

## Steps for banning veterinary drugs in India & Bangladesh: Where we are

SAVE accords a very high priority to achieving bans on veterinary use of NSAIDs that have been proven to be toxic to vultures (see [India policy summary](#)). The bans on veterinary use of diclofenac in 2006 in India, Nepal and Pakistan and in 2010 in Bangladesh were important steps and were enacted by the governments with commendable speed. However, we know that further such steps are urgently needed to ban veterinary use of other NSAIDs toxic to vultures. Achieving such bans in the near future is vital. Some progress with this is being made in India, but Bangladesh has taken an important lead with its [national ketoprofen ban](#).

Here we list the steps for achieving such a ban with the intention of making information on how to do it readily available. We welcome feedback on this document in case our list of steps is incorrect, incomplete or works differently in other SAVE member states.

### Process of Banning Veterinary Drugs In India

**Step 1:** An organisation (or individual) writes to the Drug Controller General of India (DCGI) formally requesting a ban of a specific drug, sent together with copies of relevant publications and other documents directly relevant to this request (these become the file or dossier).

- a. Although this request can theoretically come from anywhere, it is likely to be taken more seriously if submitted by a reputable organisation or, even better, by a government body. The file should contain robust, quantitative and clearly presented supporting information. Ideally, peer-reviewed scientific papers should be included. Given that the effects of NSAIDs have been shown to be similar for all Gyps vulture species tested in Eurasia and Africa, properly conducted studies based upon research done in any country should be included.

**Step 2:** At the discretion of DCGI, he/she agrees to review the request and passes the request and file to the 'Technical Drugs Regulation Review Committee' (TDRRC) which consists of 4-5 highly qualified and appointed experts. The TDRRC meets 4 times/year and reviews the validity of such requests and will put such requests on their meeting agenda assuming the file is considered adequately prepared.

- a. DCGI meanwhile consults the Animal Husbandry Commissioner (AHC) and includes feedback from the AHC within the file for review.

**Step 3:** The Technical Committee (TDRRC) may require repeated discussion at successive meetings and gathering of further information before reaching a conclusion. When it has done so, a recommendation for approval or rejection of the requested ban is returned, together with the file of supporting data, to the DCGI.

**Step 4:** If the recommendation is for the approval of a ban, then the DCGI normally endorses this and passes the file to the Secretary of Ministry of Health.

**Step 5:** Secretary of Health normally signs approval and passes the file for the final legal approval of the Law Ministry for passage into legislation.

**Step 6:** The Law Ministry publishes the signed decision into law.

**Step 7:** Final Gazettement of the decision may take a further year or two, but legally the ban is binding before this stage. This step may not be necessary if the ban is considered to already be part of earlier legislation

The ban on veterinary **diclofenac** of 2006 passed through these steps and was gazetted in 2008. The restriction of **vial size of human formulations of diclofenac** was passed in 2015, and was immediately gazetted due to the clear link with the 2008 ban. In both cases, the Bombay Natural History Society (BNHS), filed the original case with help and support from numerous parties at various stages. Note the contents of the file (dossier) are an important resource for upholding any subsequent challenges to the ban, and such challenges have been handled mainly by the DGCI's office, but have also resulted in court cases.

#### **Subsequent requests for veterinary drug bans in India:**

2008: **Ketoprofen** was demonstrated to be toxic to vultures and a peer-reviewed scientific paper giving the experimental evidence for this was published online in 2009 (print publication: Naidoo et al (2009) *Biology Letters* (2010) 6, 339–341. <https://doi.org/10.1098/rsbl.2009.0818>). Additional experimental evidence of toxic effects on vultures was published in a further peer-reviewed scientific paper in 2010 (Naidoo et al. *Archives of Toxicology* (2010) 84:761–766. DOI 10.1007/s00204-010-0521-0). A peer-reviewed scientific paper reporting the prevalence and concentrations of nine NSAIDs in the carcasses of cattle available to vultures in India in 2006 was published in 2009 (Taggart et al. *Environmental Science & Technology* (2009), 43: 4561–4566.). This study showed that ketoprofen was a contaminant of cattle carcasses in India and that tissues of some cattle contained enough of the drug to cause the death of vultures. The supporting file was submitted by BNHS in 2009 but was not progressed by the DCGI. Hence, this application is still at Step 1 after 12 years.

2019: **Aceclofenac** was confirmed to be a pro-drug of diclofenac, and to pose a very significant threat to vultures as it is effectively the same as diclofenac. A peer-reviewed scientific paper giving the experimental evidence that aceclofenac is rapidly converted to toxic diclofenac in cattle dosed with the drug was published in 2016 (Galligan et al. (2016) *Conservation Biology*, 30: 1122–1127. DOI: 10.1111/cobi.12711). A study showing the same result in domestic water buffaloes was conducted by the Indian Veterinary Research Institute in 2020. BNHS submitted a request to ban veterinary use of aceclofenac with a supporting file in March 2019. It remains under review of the TDRRC. Hence, this application is at Step 2 after two years.

2021: **Nimesulide** has been confirmed to be a toxic drug to vultures, with peer-reviewed publications confirming wild birds found dead in India with gout symptoms and nimesulide in the tissues (Nambirajan et al. 2021) , and safety trials demonstrating toxicity (Galligan et al. in press). There has been no submission (Step 1) so far so this is currently at Step 0.

2021: **Flunixin** has also been found both in dead wild vultures and treated captive vultures showing gout symptoms in Europe (Zorrilla et al. 2014, Eleni et al. 2019). But no clinical trials have been carried out so far, and is still at Step 0.

2021: **Carprofen** has demonstrated toxicity to vultures, although it appears to remain at high concentrations only close to the injection site of cattle tissues (Fouri et al. 2015).

2021: **Paracetamol, ibuprofen, piroxicam** and all other veterinary NSAIDs remain untested on vultures and therefore have unknown toxicity.

Note: For the current status and references relating to each toxic NSAID, refer to the Policy Summary for India which can be downloaded from the SAVE website here:

<https://save-vultures.org/2020/02/february-2020-indias-vultures-policy-summary/>

## Process of Banning Ketoprofen in Bangladesh

Ketoprofen was demonstrated to be toxic to vultures and a peer-reviewed scientific paper giving the experimental evidence for this was published online in 2009 (print publication: Naidoo et al (2009) Biology Letters (2010) 6, 339–341. <https://doi.org/10.1098/rsbl.2009.0818>). Vultures are known to be exposed to ketoprofen when they feed on carcasses of cattle dosed with the drug in India because the drug has been shown to be present at toxic concentrations in tissues of dead cattle sampled there in 2006 (Taggart et al. Environmental Science & Technology (2009), 43: 4561–4566.).

### The steps taken to achieve a national ban ketoprofen in Bangladesh

**Step 1:** In the 5<sup>th</sup> meeting of Bangladesh National Vulture Recovery Committee (BNVRC) it was proposed that the use of ketoprofen should be banned within Bangladesh's two government declared Vulture Safe Zones (VSZs).(Figure 1)

গণপ্রজাতন্ত্রী বাংলাদেশ সরকার  
পরিবেশ ও বন মন্ত্রণালয়  
পরিবেশ অধিশাখা-২

বিষয় : বাংলাদেশ জাতীয় শকুন সংরক্ষণ কমিটির পঞ্চম সভার কার্যবিবরণী।

সভাপতি : জনাব মো: নূরুল করিম  
অতিরিক্ত সচিব (পরিবেশ), পরিবেশ ও বন মন্ত্রণালয়।

তারিখ : ০৮/১১/২০১৫ খ্রি.

সময় : বেলা ১১.০০ টা

স্থান : পরিবেশ ও বন মন্ত্রণালয়ের সম্মেলন কক্ষ।

উপস্থিত সদস্যবৃন্দের তালিকা পরিশিষ্ট-ক সদয় দ্রষ্টব্য।

সভাপতি উপস্থিত সকলকে স্বাগত জানিয়ে সভার কাজ শুরু করেন। সভাপতির অনুমতিক্রমে কমিটির সদস্য সচিব বাংলাদেশ জাতীয় শকুন সংরক্ষণ কমিটির পঞ্চম সভার আলোচ্য বিষয় সভায় উপস্থাপন করেন। উক্ত সভায় কমিটির অনুরোধক্রমে পরিবেশ ও বন মন্ত্রণালয়ের সম্মানিত সচিব ড. কামাল উদ্দিন আহমেদ সভার প্রারম্ভিক আলোচনায় উপস্থিত থেকে তাঁর গুরুত্বপূর্ণ মতামত ও প্রয়োজনীয় দিকনির্দেশনা প্রদান করেন। সভার আলোচনা ও সিদ্ধান্তসমূহ নিম্নরূপ :

ক্রমিক নং	আলোচ্য বিষয়	আলোচনা	সিদ্ধান্ত	বাস্তবায়নকারী কর্তৃপক্ষ
১.	পূর্ববর্তী সভার (৪র্থ) কার্যবিবরণী নিশ্চিতকরণ	৪র্থ সভার কার্যবিবরণীতে উল্লেখ করা হয় ২০১৬ ও ২০১৭ সনে রিজিওনাল স্টিয়ারিং কমিটির আয়োজক দেশে বাংলাদেশ। উক্ত ২০১৬ ও ২০১৭ এর পরিবর্তে যথাক্রমে ২০১৭ ও ২০১৮ উল্লেখ করতে হবে।	৪র্থ সভার কার্যবিবরণী সর্বসম্মতিক্রমে নিশ্চিত করা হয়।	পরিবেশ ও বন মন্ত্রণালয়
২.	মহাবিপন্ন শকুন রক্ষায় কিটোপ্রোফেন নিষিদ্ধের অগ্রগতি	সভায় শকুনের উপর কিটোপ্রোফেনের ক্ষতিকর প্রভাব নিয়ে বিস্তারিত তথ্য উপাত্ত উপস্থাপন করেন বাংলাদেশ শকুন সংরক্ষণ প্রকল্পের মুখ্য গবেষক এ বি এম সারোয়ার আলম ও বাংলাদেশ বার্ড ক্লাবের প্রতিষ্ঠাতা জনাব ইনাম আল হক। এছাড়া কিটোপ্রোফেনের বিকল্প হিসেবে মেলোক্সিকাম জাতীয় ঔষধ ব্যবহারের কথা উল্লেখ করা হয়। সভায় উপস্থিত জনাব এনায়েত হোসেন, কিউটিএস, জাতীয় চিড়িয়াখানা জানান যে, কিটোপ্রোফেন একটি বহুল ব্যবহৃত ঔষধ এবং মেলোক্সিকাম জাতীয় ঔষধ সারা দেশে বহুলভাবে ব্যবহৃত হয় না এবং এই ঔষধটি গর্ভবতী গবাদিপশুর জন্য খুব বেশি কার্যকর নয়। প্রফেসর ড. মনিরুল হাসান খান শকুনের জন্য নিরাপদ মেলোক্সিকাম ও ক্ষতিকর কিটোপ্রোফেনের ব্যাপারে বিস্তারিত যুক্তি উপস্থাপন করেন। সভায় সম্মানিত সচিব মহোদয় উক্ত বিষয়ের উপর একটি কর্মশালার আয়োজন করার কথা বলেন এবং ভারতের সারা দেশ হতে কিটোপ্রোফেন নিষিদ্ধের জন্য সিদ্ধান্ত গ্রহণের কথা উল্লেখ করেন। তিনি আরও উল্লেখ করেন যে, যেহেতু শকুন একটি মহাবিপন্ন পানি এবং সারা দেশে এর সংখ্যা মাত্র ২৬০ এ নেমে এসেছে তাই সরকার যোষিত ২টি শকুনের নিরাপদ এলাকায় আপাতত কিটোপ্রোফেন নিষিদ্ধ করা যেতে পারে।	১. সরকার যোষিত শকুনের ২টি নিরাপদ এলাকায় কিটোপ্রোফেনের ব্যবহার নিষিদ্ধ করতে হবে। ২. যে সভা হতে ছয় মাসের মধ্যে বন অধিদপ্তর, ঔষধ প্রশাসন অইইউসিএন এবং বাংলাদেশ শকুন সংরক্ষণ কমিটি' কিটোপ্রোফেন নিষিদ্ধকরণের বিষয়ে একটি কর্মশালার আয়োজন করবে।	১. পরিবেশ ও বন মন্ত্রণালয় ২. বন অধিদপ্তর, ঔষধ প্রশাসন অধিদপ্তর ও আইইউসিএন বাংলাদেশ
৩.	বাংলাদেশে অনুষ্ঠিত ২০১৭ ও ২০১৮ সনের রিজিওনাল	দক্ষিণ এশিয়ার দেশ বাংলাদেশ, ভারত, নেপাল ও পাকিস্তান এর সমন্বয়ে গঠিত আঞ্চলিক পরিচালনা কমিটি এতদঅঞ্চলে মহাবিপন্ন শকুন রক্ষার জন্য কাজ করে আসছে। প্রতি বছর বিভিন্ন সদস্যভুক্ত দেশে উক্ত কমিটির	আঞ্চলিক পরিচালনা কমিটির সভা অনুষ্ঠানের লক্ষ্যে অর্থ বিভাগ থেকে অর্থ প্রাপ্তির বিষয়টি	পরিবেশ ও বন মন্ত্রণালয়

Figure 1: Decision taken on the 5<sup>th</sup> meeting to ban ketoprofen

**Step 2:** It was decided that a workshop will be held within six months of the meeting, with assistance of Bangladesh Forest Department, Drug administration and IUCN Bangladesh to present the harmful effects of the drugs to all relevant stakeholders and in order to ban ketoprofen.

**Step 3:** A national workshop was held in Dhaka where senior Government officials from MoEF, Department of Livestock Services, Bangladesh Forest Department, national level policy makers and IUCN Country Representative were present along with 100 participants from veterinary and conservation communities.(Figure 2)



**Figure 2:** National Workshop on Drug

**Step 4:** In the workshop (May 2016), chief vet of Zoological Society of London, Dr. Nic Masters and Chris Bowden of SAVE presented evidence on harmful effects of ketoprofen. All relevant stakeholders understood the harmful effects of the drug on vultures and agreed that the drugs should be banned. Later, the workshop minutes were submitted to MoEF through BNVR where the ministry decided to take necessary actions

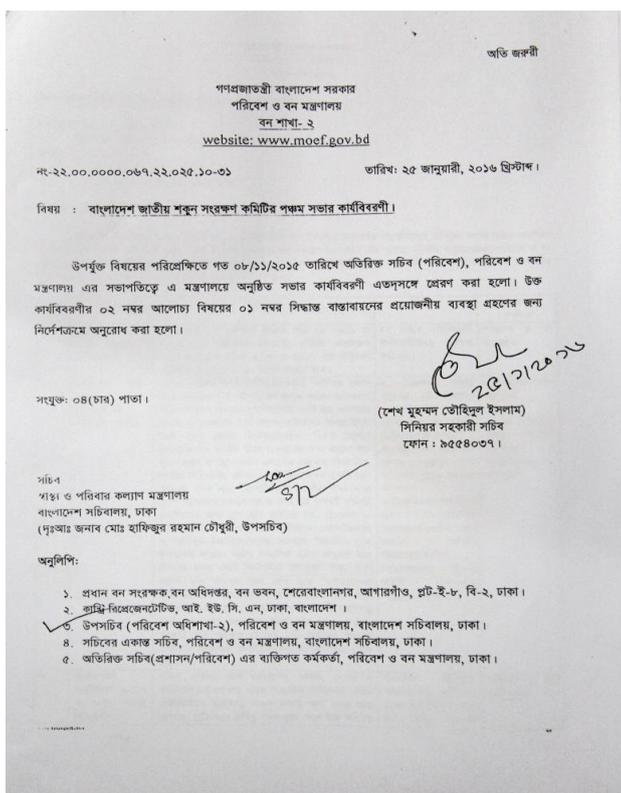


Figure 3: 1<sup>st</sup> letter was issued by MoEF to Ministry of Health and family welfare

**Step 5:** On 25<sup>th</sup> January, 2016 the first letter and on 15<sup>th</sup> December 2016 a second letter was sent to the Secretary of Ministry of Health and Family Welfare by MoEF to initiate the ban on ketoprofen.

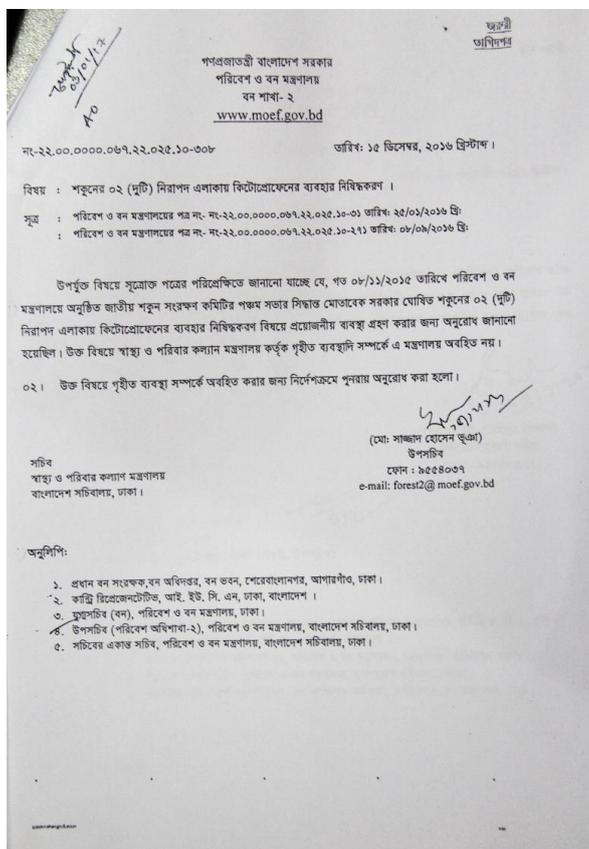
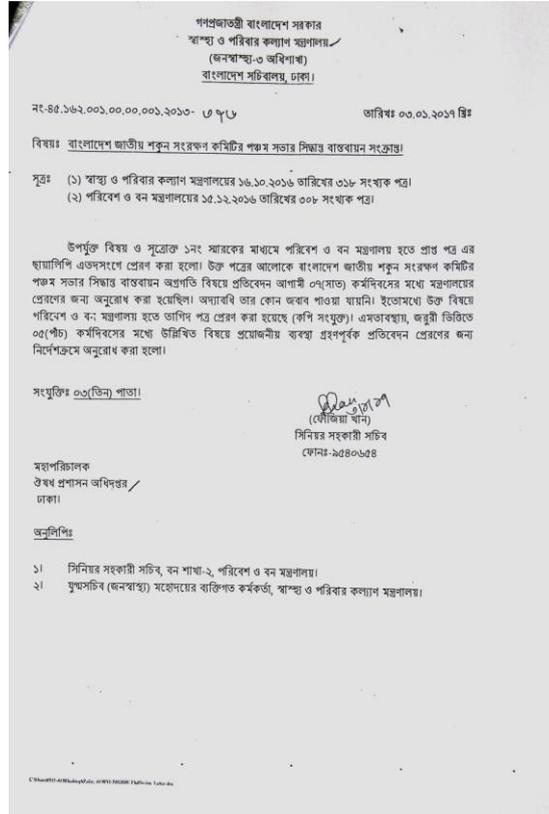


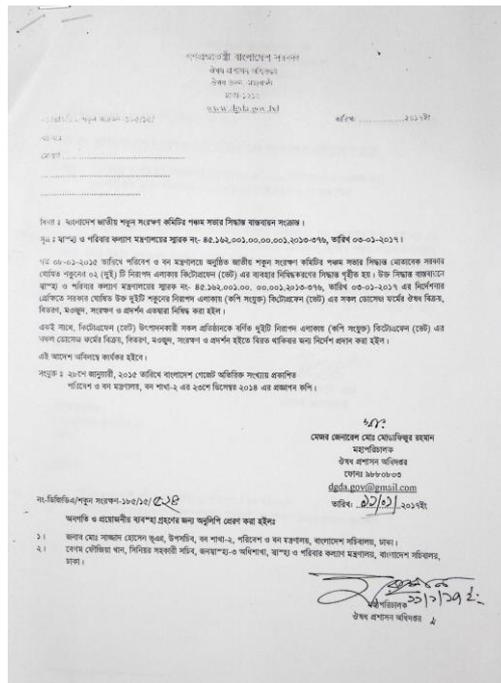
Figure 4: 2<sup>nd</sup> letter issued by MoEF to Ministry of Health and family welfare

**Step 6:** On 3<sup>rd</sup> January 2017 the Ministry of Health and Family Welfare issued a letter to the Directorate General of Drug Administration (DGDA) to take actions regarding the banning of the drug.



**Figure 5:** 3<sup>rd</sup> letter issued by Ministry of Health and Family Welfare to Drug Administration

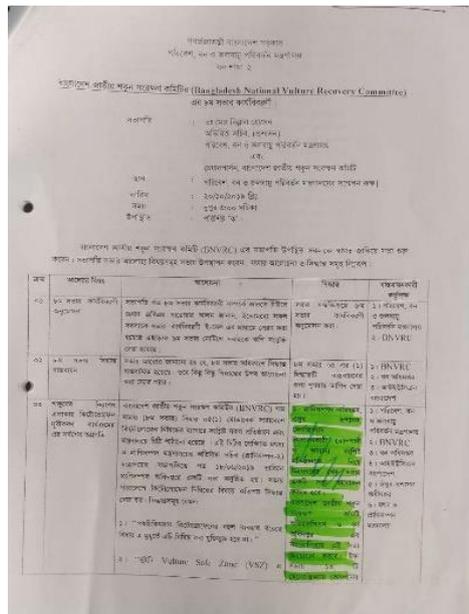
**Step 7:** On 11<sup>th</sup> January 2017, the Directorate General of Drug Administration (DGDA) issued a government order on restricting the sale, distribution, storage, preservation and exhibition of Ketoprofen in any form in the Vulture Safe Zones.



**Figure 6:** Government order to ban ketoprofen in VSZs

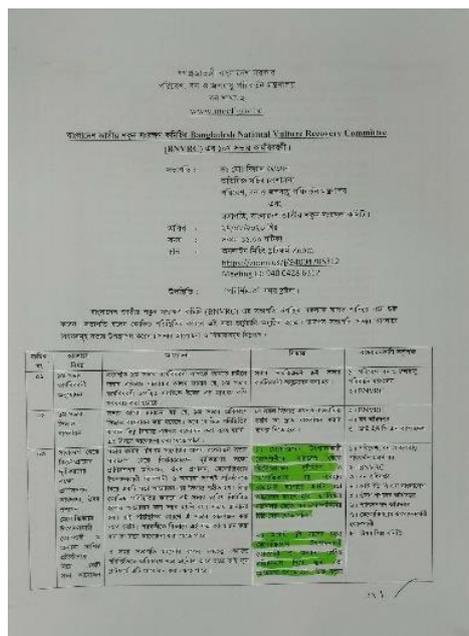
**Step 8.** In 2018, the third undercover pharmacy survey conducted in 2018 by IUCN Bangladesh and Bangladesh Forest Department, and it was seen that ketoprofen was still prevalent (62%) in the VSZs, while no diclofenac was found. It was determined ketoprofen entered the VSZs from outside the banned areas. Ketoprofen thus remains as a threat to the vulture population residing in the two VSZs.

**Step 9.** The results of the third undercover pharmacy survey was presented to the BNVR in its 9<sup>th</sup> meeting held on 20 October 2019. In the meeting it was decided that a meeting with all relevant stakeholders asking for their opinion on the country-wide ban of ketoprofen will be held.



**Figure 7.** Meeting minutes of the 9<sup>th</sup> BNVR meeting

**Step 10.** On 24 August 2020, in the 10<sup>th</sup> BNVR meeting, it was discussed that the meeting with stakeholders will be held on November 2020.



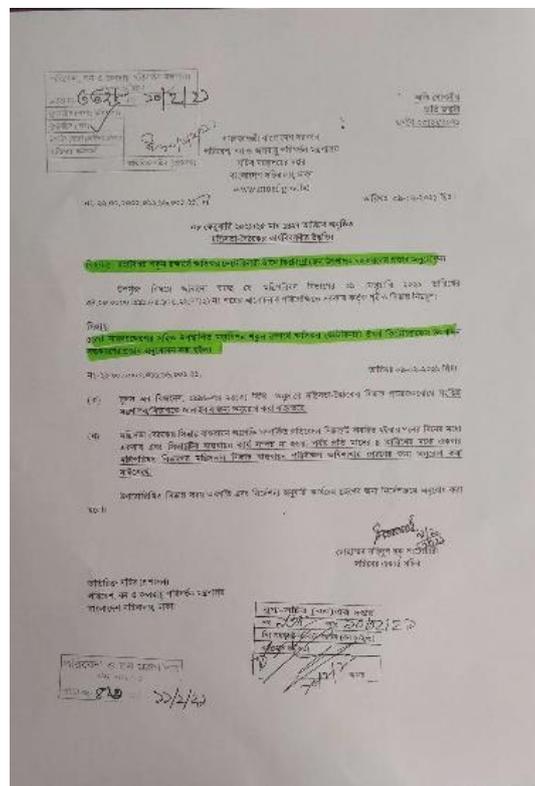
**Figure 8.** Meeting minutes of the 10<sup>th</sup> BNVR meeting

**Step 11.** On 18 November 2020, Bangladesh National Vulture Recovery Committee under the Ministry of Environment, Forest and Climate Change organized a meeting to discuss use meloxicam instead of vulture-toxic drug Ketoprofen for vulture conservatives with all relevant stakeholders, including top 13 meloxicam producing pharma-companies of Bangladesh, the DGDA, Department of Livestock and Bangladesh Forest Department. In the meeting, all stakeholders unanimously agreed that ketoprofen should be banned for the conservation of vulture. After the meeting, a proposal was drafted by MoEFCC with assistance of IUCN Bangladesh and was submitted to the Parliament Cabinet for approval.



**Figure 9.** Meeting with relevant stakeholders Nov 2020.

**Step 12.** On 8 February 2021, the Cabinet, chaired by Honourable Prime Minister approved the proposal to ban ketoprofen across the country. Thereafter on 23 March 2021, the MoEFCC issued a letter to take necessary steps on ketoprofen banning across the country to the relevant ministries.



**Figure 10.** Approval to ban national ketoprofen on 8 February 2021.