al., in prep.).
- A study in 2016-17 analysed 125 pig carcasses at registered feeding stations. Four carcasses were found to contain residues of NSAIDs (two with flunixin, one with diclofenac and one with meloxicam) (IREC-Tragsatec, 2017).
- Analysis of 228 pig and sheep carcasses from vulture feeding sites found NSAID residues in 3.07% of carcasses analysed. Flunixin was found in 1.8% of carcasses and diclofenac, meloxicam and ketoprofen were each found in 0.4% (Herrero-Villar et al., 2020). Although this study was done on a small sample size, 0.4% diclofenac falls within the critical range laid out in Green et al.’s (2004) model to cause significant population declines. Furthermore, diclofenac is not authorised for use in sheep (CVMP, 2014). It should also be noted that
administrators of vulture feeding sites are often warned in advance of visits for sampling of carcasses (Interview 1). Hence, there may be some underestimation of the proportion of contaminated carcasses if those thought to be contaminated are deliberately removed prior to inspections.

- In a telephone questionnaire of 230 veterinary pharmaceutical distributors in Spain in 2014, 36% were selling diclofenac. This equated to an estimate of 238 points of sale across Spain, with their reach covering 54% of the country’s land area. The spatial distribution of these points of sale have significant overlap with the distribution of breeding vulture populations (88% overlap with CV, 62% with EV, 58% with EGV and 42% with BV) (Camiña et al., 2019). It is likely safe to assume that since 2014, the number of points of sale of diclofenac has increased in line with the observed increases in the number of treated livestock (Figure 13; Moreno-Opo et al., 2021).

The decision to grant the marketing authorisation of veterinary diclofenac in Spain was taken by the Spanish Agency of Medicine and Sanitary Products (AEMPS) and the Ministry of Agriculture, Fisheries and Food (MAPA). However, Spain’s environment ministry (the Ministry for the Ecological Transition and Demographic Challenge, MITECO) was not involved and learned of the decision only after it was taken (Interview 9). Alarmed by the move, MITECO launched a report co-authored with MAPA and the Ministry of Health (MISAN) in July 2014 to assess the potential impacts of veterinary diclofenac on vultures and to inform public opinion (Interview 9). This report (which pre-dated the EU report discussed below) concluded that veterinary diclofenac posed a risk to Spanish vultures and that the risks posed by different exposure scenarios were unclear (AEMPS et al., 2014). The report outlined possible risk mitigation measures including carcass management, informational campaigns and the establishment of a monitoring programme.

A 2014 campaign led by conservation organisations including the Vulture Conservation Foundation (VCF), IUCN and BirdLife International also raised concern over the potential impact of the authorisation on European vultures (Interview 16). The campaign sparked EU engagement and a risk assessment was subsequently conducted at EU-level in December 2014. Under Article 30(3) of Regulation (EC) No 726/2004, the EMA’s Committee for Veterinary Medicinal Products (CVMP) is required to formulate an opinion on a requested scientific matter relating to the use of VMPs after such a request is registered by either the Executive Director of the Agency, the European Commission or a Member State. The European Commission requested such an opinion on (i) the risk posed by the use of VMPs containing diclofenac to vultures and other necrophagous birds in the EU, and (ii) any actions that could be taken to mitigate such a risk (CVMP, 2014). As a result, the CVMP compiled a report detailing the available data, subsequent conclusions and recommendations on the use of veterinary diclofenac in Europe, and its potential impact on European vultures, eagles and kites (CVMP, 2014).

The CVMP’s report concluded with the acknowledgement that a risk does in fact exist to European vultures feeding on domesticated ungulate carcasses treated with diclofenac. However, what was said to be less certain is whether it is actually likely that necrophagous birds in the EU are exposed to carcasses treated within 10 days of death. The CVMP pointed to a lack of field evidence but suggested the adoption of ‘additional risk management measures are needed.’ (CVMP, 2014, p.33). However, they fell short of recommending or evaluating the effectiveness of the eight proposed measures as such action would fall outside the ‘remit’ of the Committee. The tabled measures ranged from the supply of information to veterinarians and the inclusion of warnings in the product literature, to the withdrawal of diclofenac products from the EU market (CVMP, 2014).
The report highlighted how methods of carcass disposal impacted the level of risk posed by treated carrion to vultures. After the bovine spongiform encephalopathy (BSE) outbreak, carcass dumps for the disposal of livestock carrion were outlawed in the European Union in 2002 (Regulation (EC) No 1774/2002). However, exceptions were made for certain Member States to establish feeding stations to serve necrophagous bird populations (Decisions (EC) 332/2003 and 830/2005), including in Spain (Royal Decree 664/2007). As of 2014, Spain had 235 such stations. All stations must be registered and supervised, and any incoming carcasses must have documentation of their treatment history and farm of origin. In reality, treatment histories are not subject to scrutiny, nor is there any reporting mechanism to MITECO (Interview 1, 9). Furthermore, despite this regulatory framework for acceptable carcass dumping, illegal unregistered carcass dumps (or ‘muladares’) still exist in Spain as a traditional and cheap way of disposing of dead livestock, utilising the ecosystem services provided by vultures (Interview 1). Moreover, fallen stock in extensive farming systems (where livestock graze freely, sometimes seasonally) can legally be left in the field for necrophagous birds in Spain (Royal Decree 1632/2011).

The CVMP listed three possible exposure routes of vultures to diclofenac in Spain (CVMP, 2014):

(i) **Treated fallen stock in extensive production systems.** On average, a vulture will find a dead animal within 31 minutes (CVMP, 2014; Oliva-Vidal et al., 2022b). It is therefore likely a vulture will find fallen livestock before a farmer, especially in extensive livestock systems. If these livestock have been treated with diclofenac within 7-10 days before death, their carcasses pose a risk to vultures (CVMP, 2014).

(ii) **Treated dead livestock from intensive production transported to feeding stations.** If dead animals are transported to feeding stations shortly after treatment with diclofenac, their carcasses pose a risk to vultures (CVMP, 2014).

(iii) **Slaughterhouse material from treated livestock transported to feeding stations.** If animals are slaughtered before completion of the withdrawal period after their last treatment, their carcasses pose a risk to vultures (CVMP, 2014).

![Diagram](https://example.com/diagram.png)

**Figure 14:** Exposure pathways of European vultures to veterinary diclofenac as identified by CVMP report (2014).

Source: own representation.

Routes (i) and (ii) were confirmed as posing a real risk to vulture populations, whereas route (iii) was not considered a risk (Figure 14). Withdrawal periods in Spain specify that a period of 15 and 12 days for cattle and pigs respectively should elapse since their last treatment before slaughter.
This exceeds the 10 days it takes for carcasses to become non-toxic to vultures (<3μg/kg), and thus any carcass material will be safe to enter the vultures’ food chain (CVMP, 2014).

After publication of the CVMP’s report in 2014, the EU Commission, in consultation with Member States, decided not to ban veterinary diclofenac. Instead, Member States were asked to develop and submit risk mitigation plans. Of the eight measures proposed by the CVMP, Spain included three in their plan: information to veterinarians, warnings in the product literature and a sampling scheme (VCF, n.d.).

- Information to veterinarians. In 2015 and 2018, AEMPS distributed a note among veterinary organisations stating: ‘veterinarians must not prescribe or administer drugs containing diclofenac to: 1. Animals whose carcasses will be provided to feeding sites for avian scavengers; 2. Animals raised outdoors whose carcasses may be accessible to avian scavengers before their removal and disposal.’ (Moreno-Opo et al., 2021).

- Warnings in the product literature. The labelling on VMPs containing diclofenac in Spain was amended to include the generic message: ‘Do not administer to animals likely to enter the food chain of wildlife. In case of death or slaughter of the treated animals, ensure that they are not made available to wildlife. The use of the drug under conditions other than other recommended in the technical data sheet may pose a risk to avian scavengers.’ (Margalida and Oliva-Vidal, 2017; Moreno-Opo et al., 2021).

- Scheme to test sick/dead vultures. Under the existing Spanish veterinary pharmacovigilance system (VIGIÀVET), any suspicious adverse events (SAE) can be reported and analysed. To date, no such SAEs had been reported to VIGIÀVET nor to the European veterinary pharmacovigilance database (EUDRAVIGILANCE) (Interview 9). Similarly, routine surveys are carried out to determine the cause of mortality in threatened species in Spain (Law 42/2007, Art. 57).

After publication of both reports by Spanish and EU authorities in 2014, Spain nevertheless chose to renew the marketing authorisation of veterinary diclofenac in 2018 (Interview 9). The competent authority (AEMPS) concluded that insufficient evidence existed of a significant risk to vultures and hence the authorisation was renewed for another five years (Interview 9). Unlike in Asian vulture range states where NSAID ban requests have arisen ad hoc, such a ban in Spain would likely only occur via the refusal to renew marketing authorisation at these five-year junctures (Interview 9). Furthermore, in order for the EU to intervene against the state licensing of diclofenac, a ‘smoking gun’ would be needed confirming a real risk exists to vultures; the single cinereous vulture shown to have died from diclofenac poisoning in 2021 was not deemed enough to warrant such action (Interview 16).

Despite being excluded from the original authorisation decision in 2013, MITECO was involved in this renewal decision (Interview 9). However, they have continued to advocate for risk mitigation measures and recently collaborated with AEMPS and MAPA to co-author a report analysing the updated evidence of risk to vultures after seven years of veterinary diclofenac’s use in Spain (Interview 9). Assessing evidence and risk between 2013 and 2020, the report concluded that ‘diclofenac does not affect vulture populations as long as the [risk mitigation] measures are applied’ (AEMPS et al., 2020, p.14). These measures include the distribution of diclofenac on prescription, adherence to recommended dosage and slaughter withdrawal periods, and efforts to ensure treated carrion does not enter the food chain of necrophagous birds. MITECO has also led initiatives to increase awareness of the risk to vultures, especially among veterinarians. They are
advocating for the inclusion of warning labels on VMPs containing flunixin in addition to those containing diclofenac (Interview 9).

Throughout this process, the licence holder, Fatro Ibérica S.L., has been difficult to engage with and inherently uncooperative. Obtaining data on the sales volumes of diclofenac in Spain was hard to achieve and they have consistently deflected any responsibility for their drugs’ effect on vultures (Interview 9). Fatro was sent all relevant evidence communicating the risk of veterinary diclofenac and chose not to engage with efforts to mitigate this risk (Interview 16). Their complicit involvement has been branded ‘unethical and a disgrace to the pharmaceutical industry’ by SAVE’s programme manager, Chris Bowden (Chandresekhar, 2014). Fatro’s chief executive officer redirects blame onto the EU, arguing that ‘before the European regulatory authorities authorise a veterinary product, they should evaluate, amongst other things, safety for animals, man and the environment’; it would therefore be ‘unnecessary and inappropriate’ for Fatro to pass comment (Chandresekhar, 2014).

Since the European Commission’s decision not to ban veterinary diclofenac in 2015, the focus of the European vulture conservation has shifted towards risk mitigation and awareness raising (Interview 16). In particular, efforts are directed towards veterinarians, farmers and decision makers to encourage their engagement with the problem and knowledge of the risk. However, since the EU’s decision there has also been a concerning decline in surveillance of veterinary diclofenac despite its use increasing year on year (Figure 14; Interview 16). The lack of a routine screening system could mean diclofenac-related vulture deaths are going unnoticed. Furthermore, there is emerging evidence that EGV populations in Spain have begun to plateau (Interview 16). While it is too early to confirm the trend or its cause, the recent avian flu epidemic across Europe has already claimed the lives of EGVs in France, two BV chicks in Andalusia (Interview 16), and three BV chicks in Navarra (Interview 1). A combination of threats including poison baits, collision with electricity infrastructure, the increasing annual use of veterinary NSAIDs and now avian flu could spell trouble for the stability of future populations.
Policy Analysis

With the policies and procedures involved in NSAID licensing and banning in key vulture range states documented in the national case studies above, a comparative regional analysis will now be undertaken between the four central case studies in South Asia (India, Pakistan, Nepal and Bangladesh). This will be followed by an analysis of policies in Spain with reference to the wider European Union. First input and then throughput legitimacy indicators will be discussed, as outlined in previous sections, namely Theoretical Background (p. 15) and Data Analysis (p. 22). These indicators are then summarised in Tables 6-10, covering India, Pakistan, Nepal, Bangladesh and Spain.

South Asia

The significant overlap in vulture populations between countries in South Asia means particular heed must be paid to the transboundary misfits present in this region; first, vulture populations do not conform to national or state borders and hence vulture conservation strategies may have considerable spill-over effects into neighbouring areas (Botha et al., 2017). Second, the (il)legal trade of both human and veterinary NSAIDs throughout this region (particularly exports from India), mean national drug licensing policies have important implications for the wider availability of NSAIDs (Interview 6, 7). Furthermore, the complex multi-level governance of these densely populated countries presents vertical misfits which challenge both the internal and external coherence of efforts to create and enforce licensing policies. Even when this can be achieved, the temporal lag in vulture population recovery means the impacts of such policies will not become definitively apparent for at least a decade after their introduction (R. Green, pers. comm., 2023; Niel & Lebreton, 2005). While this temporal misfit plays out, policymaking actors must contend with the horizontal mismatches in agendas of different actors, such as the influential interests of the pharmaceutical lobby against those of NGOs advocating for vulture conservation. The regional mismatch in legal protection afforded to cattle for religious reasons also presents a unique challenge not found in the European case. Together these four misfits create a strenuous backdrop to the formation of more robust NSAID licensing frameworks, especially given the lack of conservation funding available compared to the financial resources of actors’ counterparts in Europe.

Table 5: Comparing the population of OWRV, bovine livestock and humans to country area and NVCAP budget across the Indian subcontinent. Only the population of OWRV is included as other species numbers remain highly uncertain and therefore total vulture numbers cannot be directly compared. Data from: DLS, 2018; DLS, 2021; DNPWC & DoFSC, 2022; DoAHD, 2019; Karki & Mirbahar, 2016; MoEF, 2016; MoEFCC, 2020; Shahzad, 2022.

<table>
<thead>
<tr>
<th>Country</th>
<th>OWRV population (million)</th>
<th>Bovine population (million)</th>
<th>Human population (million)</th>
<th>Country area (million km²)</th>
<th>NVCAP budget (million USD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>India</td>
<td>6,000</td>
<td>303</td>
<td>1,390</td>
<td>3.29</td>
<td>25.5</td>
</tr>
<tr>
<td>Nepal</td>
<td>&lt;2,000</td>
<td>12.7</td>
<td>29.7</td>
<td>0.147</td>
<td>1.13</td>
</tr>
<tr>
<td>Pakistan</td>
<td>150</td>
<td>57</td>
<td>225</td>
<td>0.796</td>
<td>4.94</td>
</tr>
<tr>
<td>Bangladesh</td>
<td>260</td>
<td>25.6</td>
<td>166</td>
<td>0.148</td>
<td>1.20</td>
</tr>
</tbody>
</table>
The budgets available for the implementation of NVCAPs on the Indian Subcontinent vary hugely and don’t necessarily correlate with vulture or livestock population sizes (Table 5). Nepal’s NVCAP laments how vulture conservation is poorly funded by the Government of Nepal and instead relies on the support of international NGOs (DNPWC, 2015). Similarly, India’s vulture conservation programmes received only one third of the funding required in 2016-2020, with no funding at all from the central government in 2020 (SAVE, 2021). In contrast, Spain invested €72.8 million (€30.8 million received from the EU) on 38 projects related to vulture conservation between 1993-2014 (Margalida and Oliva-Vidal, 2017). This figure far outstrips the budgets available in South Asia despite the problem being objectively far less serious in Europe.

With these limited financial action resources, the capacity of policymakers to deal with accountability dilemmas exerted by other actors without bias is challenged. National governments in South Asia have existing obligations to observe commitments and laws protecting vultures under national and international frameworks. Among others, vultures are protected under the national laws of India, Pakistan and Bangladesh (MoEFCC, 2020), while India, Pakistan and Nepal are signatories to CMS’ Raptors MoU (CMS, 2020). Despite these obligations, policymakers face conflicting pressures from non-government actors with varying agendas spanning from the local to international level (Figure 4). For instance, on one side is a group of actors whose priority is the recovery and stability of vulture populations: SAVE is the overseeing regional consortium tackling South Asian vulture conservation, national organisations including BNHS and BCN manage in-country initiatives, and some states also run programmes (e.g., Arulagam in Tamil Nadu). On the other side are industry actors whose economic interests make their priority the sale of pharmaceuticals. The pharmaceutical companies manufacturing NSAIDs can exert considerable lobbying power, which is further magnified in consortiums like the Indian Federation for Animal Health Companies (INFAH) (Interview 2).

The available action resources of different actors mean some stakeholders hold a firmer grip on the outcome of newly formed policies or those under consideration. The significant power of the pharmaceutical lobby was demonstrated in the case brought to the Madras High Court by Laborate Pharmaceuticals and Alpa Laboratories in 2016 challenging the restriction on multi-dose vial sizes (Laborate Pharmaceutical India... vs Union of India, 2017). Although the outcome of this case demonstrated internal coherence with wider Indian legal frameworks – namely, the precautionary principle – it clearly highlighted the lengths that invested private actors will go to in order to secure the stability of their revenue streams and market influence. While Pakistan’s inclusion of pharmaceutical industry actors in DRAP Registration Board meetings arguably demonstrates a high degree of transparency, it is likely a delicate balance between increasing industry participation and heightened vulnerability to lobbying (Interview 8, 18). Meanwhile in Nepal and Bangladesh, the smaller size of national pharmaceutical industries has resulted in a more positive, collaborative relationship with examples of companies voluntarily withdrawing production of vulture-toxic drugs (Interview 6, 7).

Possibly as a result of these significant industry interests, there are several instances where the weight of scientific evidence has not factored highly in drug licensing decisions taken in South Asia. Nepal’s national drug policy declares that ‘drug registration will be based on scientific facts’, and that ‘distribution of ineffective, harmful, toxic as well as irrationally combined formulations will be banned’ (National Drug Policy, 1995). Despite this, several proven vulture-toxic drugs remain licensed and widely used across the subcontinent (Table 4). This policy incoherence with the growing scientific knowledge base has now been challenged in the ongoing case at the Delhi High Court (Gaurav Kumal Bansal vs Union of India and ors., 2022). Only in Bangladesh has a second
veterinary NSAID besides diclofenac been banned (Interview 6). Moreover, aceclofenac – the drug most chemically similar to diclofenac and shown to quickly metabolise into the banned drug – remains licensed in both India and Pakistan (Table 4). As in the EU, no environmental toxicity tests are required to be performed on secondary or tertiary species like vultures before these veterinary drugs are licensed (Interview 4, 15). The safety tests performed on other domestic animals including domestic chickens are wholly inadequate for the extrapolation of risk given these species are known to hold vastly different sensitivities to veterinary NSAIDs (Naidoo et al., 2007). Furthermore, safety testing of veterinary NSAIDs on vultures has received no funding from the pharmaceutical industry, and work done so far is owed to NGOs like the RSPB (R. Green, pers. comm., 2023). A government-funded safety testing programme in India does exist, but it has achieved very little, and efforts instead continue to be led by NGOs (R. Green, pers. comm., 2023).

The lack of evidentiary foundation in support of NSAID licensing decisions across states in South Asia is also found within countries: the few states in India who have authorised the use of veterinary aceclofenac are at odds with the central CDSCO licensing process (Interview 15). This internal incoherence is also found in the state government distribution of veterinary NSAIDs in India, whereby different drugs are distributed in different regions with no regulatory mechanism to prevent the distribution of vulture-toxic NSAIDs, nor the standardisation of such programmes (Interview 4, 5). The significant regional variation in NSAID use and government distribution stocks highlights the inconsistent approach to this problem by state government actors (Interview 5). While this may in part be explained by the variation in vulture population density across the country, the lack of state policy compatibility will no doubt be affecting populations whose ranges overlap multiple states boundaries.

However, while NSAID licensing in India is arguably lacking in evidence-based foundations, the decisions that have been made demonstrate levels of internal coherence not seen in Europe. The move to restrict the vial size available in human diclofenac preparations is coherent with policies made on the veterinary side, suggesting crosstalk and transparency between regulatory government departments (MoEFCC, 2020). Similarly, the decision taken in Madras to uphold this restriction on the grounds of the precautionary principle is internally coherent with India’s established legal principles (Laborate Pharmaceutical India... vs Union of India, 2017). Elsewhere, Bangladesh’s move to legitimately enshrine vulture conservation in its national legal framework is a strong example of internal coherence across multiple levels of government, brought to life through the three-tier institutional mechanism set up to manage the country’s VSZs (MoEF, 2016). However, the decision to restrict the use of certain NSAIDs in particular states/provinces of India and Pakistan, while an admirable endeavour, is at odds with policies in neighbouring states and provinces whose incompatible NSAID use threatens to undermine such efforts (Interview 8, 10). Pakistan’s restrictions in Sindh in particular lack policy completeness as drug manufacture has not been affected, only use and sale (Interview 8, 18).

The difficulty encountered in expanding bans to more vulture-toxic veterinary NSAIDs can also be attributed to the fact that current policies are externally coherent with wider global approaches. Both veterinary ketoprofen and flunixin are widely used in Europe and North America, making them harder to ban in this region (Interview 2, 15). However, examples of external policy incoherence on the Indian subcontinent demonstrate that there are many other factors at play. The stipulation in Pakistan’s 2006 ban on veterinary diclofenac that their ban does not extend to drugs manufactured for export is inconsistent with blanket bans introduced by the other three parties to the Regional Declaration (Delhi, 2012; Karki & Mirbahar, 2016). In addition, border porosity across the region threatens policy compatibility between range states, particularly through the illegal trade of
nationally banned NSAID formulations. The import of multi-dose vials into Nepal and Bangladesh from India for example, directly undermines the effectiveness of vulture conservation efforts in those countries (Interview 6, 7). The sharp decline in multi-dose vials found in Nepal following their restriction in India demonstrates just how closely these pharmaceutical markets are linked (Galligan et al., 2021). Furthermore, the smuggling of cattle from India into Bangladesh highlights the external incoherence in policies regulating cow slaughter, as well as the lack of consensus on the legality of this trade between Delhi and Dhaka (Nair and Paul, 2015). While the variation in dominant religion goes a long way to explaining the risk to vultures across this region, insufficient carcass management in Bangladesh (as well as across the wider subcontinent) could be putting vultures at risk (Interview 6).

The lack of policy coherence on the movement of cattle across the India-Bangladesh border also suggests a level of ambiguity exists in clarifying the respective responsibilities of the two governments in regulating this issue. Similarly, the ongoing case in the Delhi High Court has exposed significant ambiguity in policy means as it has become clear there is uncertainty in the roles of actors outlined in India's NVCAP (Gaurav Kumal Bansal vs Union of India and ors., 2022; Kaur, 2022b). While the plan proposes that the MoFAHD engages only in tasks related to policy implementation, CDSCO is now alleging that their consensus must be sought before further bans can progress (Kaur, 2022b; MoEFCC, 2020). Such ambiguity is concerning in light of the lack of power held by these NVCAPs to bind other stakeholders (Interview 5). Without such bindingness, this role ambiguity may lead to policy implementation failure as meaningful decision-making is postponed while those seeking further bans are left to run in circles (Kaur, 2022a; Matland, 1995).

Furthermore, the varying approaches of range states on the veterinary NSAIDs they have chosen to ban or restrict suggests there is fundamental uncertainty over the most appropriate policy tools to tackle this problem. Some of these interventions are also ambiguous in their policy goals; in Pakistan, for example, the restriction on ketoprofen and aceclofenac in the province of Sindh appears unclear in its mandate (Interview 18). As put by one interviewee, the move can arguably be seen as more of a declaration of commitment to vulture conservation than a serious policy intervention with intention of strict enforcement (Interview 18). On a wider scale, little evidence exists of concerted efforts by range states to collaborate on the many shared policy goals listed across NVCAPs, such as the improvement of meloxicam formulations or the development of understanding of vulture ecology (MoEFCC, 2020). The fulfilment of these common goals would benefit all range states yet there appears uncertainty over how this should be achieved, and it would be inefficient for each state to work on these goals separately.

Levels of policy transparency are arguably highest in Nepal, where community outreach and education programmes are well-cited as a leading reason for Nepal's success in reducing the prevalence of veterinary diclofenac (Interview 7). Both their ‘diclofenac-for-meloxicam’ scheme, as well as the well-publicised ‘vulture restaurants’ have increased community awareness of the problem as well as public engagement (DNPWC, 2015). Yet the growing popularity of nimesulide as an alternative to diclofenac suggests more work needs to be done to increase community awareness of the safety of these different drugs to vultures (Interview 7). In Bangladesh, the embedding of vulture conservation in national legal frameworks bodes well for transparency among policymakers (MoEF, 2016). The workshops held prior to country-wide banning of ketoprofen also signal a high degree of transparency and participation among actors involved (SAVE, n.d.). Unlike in other range states where inclusive and unanimous agreements cannot be reached (in part, due to the inevitable objections of the pharmaceutical industry), Bangladesh has achieved both transparency and inclusivity in the licensing process of veterinary NSAIDs (Interview

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Such a close relationship between government actors, NGOs and pharmaceutical companies would no-doubt be more difficult to achieve in India where institutions are larger, more complex and diffusely organised.

This complexity in Indian governance structures has resulted in high variation of policy transparency, and as a result a mosaic of success in spreading ban awareness: only 22% of pharmacies in India’s southern states were found to be aware of the diclofenac ban, while 71% of pharmacies in the state of Jharkhand were fully aware (Galligan et al., 2021). Similarly in Pakistan, the use of human formulations of diclofenac (albeit not multi-dose vials) suggests community awareness of the risk is low, requiring increased policy transparency and communication (Karki & Mirbahar, 2016). However, the varied membership of Pakistan’s DRAP Board could be a valuable tool to increase engagement across sectors and actor groups (Interview 8, 18). Across South Asia, all countries deal with the challenge of disrupting engrained community beliefs and concerns. The rapid spread of misinformation through communities is a common phenomenon also seen among farmers in Spain (Margalida et al., 2014). The importance of dispelling these myths early and clearly was demonstrated by the talk given by ZSL veterinarian Dr Nic Masters to stakeholders in Bangladesh on the risks posed by veterinary ketoprofen, and efforts to dispel the false notion that meloxicam is unsuitable to give to pregnant livestock (R. Green, pers. comm., 2022; SAVE, n.d.). The collaboration between Bangladesh’s government, vulture conservation committee and pharmaceutical companies (Acme and Renata) on improving consumer awareness surely greatly reduces the potency and spread of such misinformation (MoEF, 2016).

While these strides in policy transparency are advancing across the subcontinent, little evidence exists of strict enforcement or the punishment of offenders. Since the first bans on veterinary diclofenac were introduced in 2006, few examples of policy bindingness can be found. In India, the only example known to SAVE comes from Tamil Nadu, where recent action has been taken against actors at all levels of the drug supply chain (Interview 10; SAVE, 2022). At the state level, limited monitoring of the regional restrictions on veterinary NSAIDs in both India and Pakistan has resulted in weak enforcement, meaning the restricted drugs continue to be sold in the areas, albeit at reduced levels (Interview 5, 18). Although the NVCAPs published by range states contain ambitions to increase the bindingness of conservation measures, these plans have no power to bind other stakeholders themselves (Interview 5). India’s goal to move veterinary NSAIDs from ‘Schedule-H’ to ‘Schedule-X’, requiring documentation of sale in addition to prescription, seems overly ambitious given current enforcement of the prescription requirement alone is so low (MoEFCC, 2020). Although if this could be achieved, it may improve policy bindingness as particular pharmacies or regions not adhering to the requirements could be identified more easily. Given these drugs continue to be widely administered by unqualified ‘quacks’, and hence routinely overdosed, solving this problem of enforcement will be challenging (Interview 4, 8).

The tables below summarise the throughput legitimacy indicators discussed above for the four parties to the 2012 Regional Declaration: India, Pakistan, Bangladesh and Nepal. The degree to which policies and procedures are evidence-based is also included. Coloured icons are used to denote positive (green) versus negative (red) elements of throughput legitimacy. In India (Table 6), there is a mixed amount of policy coherence although policies contain significant ambiguity and are often lacking an evidence-based foundation. Levels of procedural transparency and policy bindingness are also generally low. Licensing procedures in Pakistan are arguably more transparent among actors but procedural ambiguity and policy bindingness remain problematic (Table 7). Levels of transparency are highest in Nepal and Bangladesh, with the former achieving greater policy (i.e., community) transparency (Table 8), while the latter’s policymaking is more procedurally
transparent (Table 9). A high level of internal policy coherence has been achieved in Bangladesh, although policy bindingness is lacking (Table 9).

**Table 6**: Summary of throughput legitimacy indicators for NSAID licensing and banning procedures in India (Interview 4, 5, 10, 15, 19; MoEFCC, 2020).

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Examples</th>
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| **Internal Coherence** | - Multi-dose vial restriction is coherent with veterinary diclofenac ban (policy compatible across human and veterinary medicine).  
- Madras High Court decision to uphold multi-dose vial restriction on account of the precautionary principle is in line with wider Indian legal frameworks.  
- Licensing of aceclofenac without CDSCO approval by some Indian state governments is incoherent with central government licensing process.  
- Different veterinary NSAIDs distributed by Indian state governments: no coordinated approach.  
- Carcass management policies (e.g., discouragement of open carcass dumping in Tamil Nadu) are at odds with vulture conservation. |
| **External Coherence** | - Regional Declaration across Indian subcontinent on diclofenac ban.  
- Government distribution of veterinary NSAIDs known to be vulture-toxic remains commonplace. No existing regulatory mechanism to prevent the distribution of drugs shown to be vulture-toxic.  
- No environmental toxicity tests required to be performed on secondary or tertiary species during veterinary NSAID licensing. |
| **Evidence-based** | - Lack of clarity in actor roles outlined in NVCAP demonstrated in most recent hearing of the case in Delhi High Court. Uncertainty about roles of actors in the implementation process.  
- Uncertainty in policy means: which veterinary NSAIDs should be banned? |
| **Ambiguity** | - High variation in levels of transparency across Indian states (Galligan et al., 2021). Mixed success in spreading ban awareness regionally. |
| **Transparency** | - Tamil Nadu crackdown on diclofenac offenders is rare example of enforcement of ban/restriction. Evidence for bindingness at all levels of the supply chain.  
- Little evidence of bindingness or enforcement elsewhere.  
- Weak enforcement of restriction requirement leads to drug administration by unqualified 'quacks' and overdosing.  
- India's NVCAP has no legal power to bind other stakeholders. |
Table 7: Summary of throughput legitimacy indicators for NSAID licensing and banning procedures in Pakistan (Interview 8, 18; Karki & Mirbahar, 2016).

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Examples</th>
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<tbody>
<tr>
<td><strong>Internal Coherence</strong></td>
<td>Sindh restriction on ketoprofen and aceclofenac does not extend to manufacture, only sale and use. Lack of policy completeness.</td>
</tr>
<tr>
<td><strong>External Coherence</strong></td>
<td>Regional Declaration across Indian subcontinent on diclofenac ban.</td>
</tr>
<tr>
<td></td>
<td>Loophole in 2006 diclofenac ban which excludes manufacture for export is incoherent with policies in other vulture range states on the Indian subcontinent.</td>
</tr>
<tr>
<td><strong>Evidence-based</strong></td>
<td>DRAP has agreed to cooperate on the banning of further NSAIDs on the provision of scientific evidence.</td>
</tr>
<tr>
<td></td>
<td>Despite this, three vulture-toxic drugs are licensed.</td>
</tr>
<tr>
<td><strong>Ambiguity</strong></td>
<td>Lack of clarity in policy goals: restriction in Sindh on ketoprofen and aceclofenac can be seen as more of a declaration of commitment to vulture conservation than a serious policy to be enforced.</td>
</tr>
<tr>
<td><strong>Transparency</strong></td>
<td>Varied membership of DRAP Registration Board encourages greater transparency across sectors and actors.</td>
</tr>
<tr>
<td></td>
<td>Use of human formulations of diclofenac (although not multi-dose vials) suggests lacking communication of risks to vultures.</td>
</tr>
<tr>
<td><strong>Bindingness</strong></td>
<td>Restriction on ketoprofen and aceclofenac in Sindh has low bindingness and is not enforced: the two drugs continue to be sold in the province.</td>
</tr>
<tr>
<td></td>
<td>Requirement to purchase veterinary NSAIDs on prescription is poorly enforced.</td>
</tr>
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<td></td>
<td>Pakistan’s NVCAP has no legal power to bind other stakeholders.</td>
</tr>
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</table>

Table 8: Summary of throughput legitimacy indicators for NSAID licensing and banning procedures in Nepal (DNPWC, 2015; Interview 7).

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Examples</th>
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<tr>
<td><strong>Internal Coherence</strong></td>
<td>National Drug Policy states that the ‘distribution of ineffective, harmful, toxic as well as irrationally combined formulations will be banned’ (National Drug Policy, 1995). This is inconsistent with veterinary NSAIDs known to be vulture-toxic which have yet to be banned.</td>
</tr>
<tr>
<td><strong>External Coherence</strong></td>
<td>Regional Declaration across Indian subcontinent on diclofenac ban.</td>
</tr>
<tr>
<td></td>
<td>Border porosity threatens coherence with NSAID policies in neighbouring India (e.g., no domestic production of multi-dose vials of diclofenac but some imported from stocks made illegally in India).</td>
</tr>
<tr>
<td><strong>Evidence-based</strong></td>
<td>Government (DDA) statement that aceclofenac will not be licensed in future.</td>
</tr>
<tr>
<td></td>
<td>National Drug Policy states that ‘drug registration will be based on scientific facts’, yet ketoprofen and nimesulide (both proven to cause harm to vultures) remain licensed for veterinary use.</td>
</tr>
<tr>
<td><strong>Ambiguity</strong></td>
<td>Declaration from DDA that aceclofenac is not licensed nor will it be licensed in future: is this as good as a ban? Ambiguity in policy means.</td>
</tr>
</tbody>
</table>
High level of community transparency with vulture conservation.
Successful initiatives like ‘diclofenac-for-meloxicam’ and ‘vulture restaurants’ increase public engagement and awareness.
Nimesulide growing in popularity suggests greater transparency needed to communicate information on other vulture-toxic NSAIDs besides diclofenac.

‘Diclofenac-for-meloxicam’ scheme encourages effective ban implementation and enforcement.
Nepal’s NVCAP has no legal power to bind other stakeholders.

<table>
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<tr>
<th>Indicator</th>
<th>Examples</th>
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| Internal Coherence | Enshrinement of vulture conservation in national legal frameworks increases chance of coherence with wider policies (e.g., VSZs are government-declared).
Three-tier institutional mechanism to manage VSZs: internal coherence between multiple levels of government. |
| External Coherence | Regional Declaration across Indian subcontinent on diclofenac ban.
Border porosity threatens coherence with NSAID policies in India (e.g., no domestic production of multi-dose vials of diclofenac but some imported from stocks made illegally in India).
Smuggling of cattle across border into Bangladesh for slaughter is considered legal by Dhaka but illegal by Delhi. |
| Evidence-based | Ketoprofen ban based on evidence of harm and surveyed prevalence of the drug.                                                                                                                                  |
| Ambiguity   | Smuggling of cattle across border into Bangladesh for slaughter is considered legal by Dhaka but illegal by Delhi.                                                                                           |
| Transparency | Vulture conservation legitimately enshrined in national legal frameworks increases transparency and awareness among actors.
National workshops prior to ketoprofen ban to communicate risks and reasoning to wide array of actors. Such inclusive and unanimous agreements are rare in other range states (e.g., legal challenges from pharmaceutical companies in India).
Collaboration with pharmaceutical companies Acme and Renata. (e.g., inclusion of vulture-safe messaging on meloxicam vials).
Spread of community misinformation about side-effects or suitability of different veterinary NSAIDs in livestock. |
| Bindingness | Vulture conservation legitimately enshrined in national legal frameworks increases bindingness and hopes of effective enforcement.
A significant proportion of NSAIDs found in the VSZs in 2020 contained ketoprofen, suggesting imperfect enforcement and awareness of the ban.
Bangladesh’s NVCAP has no legal power to bind other stakeholders. |
European Union: Spain

Unlike South Asia, the primary NSAID of concern in the EU continues to be veterinary diclofenac (CVMP, 2014); other NSAIDs such as flunixin have yet to be afforded the same consideration. The key actors involved in the NSAID-vulture debate in Europe include the European Union (in particular the European Medicines Agency, EMA), the Spanish Government, veterinary pharmaceutical company Fatro, livestock farmers, and NGOs supporting vulture conservation (e.g., VCF). There are distinct differences in the action resources available to these actors: while government institutions have the force of law, infrastructure and information behind them, the financial resources of the pharmaceutical lobby are significant (Interview 9, 16). The EU’s pharmaceutical lobby has a declared annual spend of around EUR 40 million, although underreporting of such activities could put the real total closer to EUR 90 million every year (Corporate Europe Observatory, 2015). This pressure exerts significant influence on policymaking in Brussels, dwarfing the lobbying expenditure of civil society and other pressure groups (Corporate Europe Observatory, 2015).

The size of the EU’s Big Pharma lobby exacerbates the salient misfits present in the European case which challenge policy output and throughput legitimacy. At the horizontal level, there is a strong mismatch between the agendas of conservation NGOs who support vulture conservation, farmers who want to protect their livestock from the perceived risk of vulture attacks, and the pharmaceutical company (Fatro) who produces veterinary diclofenac (Interview 1). These conflicting interests add weight to the accountability dilemmas faced by policymakers (namely, the EU and the Spanish Government) who are striving to balance these different agendas (Interview 9). Meanwhile, the expansion of EGV populations means vultures are recolonising areas of Spain which have not been home to vultures in living memory, presenting a temporal misfit which puts further strain on farmer-vulture relations (Interview 16). On the transboundary plane, EU Member States have been left to decide whether or not to authorise the marketing of veterinary diclofenac, with the result being varying approaches to the drug taken across vulture ranges (CVMP, 2014). For vulture populations on the Iberian Peninsula, Spain has chosen to authorise veterinary diclofenac while Portugal has not (VCF, 2018).

Despite this transboundary misfit, coherent risk evaluation between the Spanish Government and EU has reduced the pressure of vertical misfits in this problem (AEMPS et al., 2014, 2020; CVMP, 2014). The findings of both institutions’ reports were consistent in their conclusion that the risk to European vultures from veterinary diclofenac is low, with their recommended approach being the introduction of various risk mitigation measures. As a result, neither has taken the decision to withdraw permission or marketing authorisation for the drug, presenting a level of external coherence between the policies of the two actors (AEMPS et al., 2014, 2020; CVMP, 2014). This is mirrored by the internal coherence between various Spanish Government agencies in co-authoring risk analysis reports in 2014 and 2020, which have both supported the decision to grant marketing authorisation to Fatro (AEMPS et al., 2014, 2020). However, the Spanish (and wider EU) policies on veterinary diclofenac are inconsistent with those predating them in South Asia (Delhi, 2012). Spain’s decision to authorise veterinary diclofenac in 2013 was made a decade after the discovery of the drug as the sufficient cause of South Asian vulture declines (Oaks et al., 2004), despite the evidence base for the harm caused by veterinary NSAIDs mounting year-on-year and the existence of safe alternatives (Interview 1).
There are several cases which bring into question the degree to which EU and Spanish policymaking on this issue is evidence-based. This extends beyond the fundamental decision to grant marketing authorisation, but also in the supporting arguments of that decision (AEMPS et al., 2014, 2020; CVMP, 2014). As in South Asia, there is no safety testing requirement under EU environmental risk assessment standards for veterinary drugs on scavenging birds (Directive 92/18/EEC), and the consumption of carrión treated with VMPs is not listed as a risk of exposure to the terrestrial environment (EMA, 2008). Furthermore, some of the field survey data presented by the Spanish Government reports in support of their argument that the environmental prevalence of diclofenac is low is questionable:

- The use of carcass sampling data from slaughterhouses as an indicator of risk (AEMPS et al., 2020) is dubious since: (i) the CVMP’s report explicitly disregarded such material from posing a risk to vultures due to the withdrawal times required before slaughter (CVMP, 2014), and (ii) diclofenac is not authorised for use in livestock intended for human consumption (AEMPS et al., 2020). It is therefore not surprising that no trace of diclofenac was found in carcasses at slaughterhouses.
- Similarly, the sampling of sheep carcasses at feeding sites (Herrero-Villar et al., 2020) is unlikely to yield traces of diclofenac as the drug is not authorised for use in sheep (AEMPS et al., 2020). The sampling of cattle, pig or horse carcasses would likely present a better picture of the environmental presence of the drug as diclofenac is authorised for use in these livestock (AEMPS et al., 2020).
- In sampling of over 5000 vultures in rescue centres, less than one fifth had a full necropsy or clinical check, severely limiting the likelihood of discovering those contaminated with veterinary NSAIDs (Moreno-Opo et al., 2021). This is concerning given the level of carcass contamination required to cause significant population decline in South Asia was found to be so small, and hence could easily be missed (Green et al., 2004). Moreover, the likelihood of a vulture poisoned with NSAIDs being brought into these rescue centres is low compared to other causes of death or injury (R. Green, pers. comm., 2023); it takes several days for the vulture to die of kidney failure, meaning it can travel far from the site of poisoning, thereby reducing suspicion raised over its death among civilians (R. Green, pers. comm., 2023).

Furthermore, until 2016 there was no monitoring of NSAID contamination in livestock carcasses available to scavengers anywhere in Europe (Margalida and Oliva-Vidal, 2017). This significantly restricts the timeframe over which risk assessment data can be compared, and thus leads some scientists to believe that ‘the current risk cannot be effectively assessed’ (Margalida and Oliva-Vidal, 2017). The increasing annual use of veterinary diclofenac and falling levels of surveillance is also concerning and highlights the mismatch in risk perception between conservation scientists (Green et al., 2016) and the Spanish Government (AEMPS et al., 2014). However, the evidence base does currently suggest that the risk to Spanish vultures from veterinary diclofenac is indeed lower than that on the Indian subcontinent (AEMPS et al., 2020; Galligan et al., 2021).

This lack of evidence-based policy support is at odds with the high degree of policy clarity surrounding the types of species in which veterinary diclofenac is authorised for use in Spain (AEMPS et al., 2020). However, policy goal ambiguity does exist in the sense that no clear threshold of vulture deaths or diclofenac prevalence has been identified as an unacceptable level of risk (Interview 1, 16). It is clear that the one diclofenac-related vulture death confirmed so far was not the ‘smoking gun’ required, but at what point would the risk posed be considered sufficient to withdraw authorisation (Interview 16)? And while the risk is considered sufficiently low, there exists
ambiguity in policy means in terms of which mitigation strategies are most appropriate (CVMP, 2014). Of the eight strategies suggested in the CVMP’s report, no explanation has been given as to why Spain chose the three options it did (AEMPS et al., 2014). On top of this, there is a fundamental lack in clarity over the role of actors in taking ownership of that risk (Interview 16). Of the three actors who could be shouldering this burden, each have built up contingencies to evade blame: Fatro does not believe they have any responsibility to withdraw their product (they place responsibility on the EU) (Interview 9), Spain does not think it necessary to act in light of the EU’s decision not to ban veterinary diclofenac (AEMPS et al., 2014, 2020), and the EU itself has left the authorisation decision up to individual Member States (CVMP, 2014). Without clarity as to the ‘responsible’ party, this circle of blame avoidance could be reducing responsiveness to the emergence of a rising threat level.

The EU’s response to concerns raised in 2014 and quick commissioning of the CVMP’s report (and subsequent transparency of findings) supports the accessibility of information to other actors and the wider public (CVMP, 2014). However, the level of transparency offered by Fatro is lacking in comparison (Interview 9). While this is understandable given the sensitive nature of sales figures and industry competition, their staunch unwillingness to cooperate with risk reporting by MITECO is unhelpful to increasing coherence and clarity of policy goals and means (Interview 9). Furthermore, the exclusion of MITECO from the original decision to authorise veterinary diclofenac in 2013 by other Spanish Government agencies suggests internal transparency at this institution is imperfect (Interview 9). MITECO, on the other hand, was quick to co-author a risk assessment in response to the decision which aimed to increase public understanding of the problem (Interview 9). Similarly, the risk mitigation strategies identified in their report have increased transparency of the issue and risks among other actors including farmers and veterinarians (AEMPS et al., 2014). Yet risk reporting which informs these assessments continues to lack in transparency: in particular, the reporting mechanisms legally required at Spain’s registered feeding stations (Spanish Royal Decree No 664/2007). There is currently no reporting mechanism from these stations to MITECO, and illegal sites continue to operate (Interview 1, 9). This lack of both transparency and bindingness is a persistent issue, and no clear examples exist of enforcement or punishment of rule-breakers.

The table below summarises the throughput legitimacy indicators discussed above as applied to the NSAID licensing procedure in Spain and the wider European Union (Table 10). The degree to which policies and procedures are evidence-based is also included. Coloured icons are used to denote positive (green) versus negative (red) elements of throughput legitimacy. Overall, there is a high level of internal coherence yet significant policy ambiguity and a lack of evidence-based foundations. Levels of policy transparency are mixed: while a high level of transparency is achieved at the national and EU-level, problems remain with communication between Spanish Government departments on decision-making, as well as data collection and availability. Policy bindingness is also generally low.
Table 10: Summary of throughput legitimacy indicators for NSAID licensing and banning procedures in Spain and the wider EU (AEMPS et al., 2014, 2020; CVMP, 2014; Interview 1, 9, 16).

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Examples</th>
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<tbody>
<tr>
<td>Internal Coherence</td>
<td></td>
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</table>
| CVMP report findings are consistent with EU’s decision not to ban veterinary diclofenac.  
| Spanish report findings are consistent with Spanish Government’s decision to authorise the marketing of veterinary diclofenac. |
| External Coherence |  
| Coherent conclusions and risk perception of CVMP and Spanish reports: both suggest risk mitigation measures are needed.  
| Incoherent with veterinary diclofenac policies on the Indian subcontinent. |
| Evidence-based |  
| No safety testing requirement in EU’s environmental risk assessment for veterinary drugs in scavenging birds. Consumption of carrion treated with VMPs is not listed as an exposure risk to the terrestrial environment (EMA, 2008).  
| Different mortality risk projections of Spanish Government, Green et al. (2016), and Herrero-Villar et al., (2020).  
| Falling levels of environmental surveillance alongside increasing annual use of veterinary diclofenac in Spain.  
| Field survey data used to support the argument that risk to Spanish vultures is low uses data inconsistent with regulations. |
| Ambiguity |  
| No clear threshold identified where risk would be considered sufficient to take further action.  
| Uncertainty over policy tools: unclear which mitigation strategy is most suitable (eight listed in CVMP report). No reasoning given why the Spanish Government chose to adopt the three it did.  
| Ambiguity in actor roles or responsibility: EU vs. Member States (Spanish Government) vs. Fatro. |
| Transparency |  
| Responsiveness of the EU in responding to public concern in 2014 and launching CVMP report to investigate the risk.  
| Spanish Government’s two reports (2014 & 2020) aimed to investigate potential impact and inform public opinion.  
| Note distributed to veterinary organisations by AEMPS communicating risk of veterinary diclofenac.  
| Vials of veterinary diclofenac come with warning label.  
| Lack of transparency between Spanish Government departments on decision to authorise marketing of veterinary diclofenac (MITECO not consulted on initial decision).  
| Screening information not publicly accessible and hence levels of accountability and scrutiny are limited.  
| No reporting mechanism to MITECO from feeding stations.  
| Fatro’s reluctance to share data and information about drug use. |
| Bindingness |  
| Little evidence for enforcement of feeding station rules in Spain or the punishment of offenders.  
| The sampling of sheep for veterinary diclofenac suggests the drug is being used in unauthorised species. |
DISCUSSION

South Asia vs EU

The case studies presented in this thesis span two geographic regions: Europe and South Asia. The handling of the threat posed to vultures by veterinary NSAIDs cannot be directly compared between these regions (or even between the countries within them in some cases) for many reasons (AEMPS et al., 2020; Moreno-Opo et al., 2021):

- **Livestock management.** Sanitary regulations in Spain are stricter than those in South Asian countries owing to stringent EU food safety laws (Regulation (EC) No 1069/2009). As a result, tight controls exist regulating the disposal of animal carcasses and all feeding stations in Spain must be registered (Spanish Royal Decree No 664/2007). In addition, mandatory withdrawal periods prior to slaughter reduce the chance of contaminated carcasses being exposed to the environment (CVMP, 2014). In South Asia, there is comparatively little control on carcass management, thereby greatly increasing the risk of vulture exposure to NSAID-contaminated carrion (DNPWC, 2015; Karki & Mirbahar, 2016; MoEFCC, 2020; MoEF, 2016).

- **Dietary and religious norms.** The majority-Hindu populations found in India and Nepal are opposed to the consumption of beef, while the majority-Muslim populations of Bangladesh and Pakistan have rules on permissible (‘halal’) slaughter practices. There is therefore an abundance of carrion available to vultures on the Indian subcontinent, particularly in India which is home to the largest cattle population on the planet and where cows are legally protected (Gujarat Animal Preservation (Amendment) Act, 2011). These ageing livestock are routinely dosed with veterinary drugs until their natural death as part of the palliative care provided by cattle welfare charities (after which, their carcasses are often dumped). In Spain, the consumption of beef is culturally acceptable: the number of ageing livestock and individuals requiring or receiving medical care are hence both significantly reduced.

- **Drug accessibility and veterinary surveillance.** The poor enforcement of requirements to buy veterinary NSAIDs on prescription in South Asia mean these drugs are routinely sold to, and administered by, unqualified personnel (DNPWC, 2015; Karki & Mirbahar, 2016; MoEFCC, 2020; MoEF, 2016). Overdosing is common and hence the toxicity of a carcass is amplified and prolonged, increasing the chance of vultures ingesting lethal levels of the toxic drugs. When combined with the low cost and widespread availability of veterinary NSAIDs, their pervasive use on the Indian subcontinent surpasses that in Spain.

- **Vulture ecology.** Vultures in South Asia predominantly rely on the consumption of carcasses from domesticated ungulates, often found in urban and semi-urban environments where the risk of NSAID contamination is high (IUCN, 2004). However, food sources available to Spanish vultures are less likely to be contaminated: a greater proportion of their diet is made up of wild ungulate carcasses, and where they do scavenge on domesticate ungulates, these are usually at feeding sites or fallen stock in extensively managed systems (Moreno-Opo et al., 2021). Both of the latter two sources hold a lower risk of NSAID contamination as feeding stations are supposedly strictly monitored and livestock in extensive farming are less likely to have been treated with veterinary medicines than those in intensive systems (CVMP, 2014).
• Monitoring and active surveillance. Spain and the wider EU’s capacity for monitoring vulture populations is greater than that found in South Asian countries (AEMPS et al., 2020). In addition, there is a significantly smaller geographical area across which monitoring must occur as the EU’s vulture populations are concentrated in specific areas (Moreno-Opo et al., 2021). South Asian vulture habitats, on the other hand, cover vast swathes of land comprising a plethora of different habitats (Botha et al., 2017). This presents challenges to systemic monitoring efforts, especially of non-resident species whose ranges overlap multiple states.

• Balance of threats. The portfolio and makeup of threats facing vultures in South Asia and Europe are significantly different (Botha et al., 2017; Figure 6). The risk of veterinary NSAIDs continues to dwarf other threats facing vultures on the Indian subcontinent whereas the threat of deliberately set poison baits is the dominant concern for those in Spain (Directive 2009/147/EC). However, the threat of deliberately set poison baits may be on the rise in South Asia: one interviewee believes that these baits pose a more significant threat to South Asian vultures than is acknowledged, particularly in Northeast India (e.g., Assam). In their view, Asian vulture conservation should be devoting more resources to investigating and dealing with this problem but there are concerns it will divert attention away from efforts to ban more NSAIDs (Interview 16).

• Societal perceptions of vultures. Vultures on the Indian subcontinent are culturally respected and valued for the ecosystem services they provide (Markandya et al., 2008). In Spain however, there is growing animosity amongst farmers amid reports of vulture attacks on livestock (Margalida and Donázar, 2020).

These factors mean the potential pathways of exposure to veterinary NSAIDs differ between the two regions. Due to cultural factors, it could be argued that the South Asian vulture crisis was an ‘accident waiting to happen’: any veterinary drug used in palliative care across an area where large populations of ageing livestock roam and whose carcasses are unmanaged could pose an exposure risk to scavengers (R. Green, pers. comm., 2023). In Spain, on the other hand, livestock management practices mean a similarly sudden population die-off would be less likely. However, the significant differences do not mean that lessons learned in one region cannot be heeded by the other. The Spanish governments’ assertion that the two are ‘hardly comparable’ may lead to a blinkering of European awareness and responsiveness to a growing threat despite the wealth of data accumulated on the Indian subcontinent (AEMPS et al., 2020, p. 17).

Does veterinary diclofenac pose a risk to Spanish vultures?

Although it can indeed be argued that the situations in South Asia and the EU cannot be directly compared, the Spanish authorities should be wary of conflating their conclusion that there is an absence of evidence that a significant risk exists with the conclusion that this is evidence that no significant risk exists. Considering Green et al.’s (2004, 2007) data from the Indian vulture crisis, close to 1000 ungulate samples would be needed to have a chance of detecting a significant level: this has not been achieved. Furthermore, of the data that is available and utilised to support the Spanish Government and EU’s decision-making, samples are small, data biases exist, and the use of certain studies is misleading. For example, the inclusion of sheep in sampling at feeding sites is questionable since diclofenac is not authorised for use in sheep, and the subsequent discovery of NSAID prevalence in the same study is therefore alarming (Herrero-Villar et al., 2020). The forewarnings given to feeding site managers prior to inspections may also significantly reduce any
meaningful findings in such studies if there is time for suspect carcasses to be removed. Similarly, the use of data from slaughterhouses is strange given the rules on drug withdrawal periods prior to slaughter should exclude any potential risk to vultures (AEMPS et al., 2020). While this study supports the argument that withdrawal periods are being respected, slaughterhouse material was specifically excluded as a source of risk to vultures by the CVMP’s report (2014), and its inclusion to support the absence of risk is therefore invalid.

The argument in favour of Spain’s superior wildlife hazard surveillance infrastructure, while likely true compared to South Asia, is also problematic. Regardless of Spain’s network of wildlife rescue centres, the chance of a vulture poisoned with NSAIDs being brought into such a facility is very low (R. Green, pers. comm., 2023). The nephrotoxic effects of NSAIDs take several days to kill a vulture which has ingested a lethal dose, meaning individuals can travel far from the site of the contaminated carcass (Swan et al., 2006). This is in contrast to other poisonous chemicals used in deliberately set baits like carbofuran or aldicarb, whose lethal effects manifest much faster and hence whose victims are found nearby (Bodega Zugasti, 2014). While citizens are likely to report finding many dead animals within a small area to a rescue centre, the discovery of a single dead vulture is unlikely to trigger cause for concern. The data from these rescue centres is therefore biased towards vultures who are injured (e.g., collision with electricity infrastructure), who appear ill (e.g., lead poisoning) or who have died at the site of a deliberately set poisoned bait. This quantifiable bias is against vultures who have died from ingesting lethal doses of veterinary NSAIDs, thereby lowering the chance of risk detection.

These data inconsistencies support the argument that there remains significant uncertainty over the magnitude and extent of risk posed to Spanish vultures from the use of veterinary NSAIDs. Overall, populations of EGV are strong and showing positive trends (Moreno-Opo et al., 2021), and only four NSAID-related vulture deaths have been confirmed (with only one involving diclofenac) (Herrero-Villar et al., 2021, 2020; Zorilla et al., 2015). However, the annual use of veterinary diclofenac in Spain continues to rise (Moreno-Opo et al., 2021) and evidence of carcass contamination exists from the limited sampling performed at feeding sites (Herrero-Villar et al., 2020; IREC-Tragsatec, 2017). The use of another vulture-toxic NSAID – flunixin – also appears as a potential threat (Herrero-Villar et al., 2020). While it remains debateable how grave a threat the use of vulture-toxic drugs represents to Spanish vultures, it is not contested that a risk does exist (CVMP, 2014). Does it then follow that these drugs should continue to be authorised until that risk can be quantified; and what is an appropriate threshold at which point further action would be warranted?

Regardless of the differences in cultural background and case specifics between South Asia and Europe, it could be argued that Spain and the wider EU – a world leading body on environmental policy – have a duty to other vulture range states to ban the use of NSAIDs found to be toxic to vultures. As discussed in the case of Saudi Arabia, the EU’s reluctance to ban veterinary diclofenac is a key factor impeding the progression of a national ban. After all, why should the Saudis ban a drug deemed safe, or at least whose risk is seen as manageable, by the European Union? However, this argument that the EU is setting a poor example by continuing to allow the authorisation of vulture-toxic veterinary NSAIDs in Member States was not supported by other interviewees: some are satisfied that a robust series of risk mitigation measures are in place and that evidence of a significant threat to European vultures from the use of these drugs remains low. The notion that the EU should curtail the use of these drugs merely to set an international example is seen as unfair: the EU should not have to ban a drug just to appease other countries with less rigorous risk management strategies. Some interviewees remain confident that should the risk level change and
concrete evidence of a threat come to light, the EU would be quick to respond. While arguments in favour of both points of view can be found, the existence of safe alternatives to vulture-toxic drugs begs the question of why such a risk is worth taking. Both meloxicam and tolfenamic acid are vulture-safe, cost-competitive and readily available: why then would the EU choose to persist in their endorsement of the use of vulture-toxic drugs in Member States?

**Precautionary Principle**

Questioning the EU’s decision to endorse the use of vulture-toxic drugs is further legitimised by a key principle underpinning EU environmental law – a principle which is in part responsible for the international acclaim to which EU environmental law is held (Kelemen and Knievel, 2015). The Precautionary Principle (PP), set out in Article 191 of the Treaty of the Functioning of the European Union (2016), aims to ensure preventative decision-making in cases where the risks associated with a product or approach are poorly understood and hence the potential impacts uncertain. Interpretations of the PP in EU case law are broad and varied, ranging from a requirement for absolute proof of safety to a more subjective discretionary approach based on cost-benefit analysis (Foster et al., 2000). However, the potential application of the PP to the veterinary use of NSAIDs in EU Member States appears straightforward: (i) the CVMP’s 2014 report concluded that a risk to European vultures from the use of veterinary diclofenac exists (CVMP, 2014), (ii) two alternative drugs have been identified as vulture-safe, (iii) there is a large body of objectively alarming evidence from the Indian subcontinent demonstrating the potential consequences of vulture population exposure, and (iv) the number of peer-reviewed scientific studies on the species at risk, as well as the NSAIDs which are vulture-toxic, is growing.

Based on the EU’s guidelines for the application of the PP, namely that measures taken are based on the principles of proportionality, non-discrimination and consistency, as well as the examination of costs, benefits and scientific developments (European Commission, 2000), it would seem the vulture-NSAID debate should warrant a precautionary approach. The principle of consistency in regard to the application of the PP is particularly interesting in this case. Heed to consistency means the measures taken ‘should be comparable in nature and scope with measures already taken in equivalent areas in which all the scientific data are available.’ (European Commission, 2000, p. 4). On examination of the EU’s approach to other diffuse ecotoxic chemicals, it could be argued that such consistency is lacking. For example, neonicotinoid pesticides (‘neonics’) have been used as potent insecticides since the mid-1990s (e.g., to prevent the spread of aphid-transmitted viral diseases in sugar beet), and their use has been shown to cause adverse effects in pollinators, particularly bees (Wood and Goulson, 2017). Just as exposure to veterinary NSAIDs is not limited to the livestock injected, only 5% of the active neonic remains in the treated crop (Goulson, 2014). The agricultural use of neonics can see their migration into, and persistence in, soils and waterways (Wood and Goulson, 2017), similar to the aquatic prevalence of NSAIDs (Lonappan et al., 2016). In response to the strong evidence-base for the effects of neonics on non-target species, the European Food Safety Authority (EFSA) was commissioned to write a report in 2012 in which they concluded that the use of three different neonics on certain flowering crops posed a high risk to bees (EFSA, 2013). In light of these findings, an EU-wide ban on their use in bee-attractive crops was enacted in 2013 (Regulation No 485/2013), followed by a more stringent ban in 2018 on all outdoor use (Regulation No 783/2018; 784/2018; 785/2018). This is in contrast to the CVMP’s report on veterinary diclofenac in 2014 which concluded that a risk to vultures exists, but which did not trigger the EMA to take regulatory action (CVMP, 2014).
Although the regulation of neonics and NSAIDs falls under the jurisdiction of different EU departments – namely pesticides (EFSA) and medicinal products (EMA) – these cases are nonetheless similar in nature. Both neonics and veterinary NSAIDs are diffuse ecotoxic chemicals which cause adverse effects on a group of non-target species (i.e., pollinators vs. avian scavengers), with one subset of that group particularly at risk (i.e., bees vs. vultures). The use of these chemicals by farmers in crops or livestock has shown to have spill-over effects and their application cannot be confined to the target species (e.g., sugar beet or cattle). Yet the EU has dealt with the regulation of neonics with a more precautionary approach than that taken with veterinary NSAIDs. Furthermore, in January 2023 the European Court of Justice ruled that derogations from the neonic ban by Member States on seed treatments were not in line with EU law (Pesticide Action Network Europe ASBL and Others v État belge, 2023). Prior to this, frequent emergency authorisations had been issued by Member States to allow the treatment of seeds with banned neonics in cases where it was argued that significant crop damage would ensue without their employment (PAN, 2023). ‘Consistent’ application of the precautionary principle and stringency of regulatory action to the use of ecotoxic pesticides in the EU has therefore yet to be afforded to similarly diffuse ecotoxic medicinal products such as veterinary NSAIDs or hormonal contraceptives.

The apparent neglect of the precautionary principle in the case of veterinary diclofenac in the EU is in contrast to its direct citation as a reason to uphold the restriction on multi-dose vial sizes in India. The case at Madras High Court cited the PP as a well-established principle of Indian law in its reasoning to uphold the restriction in the face of opposition from pharmaceutical companies (Gill, 2019; Laborate Pharmaceutical India… vs Union of India, 2017). Furthermore, the pre-emptive bans on veterinary diclofenac in both Oman and Cambodia are similar, albeit less explicit, examples of a precautionary approach.

There is also a point to be made on vultures’ unusual life history characteristics with regards to the precautionary principle (R. Green, pers. comm., 2023). As discussed in the Background and Context section (p. 5), vultures are long-lived (annual adult survival rate c. 95%), late to maturation (4-5 years) and exhibit low fecundity (with a maximum of one fledgling per year). Being at the extreme end of K-selected species, the maximum annual growth rate of vulture populations under the most favourable conditions is just 8-9% (Niel & Lebreton, 2005). It would hence take a minimum of ten years for a vulture population to double even under ideal conditions. The stability of vulture populations is therefore particularly vulnerable to sudden changes in adult mortality, and the nephrotoxic effects of diclofenac saw OWRV in India and Pakistan decline by 50% in just one year (Prakash et al., 2012). If population halving time under the influence of veterinary diclofenac is 1 year (in the case of India and Pakistan) and the fastest possible doubling time is 10 years, each year that passes without effective diclofenac regulation prolongs population recovery by at least a decade. It could therefore be argued that a heightened level of precaution should be afforded to anthropogenic activities which affect species whose intrinsic life history characteristics mean they are predisposed to drastic population-level impacts of additional mortality (R. Green, pers. comm., 2023).
Despite the varying degree of consideration for the PP between vulture range states in South Asia and Europe, there is a distinct lack of safety testing carried out on veterinary NSAIDs as part of the licensing process in both regions. The original regulatory approval granted by South Asian governments to companies marketing veterinary diclofenac in the 1990s (starting with India in 1993) were given based on the results of ‘acute-to-chronic, aquatic, single species testing’ (Enick and Moore, 2007). The extrapolation of these results led to the inappropriate conclusion that the test subject had the same response to veterinary NSAIDs as Gyps vultures. To this day, the licensing processes in South Asia and Europe do not require that prospective veterinary NSAIDs be tested on vultures or other secondary or tertiary species (Interview 15; Moreno-Opo et al., 2021). Instead, avian test subjects with incomparable susceptibilities (domestic chickens, for example) continue to be used, if at all (EMA, 2008; Naidoo et al., 2007). Of the NSAIDs which have been safety tested on vultures to date (four of the fourteen NSAIDs on the market in India (MoEFCC, 2020)), these tests have all been carried out as part of independent scientific studies or by NGOs, with funding mainly coming from the RSPB (R. Green, pers. comm., 2023). A government-funded testing programme was established in India in 2013, but it has achieved little so far (R. Green, pers. comm., 2023). Safety testing does not form part of established pharmaceutical licensing procedures, although ambition to create such a process is laid out in both CMS’s Vulture MsAP as well as several NVCAPs. It is also crucial that any future safety testing procedure is retrospective as well as prospective: testing drugs which are already licensed as well as those under consideration (Botha et al., 2017).

The development of an in vitro testing system, as suggested in CMS’s Vulture MSaP, might support the incorporation of accurate, low-cost testing into licensing processes (Botha et al., 2017). This would be especially useful given the constraints of the in vivo testing process: not only are critically endangered vultures at risk from potentially lethal in vivo trials (making testing on sufficient sample sizes very hard to achieve), but the legal restrictions on cattle slaughter in India mean testing on vultures using tissue-incorporated NSAIDs is challenging in this region (CMS, 2014). However, even if in vitro testing capacity was created, pharmacokinetic constraints mean the usefulness and applicability of results may be limited. For instance, in vitro testing would not be able to capture the rate at which veterinary NSAIDs are absorbed, metabolised or excreted in vivo, and the implications of these processes on drug toxicity (Hutchinson et al., 2014). For example, the toxicity of NSAIDs to vultures depends on the toxicity of the compound to kidney cells: if a drug tested in vitro is found to be non-toxic to kidney cells, it is unlikely to be nephrotoxic to vultures in vivo. However, a drug that is toxic to kidney cells in vitro might not be nephrotoxic to vultures in vivo if it can be quickly metabolised to harmless compounds on ingestion (Hutchinson et al., 2014).

This lack of institutionalised safety testing reflects the divergent priorities of scientists and those appointed by governments to assess risk, including drugs regulators. While the former’s epistemic values seek to avoid the acceptance of a false hypothesis, the latter seek to avoid stifling economic growth by falsely concluding that a substance is harmful when it is not (Wandall, 2004). This dichotomy is a common debate in drug policy decision-making, and one that reaches far beyond vultures and NSAIDs. In the United States (US) for example, the routine administration of antibiotic growth promoters (AGPs) to livestock will be allowed to continue until scientists can bring forward sufficient and quantifiable proof of harm (Enick and Moore, 2007). Consequently, approximately 80% of all antibiotics sold in the US are used on livestock, with 70% of these considered medically important for human health despite the threat of a looming so-called ‘antibiotic apocalypse’ (Martin et al., 2015; Wallinga et al., 2022). In the EU on the other hand, the burden of proof is reversed in accordance with the PP, such that a suspected risk of harm is sufficient to warrant
protective action (Foster et al., 2000; Sanderson et al., 2004). As a result, antibiotics used in human medicine have been banned in animal feed in the EU since 2003, before a complete ban on AGPs was introduced in 2006 (Regulation No 1831/2003). Although the conservative approach employed in the US is arguably more conducive to innovation, this comes at the expense of preventative, anticipatory intervention. As put by Enick and Moore (2007), ‘demanding incontestable proof in a system designed to protect against oversensitivity may give aid and assistance to polluters until it is unequivocally proven that their actions are harmful’. What is surprising in the case of veterinary NSAID regulation is that the approach of governments in the EU and South Asia seems to contradict their PP, and instead arguably aligns more strongly with the US’s conservative regulatory approach. The decisions made in the licensing of veterinary NSAIDs seem to extend beyond merely an ‘assessment error’ (CMS, 2014): nearly two decades on from the original discovery of the cause of vulture declines, precautionary multi-species safety testing is still not an embedded part of regulatory decision-making. This is despite NSAIDs (including diclofenac) having been identified as pharmaceutically active compounds (PhACs) of interest under the EU Water Framework Directive, and yet this same concern is not extended to their veterinary use in Member States (Lonappan et al., 2016; Rasheed et al., 2019).

Another goal set out by CMS is that the burden of proof for NSAID safety testing should be shifted to the licence applicant (CMS, 2014). In other words, it should not be up to NGOs to fund and execute retrospective scientific studies to demonstrate that licensed drugs cause harm to vultures. Instead, pharmaceutical companies should have to demonstrate that their drugs are safe for non-target species before they are licensed, just as chemical companies now have to demonstrate that their pesticides are safe for use under EU law (Regulation (EC) No 1107/2009). After the ecotoxic effects of organochlorine pesticides (such as DDT) were publicised by the likes of Rachel Carson in the second half of the twentieth century, global awareness of the potential impact of pesticides on non-target species were heightened (Carson, 1996). An overhaul of EU regulations on the licensing of chemical plant protection products was undertaken to prevent future licensing occurring in ignorance of products’ wider impacts. All new pesticide active substances in the EU must be shown not to cause ‘unacceptable effects on the environment, particularly with regards to non-target species and biodiversity’ before they can be authorised for use (EFSA, n.d., p. 4). The burden of proof lies with the manufacturer to prove that their product is safe to use, and such testing must be funded and commissioned by the licence applicant. However, the same obligations are not extended to veterinary medicinal products: safety testing of veterinary NSAIDs on vultures has received no funding from the EU pharmaceutical industry to date, and work done so far is owed to NGOs like the RSPB (R. Green, pers. comm., 2023). The lack of safety testing is another example of a lack of consistency in EU licensing procedures, particularly between the regulation of pesticides and medicines.
Policy Recommendations

Based on the information gathered in this thesis from interviews, literature research and policy analysis, several challenges to the legitimacy of current policy frameworks have been identified. Recommendations on how some of these could be addressed to improve throughput legitimacy and evidence-based policymaking are discussed below. These recommendations vary in specificity, with some relevant to all range states considered, while others are region or country-specific, as shown in Figure 15.

1. Coherence

There is currently a mosaic of licensed, banned and restricted veterinary NSAIDs across the four countries of the Indian subcontinent (Table 4). There is considerable variation in preferred drugs across countries and states, leading to significant policy incoherence and downstream ambiguity. Although evidence of toxicity to vultures now exists for several of these drugs, little progress has been made on advancing further bans besides ketoprofen in Bangladesh. The ban and restriction mosaic has also created particularly challenging conditions in border regions where drugs banned in one country are crossing the border from another.

The Indian government does not see the sequential banning of a host of drugs as an appropriate long-term, ‘constructive’ solution (Interview 5). There is also significant lobbying power at play on the part of the pharmaceutical industry against the banning of further drugs, while the power of conservation organisations calling for the bans is significantly weaker. Moreover, the apparent stabilisation of vulture populations in India, together with the fact that vultures face other significant threats, both serve as convenient reasons to negate further action. Although stabilising in some areas, vulture populations remain critically low. The fragility of their numbers makes it unlikely they would survive another crisis of this magnitude (R. Green, pers. comm., 2023). The effects of veterinary diclofenac saw the population of OWRVs fall by a factor of a thousand from millions to thousands in the space of a decade. Another unregulated NSAID of similar toxicity and use could reduce the population to one-thousandth of its present low level, likely leading to species extinction in the wild. The view that banning drug after drug is not feasible is understandable but arguably unreasonable: knowledge of the exposure pathway to harm is well understood and safe alternatives exist with comparable cost and performance.

The current case at the Delhi High Court is considering a challenge to the lack of progress in banning further drugs and a motion to ban three more drugs known to be vulture-toxic: aceclofenac, ketoprofen and nimesulide (Gaurav Kumal Bansal vs Union of India and ors., 2022). If successful, this case could prove a pivotal turning point in the vulture-NSAID crisis. If India were to ban further vulture-toxic NSAIDs, neighbouring countries would likely follow, and this decision would impact the drugs traded across borders into Nepal and Bangladesh. A blanket ban on these drugs across the region is likely the only way to achieve true policy coherence and the existing Regional Steering Committee and Regional Declaration could provide the framework necessary to achieve this efficiently (Delhi, 2012).

- **Recommendation:** a more coherent system for identifying vulture-toxic veterinary NSAIDs in South Asia and banning veterinary use of those shown to be harmful.
The size of India and complexity of its governance system presents a significant challenge to coordinated vulture conservation involving vertical, horizontal and transboundary misfits. Until a more efficient system for approving and regulating veterinary NSAIDs can be achieved, the harmonisation of drug distribution by government departments across Indian states would improve policy coherence within India. There is currently no coordination between states on the NSAIDs distributed in such programmes and many states continue to distribute drugs known to be nephrotoxic to vultures. A regulatory instrument could be introduced (under the purview of CDSCO) to ensure that only vulture-safe drugs are distributed under such programmes country-wide.

- Recommendation: use of regulatory instruments to prevent the distribution of vulture-toxic NSAIDs by government agencies in Indian states.

Loopholes in the national drug licensing policy mean certain states have authorised the use of veterinary aceclofenac without central approval from the CDSCO. It is within the power of the CDSCO to rescind these licences, and such action would reduce policy incoherence between Indian states and the use of vulture-toxic NSAIDs across the country.

- Recommendation: use of CDSCO to rescind the marketing licences granted for veterinary aceclofenac in certain Indian states.

In Pakistan, the loophole in the 2006 ban on veterinary diclofenac which permits exports increases the likelihood of illegal domestic use of the vulture-toxic NSAID, as well as increasing the risk to vultures in neighbouring China and Afghanistan who have yet to impose similar bans. A revision of this ban to include the outlaw of diclofenac exports would be more coherent with other parties to the Regional Declaration (Delhi, 2012).

- Recommendation: tightening of Pakistan’s 2006 ban on veterinary diclofenac to include exports.

2. Evidence-based

As discussed above, the lack of safety testing performed on secondary and tertiary species during the licensing of veterinary NSAIDs is at odds with comparable procedures for plant protection products in the EU. In the case of South Asia, this mismatch is particularly apparent given the well-studied effects caused by the use of veterinary diclofenac on vulture species and the well-understood economic and human health value they contribute to the region. The cost of in vivo safety testing is considerable, and it would also be costly to develop in vitro tests, which in any case may not be reliable. It can be argued that the potential polluters should bear these costs, with the pharmaceutical companies being required to submit test outcomes when applying for marketing authorisations. This would extend the approach required of pharmaceutical companies when applying for marketing authorisations, who are obliged to perform safety testing on humans and livestock for whom their drugs are designed. If Fatro were producing a pesticide in the EU, they would be legally compelled to provide evidence that their product did not cause significant environmental harm. It is difficult to see a valid argument why similar evidence should not be required for veterinary pharmaceuticals, especially those adversely affecting species whose life history characteristics make their populations particularly vulnerable to sudden changes in adult mortality. Furthermore, a shift in the burden of proof to the pharmaceutical industry may accelerate research and development funding of an in vitro safety testing method. This would eliminate the
need to use critically endangered vultures in trials, as well as allowing larger sample sizes to be studied.

- Recommendation: inclusion of mandatory provision of evidence of safety to vultures as part of veterinary NSAID licensing procedures, with the burden of proof on the licence applicant.

Several flaws and biases in the data presented to support the EU and Spanish Government’s diclofenac licensing decisions exist. The degree of evidence-based policy making is hence debateable and could benefit from frequent revision, especially given the rising annual use of veterinary diclofenac. Furthermore, the decisions taken are incoherent with the application of the precautionary principle to other diffuse environmentally toxic chemicals in the EU (e.g., neonics, AGPs), considering the significant evidence base for the potential harm to vultures. The decision to authorise the use of veterinary diclofenac could be revisited, and an acceptable threshold identified at which point it would be agreed that further action would be warranted. It is also important that the EU is cognisant of their role as a catalyst in global environmental policy-making, and that a ban on veterinary diclofenac in the EU would likely accelerate diclofenac bans in the Middle East, and perhaps strengthen the case for the banning of further NSAIDs in South Asia.

- Recommendation: revision of risk assessments on the use of veterinary diclofenac in Spain and the wider European Union.

In response to concern over the potential effects of veterinary diclofenac on European vultures, the CVMP was commissioned to evaluate the risk posed by the use of this drug to European necrophagous birds (CVMP, 2014). The Spanish Government has also published two risk assessment reports since 2014. The data collected suggests vultures may also be at risk from the veterinary use of flunixin. However, this other veterinary drug has yet to be afforded the same consideration as diclofenac. Flunixin is known to have killed at least three vultures so far (Herrero-Villar et al., 2020, 2021), which is higher than the single vulture found poisoned by diclofenac (Herrero-Villar et al., 2021). To improve the degree of evidence-based policymaking surrounding the licensing of these drugs, the CVMP and Spanish Government could author similar risk assessments to consider this potential threat. If found, the same level of concern should be afforded as to veterinary diclofenac, and a potential ban enacted if appropriate.

- Recommendation: risk assessment conducted on the use of veterinary flunixin in Spain and the wider European Union.

3. Transparency

There is considerable variation in NSAID policy awareness across Indian states (Galligan et al., 2021). This is in contrast to the examples of successful community initiatives elsewhere: Nepal’s ‘vulture restaurants’ and ‘diclofenac-for-meloxicam’ schemes have engaged and educated both farmers and general citizens on the risks to vultures from the use of these drugs. Neighbouring countries could learn from the success of these programmes and replicate or adapt them to improve policy transparency. Nepal’s success, as well as the distribution of vulture-safe drugs by IUCN Bangladesh, highlights the importance of assistance in helping farmers to transition to vulture-safe alternatives, and could be implemented elsewhere. In Spain, the growing animosity towards vultures from farmers who fear vulture attacks on their livestock is proliferated via the spread of misinformation on social media (Oliva-Vidal et al., 2022a; Margalida et al., 2014). Community education
programmes to reassure livestock owners of the rarity of these events, as well as refocusing their attentions towards the risk posed to vultures from both deliberately set poisoned baits and veterinary NSAIDs could be beneficial.

- **Recommendation:** learning and knowledge-sharing between countries and regions to improve policy transparency, awareness and community engagement.

There is currently no reporting mechanism from registered feeding stations in Spain to MITECO, meaning continued risk assessment by the Spanish Government on the threat to vultures from these sites is difficult. Furthermore, levels of vulture population surveillance have fallen in recent years despite acknowledgement from the EMA that a risk exists from the use of veterinary diclofenac. In order to improve policy transparency and accurate risk reporting in the EU, efforts could be made to ensure risk assessment data is continually updated and shared between relevant actors so an appropriate response can be timely actioned if required (Moreno-Opo et al., 2021). Similarly in India, nationwide surveys are conducted every four years by BNHS in collaboration with State Forest Departments and the MoEFCC (MoEFCC, 2020). However, Gujarat is the only Indian state where systemic vulture population monitoring is being carried out (Kamboj et al., 2019). This initiative could be replicated across the country with data combined to improve understanding of national population levels.

- **Recommendation:** increased surveillance and data reporting.

4. **Bindingness**

As it stands, NVCAPs published by a responsible government department in vulture range states on the Indian subcontinent have no legal power to bind other stakeholders. This severely limits their prospects of successful implementation and has led to ambiguity over the roles of various actors. At the most recent hearing of the Delhi High Court case, the CDSCO disputed the role of the MoFAHD which had been laid out in India’s NVCAP by the MoEFCC (Kaur, 2022b). This ambiguity afforded by the lack of bindingness in NVCAPs has allowed the CDSCO to further delay decision-making on banning more vulture-toxic NSAIDs. To improve future policy bindingness and clarity, subsequent NVCAPs could be signed and endorsed by all involved government ministries.

- **Recommendation:** expansion of NVCAP signatories

The recent clamp-down on offenders in Tamil Nadu remains the only example known to SAVE where policy bindingness has been enforced. Similarly, the provincial restriction on ketoprofen and aceclofenac in Sindh (Pakistan) is poorly enforced and serves more as a declaration of support to vulture conservation (Interview 18). Until nationwide bans on more vulture-toxic NSAIDs can be introduced, the enforcement of existing bans and restrictions could be improved. Similarly, until a ban on veterinary diclofenac (and potentially flunixin) can be achieved in Spain, the existence of illegal feeding sites which operate without checks on carcass contamination is problematic. The forewarning of registered site managers prior to inspections is also counterproductive to the accurate assessment of risk posed by the use of veterinary pharmaceuticals.

- **Recommendation:** greater enforcement of bans and restrictions
Figure 15: Schematic summarising recommendations to improve throughput legitimacy and evidence-based policymaking. Source: own representation.
CONCLUSION

This thesis set out to answer the following questions: in vulture range states with existing procedures for regulating veterinary NSAIDs, (i) how do these procedures work and (ii) are they reducing the risk posed to vultures through legitimate and evidence-based regulation of drugs known to be vulture-toxic? For the former, interviews were held with experts across eight key vulture range states in Europe and South Asia representing provincial, national and international actors involved in the vulture-NSAID problem. Together with comprehensive literature analysis, the licensing and banning procedures currently used in these countries have been elucidated and compiled for the first time. It was found that:

- In the five central case studies analysed (India, Pakistan, Nepal, Bangladesh and Spain), decisions on veterinary NSAID licensing have been made without regard to safety testing in non-target species including vultures. Any bans or restrictions have only been achieved after retrospective assessment of certain drugs and campaigning by NGOs.
- Since the 2012 Regional Declaration on veterinary diclofenac, Bangladesh remains the only range state to ban a second vulture-toxic NSAID (ketoprofen), while a mosaic of other NSAID drug licenses exist across the Indian subcontinent including aceclofenac, ketoprofen, nimesulide and flunixin (Table 4).
- The decision to license veterinary diclofenac in Spain was made without consultation of all relevant government departments and much of the data used in risk assessments to support the decision is problematic: sample sizes are small, significant biases exist and the inclusion of certain studies is misleading. Furthermore, no similar risk assessments have been conducted to investigate the risk associated with the veterinary use of the vulture-toxic NSAID flunixin in Spain and the wider EU despite evidence for its environmental prevalence (Herrero-Villar et al., 2020, 2021).
- The additional three case studies presented (Cambodia, Oman, Saudi Arabia) cover countries which have only more recently engaged in the vulture-NSAID debate. Lessons have been learnt from work done on the Indian Subcontinent and pre-emptive, precautionary bans enacted in Cambodia and Oman. Saudi Arabia is an example of a country which stands on the precipice of regulatory action, but whose policymakers are perturbed by the endorsement of veterinary diclofenac in the EU.

For the second question, an analysis of various policy indicators yielded mixed results on whether current procedures are reducing the risk posed to vultures through legitimate and evidence-based regulation of these drugs. The bans on veterinary diclofenac in the early 2000s across the Indian subcontinent were swift, coordinated and well supported by robust regulatory instruments (Delhi, 2012). However, the power, reach and enforcement of further measures has been incomplete, despite the Regional Declaration in 2012. The ban on the manufacture of large vials of human diclofenac in India, the ban on veterinary ketoprofen in Bangladesh, and the successful awareness-raising campaign in Nepal to phase out veterinary diclofenac are three outstanding achievements, but otherwise progress with regulation and enforcement has been limited. Across all cases, analysis of the input legitimacy indicators produced a similar picture: a powerful pharmaceutical industry with action resources that outstrip those of conservation NGOs, and government actors balancing multiple accountability dilemmas as they navigate this problem. These differences are more pronounced in India and Spain, while relationships between opposing actors in Nepal and Bangladesh appear more conducive to cooperation thanks to their smaller pharmaceutical industries and closer NGO-government relationships. For throughput legitimacy indicators, while the Regional Declaration bolstered external policy coherence on diclofenac across South Asia, national variation in the licensing of other drugs threatens to undermine further progress (Table
4). The effects of these policy incompatibilities are felt most in border regions and in countries where pharmaceuticals are imported, such as between Bangladesh and India, or Cambodia and Vietnam. The variety in regional restrictions on NSAIDs, such as in Tamil Nadu and Sindh, has also bred policy incoherence and ambiguity and highlighted the difficulty in tackling this problem at the state level. Levels of policy transparency and awareness vary regionally, with Nepal remaining the best example of successful community engagement. However, overall policy bindingness and enforcement are so far limited. The lack of power held by NVCAPs to bind other stakeholders has increased policy ambiguity, whereby the roles and means of actors can be brought into question. This loophole is currently being played out in the ongoing case at the Delhi High Court (Gaurav Kumal Bansal vs Union of India and ors., 2022; Kaur, 2022b). Furthermore, the lack of evidence-based policy making countermands commitments made by governments in both national and international legal frameworks and agreements (CMS, 2020). Pledges made by several South Asian governments that drug registrations will be based on scientific facts are at odds with licensing decisions (DNPWC, 2015), and the EU’s approach is in stark contrast to equivalent decision making (CVMP, 2014).

Some defining distinctions exist between Europe and South Asia in both context and problem framing, meaning their approach to NSAID regulation cannot be directly compared. The use of deliberately set poison baits is the leading threat to European vultures, while NSAIDs remain the most prominent risk to vultures in South Asia (Botha et al., 2017). Similarly, livestock management practices, drug availability and cultural factors further set these cases apart (Moreno-Opo et al., 2021). At present, Spanish vulture mortality rates appear to be low, suggesting risk mitigation measures are working (Moreno-Opo et al., 2021). The question in Spain is therefore not whether to ban diclofenac for the sake of the observed risk (as is the case for bans on other vulture-toxic NSAIDs in South Asia), but in order to safeguard against the growing risk posed by the increasing annual use of this drug. Falling levels of surveillance, minimal reporting of figures to the authorities, and low accessibility of screening information could mean NSAID-related vulture deaths are going unnoticed, while flaws in the data presented by Spanish Government risk assessments expose uncertainty over the true level of risk that exists. Moreover, diclofenac’s authorisation directly contradicts the EU’s hallowed precautionary principle – a stalwart pillar of EU environmental law and one used to defend regulatory decisions taken over other ecotoxic chemicals such as neonicotinoids or antibiotic growth promoters.

While contributing to the understanding of NSAID licensing decisions in vulture range states, limitations exist to the approach taken in this thesis and its subsequent results. The case study approach was an unavoidable rationalisation of the 128 range states in which Old World vultures are found, but nonetheless it limited the scope and applicability of results and conclusions. A balance had to be sought between covering enough countries in order for meaningful comparisons to be made and significant trends identified, while not compromising on case depth and analytical quality. Furthermore, the use of interviews as the primary source of data meant difficulties sometimes arose on receipt of contradictory information. My ability to perform detailed analysis of legal documents in South Asian range states was limited by the language barrier present, as well as the fact that many of these documents were inaccessible or elusive. This meant I relied heavily on the knowledge and regional expertise of my interviewees and thus made contradictory information difficult to resolve. The most difficult of these instances arose regarding the question of whether Indian states have the explicit power to enact state-wide bans on veterinary NSIADs. Given I interviewed five different people on the situation in India, the variety of answers I received on this question were challenging to settle definitively, especially given the complexity of the Indian legal system.
Furthermore, while this thesis clarified the processes involved in licensing and banning of veterinary NSAIDs in key vulture range states, further questions have arisen which could be addressed by future work:

- Does flunixin pose a risk to Spanish vultures? Field survey data suggests that flunixin is just as prevalent, if not more so, than veterinary diclofenac yet its potential impact has not been similarly evaluated by the European Medicines Agency nor the Spanish Government (Herrero-Villar et al., 2020, 2021).
- The non-binding NVCAPs of South Asian range states include the repetition of many common goals, such as the improvement of meloxicam formulations or increased understanding of vulture ecology. It would be inefficient for each country to address these goals separately, but it is unclear how they could be worked on collaboratively.
- What pre-emptive action could be taken to prevent the increase in use of NSAIDs in Africa? Africa has not been considered in this thesis as African vultures have not yet suffered the same widespread effects from veterinary NSAIDs as South Asian vultures (Botha et al., 2017). However, vulture populations in Africa are also undergoing significant population declines, especially as a result of other intentional, unintentional and sentinel poisoning incidents (Botha et al., 2017). As countries on the continent continue to develop and agricultural supply chains evolve, a potential threat from veterinary NSAIDs could emerge.

Overall, it is my opinion that some or all of the following three things would lead to significant progress on the legitimate and evidence-based licensing of veterinary NSAIDs in vulture range states:

(i) The Delhi High Court finds in favour of Gaurav Bansal’s petition that more drugs known to be vulture-toxic should be banned in India, thereby catalysing a chain reaction in neighbouring states and prompting another Regional Declaration to be signed on the coordinated regulation of these drugs across the Indian subcontinent.

(ii) Mandatory safety testing becomes an established and accepted part of veterinary NSAID licensing in order to prevent the future licensing of vulture-toxic drugs. The burden of proof for such testing would lie with the pharmaceutical company and this obligation would extend to the retrospective assessment of NSAIDs already on the market. Furthermore, in the EU’s case, safety testing standards required of plant protection products would be extended to veterinary pharmaceuticals in line with consistency under the precautionary principle.

(iii) Veterinary diclofenac and flunixin are banned in the European Union, or at least in the Member States home to vultures. This is important not only to safeguard the stability of Europe’s vulture populations, but to set an example of prioritising precautionary environmental protection on the global stage.

Until these steps are taken, other ‘low-hanging fruit’ could be addressed: for instance, the introduction of a policy instrument to prevent the government distribution of vulture-toxic NSAIDs in Indian states, the tightening of Pakistan’s diclofenac ban to include exports, or the establishment of more ‘vulture restaurants’ following their success in bolstering community engagement in Nepal. Furthermore, while national vulture conservation action plans are detailed and well thought out, they are insufficient alone to catalyse regulatory action. What is needed is a legitimate policy framework at a higher level of government which spans and binds several implementing actors in order to enact real, lasting change.
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Herrero-Villar, M., Velarde, R., Camarero, P.R., Taggart, M.A., Bandeira, V., Fonseca, C., Marco, I., Mateo, R., 2020. NSAIDs detected in Iberian avian scavengers and carrion after diclofenac registration...


LIST OF ENACTMENTS

Bangladesh


European Union


Judgement of the Court (First Chamber) of 19 January 2023, Pesticide Action Network Europe ASBL and Others v État belge, Case C-162/21, EU:C:2023:30. Available at: https://eur-


India

Drugs and Cosmetics Act, 1940. Act No. 23 of 1940. Available at: https://legislative.gov.in/sites/default/files/A1940-23.pdf [Accessed 23.12.22]

Gaurav Kumar Bansal vs Union of India and Ors. on 24 March 2022 in the Supreme Court of India. Available at: https://indiankanoon.org/doc/111593765/ [Accessed 23.12.22]


Laborate Pharmaceutical India... vs Union of India on 24 October 2017 in the High Court of Judicature at Madras. Available at: https://indiankanoon.org/doc/194709922/ [Accessed 23.12.22]

Multilateral or Non-Governmental


Nepal


Pakistan


Spain


APPENDIX

Appendix 1

Interviews were held with experts across South Asia and Europe. Most of these contacts came about thanks to the broad network of partners involved in the international consortium SAVE. Interviewees included those from a range of fields: local, regional and international NGOs, research institutes, government ministries and pharmaceutical companies (Table 3). The unique problem framing and regulatory history of the vulture-NSAID debate across range states meant these interviews could not be standardised, and instead were tailored to the country in question and expertise of the interviewee. However, each interview was based on the generalised interview template below:

**Legal vs banned: the basic facts**
- In X country, which NSAIDs are legally approved for veterinary use?
- In X country, which NSAIDs are banned for veterinary use?
- What does the above ban or restriction encompass for each drug mentioned? (e.g., sale, manufacture, importation, use)
- In X country, which NSAIDs are ‘restricted’ for veterinary use (e.g., in certain areas like VSZs), and what does this mean in practical terms? At what level is this implemented/enforced?

**Procedure**
- Can you explain the procedure involved in obtaining legal approval for veterinary use of an NSAID not previously approved in X country?
- Can you explain the procedure involved in banning the use of an already approved veterinary NSAID in X country?
- Which veterinary NSAIDs are currently being considered under such procedures for banning or legalisation?
- If there are veterinary NSAIDs currently being considered for banning or legislation, how much time has elapsed since a decision was requested? Is this a comparable time to other pharmaceutical regulatory decisions in country X? Has the procedure requested evidence beyond that initially submitted?

**Evidence**
- Does the law require evidence to be presented about the safety of new veterinary NSAIDs to vultures before legal approval of their marketing and use is given?
- Are there any standard tests and test criteria set by government agencies in country X which determine whether legal approval of a veterinary NSAID is given or withdrawn? (e.g., experimental testing on captive birds)
- Do authorities assessing evidence about the safety of a veterinary NSAID have any stated rules or preferences about the types of evidence they consider? (e.g., evidence published in peer-reviewed/international/local scientific journals, study done in home country etc).
- What is the burden of proof in this procedure, and with whom does it lie? Is this in line with legal norms in X country? (e.g., precautionary principle).
- Does a decision made in a neighbouring country or by some authority (e.g., EMEA) set a precedent or impose pressure on country X?

**Actors**
- Which actors have the power to request changes in the legal approval given to veterinary NSAIDs and which government ministries deal with such requests?
o Which (if any) government ministries have the power to influence the procedure for banning of a veterinary NSAID? (e.g., drug controller, animal husbandry department)
o Which governmental ministries are involved in the decision-making to give and withdraw legal approval for veterinary use of a NSAID in X country? (Which ministry is ultimately responsible, and which play at least some role).
o Is there any engagement of pharmaceutical companies in country X in efforts to increase the safety of veterinary NSAIDs? (e.g., through labelling and marketing, or avoidance of marketing vulture-toxic drugs even though they remain legally licensed)
o Have pharmaceutical companies in country X been involved in legal or lobbying efforts to overturn existing restrictions on veterinary NSAIDs? (Any details? Which drugs?)
o Have environmental NGOs or private individuals in country X been involved in legal or lobbying efforts to extend or enforce restrictions on veterinary NSAIDs?

NSAID supply chains
o In some vulture range states, national and state government agencies purchase veterinary drugs for distribution without charge or with a subsidy to livestock keepers or for the use of government veterinarians. Is this the case in X country? Which veterinary NSAIDs are routinely purchased under such schemes? Are there any mechanisms (or efforts) to ensure the purchase of only vulture-safe drugs?
o Does the sale of veterinary NSAIDs in country X require a prescription? If so, does this prescription require documentation? (e.g., ‘Schedule X’ goal in India)
o If a prescription is required for the sale of veterinary NSAIDs is this requirement typically complied with or ignored? Are there any enforcement mechanisms in place?
o Are there any procedures to encourage or ensure that only trained veterinarians administer veterinary NSAIDs in country X?
o What is the main challenge to the circumvention of a veterinary NSAID ban in country X? (e.g., use of human formulations, importation of banned NSAID)

Communication and transparency
o Is there any communication for education and raising awareness involved in the enforcement of NSAID regulations? If so, what does this involve?
o How transparent is NSAID legislation in X country? How accessible is it for members of the public, local veterinarians or manufacturers?
o Do vials of (some) veterinary NSAIDs legally require warning labels communicating their effects on vultures (e.g., in Spain)?
o Are importers, manufacturers, wholesalers, retailers, veterinarians and consumers all liable for prosecution or only some of these? Are you aware of sources of official data on the numbers of prosecutions taken and convictions obtained?

Cultural factors
o What is the primary method of carcass disposal in country X? Has this changed significantly since the start of the vulture crisis?
o What are the main factors driving carcass disposal preferences? (e.g., loss of vultures, increase in feral dogs/pests, BSE outbreak etc).
o What are most ‘popular’ veterinary NSAIDs in country X? Is this due to its popularity with veterinarians or because of another reason? (e.g., marketing, price, availability, formulation)
o What are the main barriers to the widespread adoption of vulture-safe meloxicam and tolfenamic acid in country X? (e.g., veterinary norms, price, efficacy of the drug)
o Why have other vulture-toxic NSAIDs struggled to receive the same quick response as diclofenac? What are the main conflicts at play in hampering progress to ban more harmful NSAIDs?
Appendix 2

Further detail on the actors involved in vulture conservation discussed in this thesis:

- **CMS & Raptors MoU**: In 2017, Parties to the Convention on the Conservation of Migratory Species of Wild Animals (CMS) adopted the Vulture multi-species action plan (MsAP). The MsAP set out a conservation action plan covering the range of all 15 Old World vulture species. Among many threats, its second objective aims to reduce the impact, occurrence and threat of NSAIDs on vultures (Botha et al., 2017). The development of the MsAP was funded by Switzerland and the Environment Agency of the United Arab Emirates. In 2020, Raptors MoU (the CMS Memorandum of Understanding on the Conservation of Migratory Birds of Prey in Africa and Eurasia) published the first strategic implementation plan for the MsAP which summarised efforts to date and set out a roadmap for the delivery of the MsAP by 2029. India, Pakistan and Nepal are signatories to the MoU, Bangladesh is not (CMS, 2020).

- **IUCN Species Survival Commission: Vulture Specialist Group** (IUCN SSC VSG) was founded in 2011 and aims to ‘advocate and create greater awareness of the plight of vultures and coordinate effective conservation activities to their benefit’ (IUCN SSC VSG, 2020). It works closely with other international NGOs including BirdLife International.

- **Saving Asia’s Vultures from Extinction (SAVE)** is an international consortium of 25 organisations endorsed by CMS Raptors MoU and the IUCN Vulture Specialist Group. Established in 2011, it engages with governments across South Asia to facilitate vulture conservation and cooperation between range states (SAVE, n.d.).

- **Vulture Conservation Foundation (VCF)** work to conserve Europe's four vulture species with a goal to populations becoming healthy and self-sustaining (VCF, n.d.). Established in 2009, the VCF collaborate with various actors to develop and execute conservation initiatives across Europe. They led the Europe-wide campaign to ‘Ban Vet Diclofenac’.

- **Regional Steering Committee (RSC)** was set up following the 2012 Regional Declaration between four South Asian vulture range states. It is made up of relevant government officials to coordinate and facilitate future efforts across the range states (Interview 17).

- **FACC Pharma Working Group (PWG)** is not yet established but the goal is to form national pharma working groups under NVRCs (Interview 6). Members will include representatives from pharmaceutical companies, government officials, environmental lawyers and NVRCs. National PWGs will present evidence of NSAID safety to NVRCs who will then submit ban requests to national governments where needed. National PWGs will communicate with each other across South Asia.

- **National Vulture Recovery Committees (NVRCs)** coordinate in-country vulture conservation activities. They may also be involved in applications to acquire national bans on vulture-toxic NSAIDs (Interview 6). State-level iterations of these committees also exist in certain areas including Tamil Nadu (Interview 10).

**Vulture Conservation Teams (VCTs)** are a regional initiative set up in Bangladesh to facilitate vulture conservation. There are three tiers of VCTs that function within divisions for the management of vulture safe zones (VSZs): Village-VCT, Upazilla-VCT and District-VCT. Each tier has different roles, e.g., the provision of vulture-safe carcasses to specific feeding sites in the VSZ by Village-VCT. The VCTs include representatives from the RSC, Bangladesh's NVRC and government agencies (MoEF, 2016).

**Vulture safe zones (VSZ)** were first pioneered by Nepal and are now an established tool for vulture conservation endorsed by SAVE. To create a VSZ, a provisional VSZ (pVSZ) is first set up surrounding a nesting colony of at least two species of vultures, with a radius of at least 100km. After several years of advocacy and evaluation, a VSZ will be declared an official VSZ if, after 2 years of monitoring, the area is free from vulture-toxic NSAIDs and populations are stable or increasing (MoEFCC, 2020).

**Vulture safe feeding sites (VSFS)** are community-managed sites where wild vultures are fed carcasses free from vulture-toxic NSAIDs. In Nepal, these VSFSs are called ‘vulture restaurants’ (DNPWC, 2015).

**Vulture conservation breeding centres (VCBC)** are facilities where captive vultures are bred and later released to facilitate wild population recovery (DNPWC, 2015).
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