

# Are the Processes Regulating the Licensing of Veterinary NSAIDs in Vulture Range States Fit-for-Purpose?

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## Summary

- 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 starting in 2006, vulture populations in some areas have stabilised although numbers remain critically low.
- Further regulatory progress on banning other veterinary 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.
- All vulture range states face similar challenges which have so far limited the degree to which their processes for regulating the veterinary use of NSAIDs are legitimate, evidence-based and fit-for-purpose:
  - (i) Decisions on NSAID licensing have been made without regard to safety testing in non-target species including vultures.
  - (ii) Prescribed national and international vulture conservation actions have not been binding and have only been partially implemented.
  - (iii) Policy variation across the Indian subcontinent has engendered incoherence and ambiguity, and the transparency and enforcement of measures remains a challenge.
  - (iv) The precautionary approach applied to the regulation of other diffuse ecotoxic chemicals elsewhere (e.g., neonicotinoids in the European Union) has not been applied to veterinary use of NSAIDs.



## Background

In the late 1990s and 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<sup>1</sup>. Consumption of carrion contaminated with diclofenac caused vultures to die from kidney failure within days of exposure<sup>1, 2</sup>. Within barely a decade of its first veterinary licensing in 1993, the widespread use and nephrotoxic effects of diclofenac saw the collapse of vulture populations across South Asia. By 2007, the population of white-rumped vultures in India had fallen to 0.1% of their numbers in the early 1990s, and the population of long-billed and slender-billed vultures combined had fallen to 3.2% of its former level<sup>3</sup>. 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<sup>4</sup>. However, cattle carcass contamination with diclofenac in India was shown to be the only driver capable of causing population declines at the observed rates, supporting the conclusion that diclofenac alone was sufficient to have caused the observed population crash<sup>5, 6</sup>.

## Status Quo

In response to the crisis, 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 efforts to promote population recovery, including by reducing threats posed by veterinary NSAIDs other than diclofenac<sup>7</sup>. Other vulture range states across Asia have since moved to ban veterinary diclofenac, including Iran (2015)<sup>8</sup>, Cambodia (2019)<sup>9</sup> and Oman (2020)<sup>10</sup>. Although studies have shown incomplete enforcement and awareness of the bans, there is evidence that populations are stabilising and, in some areas, beginning to recover<sup>11, 12, 13, 14</sup>. However, even in these cases, numbers remain critically low<sup>13, 14</sup>.

Moreover, there is evidence that widespread illegal use of diclofenac persists in India, including via the veterinary use of human formulations of the drug<sup>15, 16</sup>. Despite the relatively fast South Asian 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<sup>17</sup>. Among these, several have now also been shown to also cause nephrotoxic effects in vultures (Table 1) and their continued use is likely inhibiting further population recovery<sup>18</sup>.

**Table 1:** Toxicity of NSAIDs to *Gyps* vultures<sup>2, 17, 18, 19, 20, 21, 22</sup>

NSAID	Vulture threat
Diclofenac	Toxic with full safety-testing results published
Ketoprofen	
Aceclofenac	
Nimesulide	
Flunixin	Toxic
Carprofen	Toxic at high doses
Meloxicam	Safe
Tolfenamic acid	

While regulatory action is starting to be taken against a few of these other drugs, they remain largely unregulated (Table 2). Bangladesh recently became the first nation to ban a second vulture-toxic NSAID (ketoprofen), but others have yet to receive the same stringent and coordinated regulatory attention. 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'<sup>4</sup>. The goal to establish such an instrument is one repeated in both international and national action plans and frameworks<sup>4, 23</sup>.

### Box 1: Importance of vultures

Vultures contribute to a multitude of ecosystem services, mainly stemming from their removal of carrion. In addition to serving as pest and disease control agents<sup>24</sup>, they have been shown to contribute to the reduction of greenhouse gas emissions<sup>25</sup>, as well as efficiently removing vast quantities of organic waste from landscapes at no cost. The precipitous declines of vulture populations in South Asia have been linked to increases in feral dog populations, rabies and all-cause human mortality<sup>24, 26</sup>. Furthermore, vultures have significant spiritual and existence values to people across South Asia<sup>27, 28</sup>. The economic cost of replacing the waste-disposal services provided by vultures is expected to be considerable<sup>25, 26</sup>.

Meanwhile, 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<sup>29</sup>, the European Commission has chosen not to ban veterinary diclofenac and it is marketed in five EU Member States: Spain, Italy, Estonia, Latvia and the Czech Republic<sup>30</sup>. Diclofenac's marketing authorisation in Spain is particularly concerning given the country is home to over 90% of vultures found in the Western Palearctic<sup>31</sup> and veterinary use of the drug is increasing year-on-year<sup>32</sup>. Amid concerns over future population stability<sup>31, 33</sup>, the Spanish Government argues that sufficient risk mitigation measures have been put in place to ensure the chance of vulture exposure to diclofenac is low<sup>32</sup>. 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<sup>34</sup>.

This document reports research undertaken to better understand the workings of existing veterinary NSAID licensing and banning procedures in South Asian and European vulture range states. Case studies covering India, Pakistan, Nepal, Bangladesh, Cambodia, Oman, Saudi Arabia and Spain were collated, thanks to the help of in-country experts<sup>35</sup>, and evaluated alongside the existing literature base. Most of these contacts came about thanks to the broad network of partners involved in the international consortium Saving Asia's Vultures from Extinction (SAVE). The data was then analysed through the lens of various policy legitimacy indicators to discern whether current policy frameworks are reducing the risk posed to vultures through legitimate and evidence-based regulation of drugs known to be vulture-toxic, and to help rationalise policy output (i.e., drug licensing status, as shown in Table 2). Below is a summary of key findings but for more information, see [here](#).

### Box 2: Regional & Social Context

Beyond South Asia's *Gyps* vultures, other species of Old World vultures – those found across Eurasia and Africa, belonging to the family Accipitridae – have also been shown to be vulnerable to the fatal effects of certain NSAIDs<sup>12, 36</sup>. Other necrophagous bird species including steppe eagles and black kites may also be at risk. However, the unrelated New World vultures of the Americas (family Cathartidae) are less susceptible<sup>37</sup>. It is important to remember when discussing this problem that Old World vultures in different geographic regions face a distinct portfolio of threats, each with varying local severity<sup>4</sup>. 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<sup>4</sup>. 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.

**Table 2:** Vulture-toxic veterinary NSAIDs currently banned, licensed or restricted in South Asian vulture range states<sup>35, \*</sup>

NSAID	India	Pakistan	Nepal	Bangladesh
Diclofenac	Banned (2006)	Banned (2006)	Banned (2006)	Banned (2010)
Multi-dose vials of diclofenac	Banned (2015)	Not in use	Not in use	Not in use
Ketoprofen	Licensed Restricted in Tamil Nadu (2015)	Licensed Restricted in Sindh (2018)	Licensed	Banned (2021)
Aceclofenac	Licensed in certain states	Licensed Restricted in Sindh (2018)	Not in use	Not in use
Nimesulide	Licensed in certain states	Not in use	Licensed	Banned (for unrelated reason)
Flunixin	Licensed Restricted in Tamil Nadu (2019)	Licensed	Unknown	Not in use

\*In Tamil Nadu, 'restricted' refers to drugs whose government distribution is prevented. In Sindh, the sale and use of these drugs is disallowed.

## Key findings

- In the five central case studies analysed (India, Pakistan, Nepal, Bangladesh and Spain), decisions on veterinary NSAID licensing have been made without regard to prior safety testing in secondary or tertiary species including vultures. Bans and 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 licences exist across the Indian subcontinent which maintain lawful veterinary use of nephrotoxic aceclofenac, ketoprofen, nimesulide, flunixin, and several other NSAIDs of unknown toxicity (Table 2).
- 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 are problematic: sample sizes are small, unquantified but potentially 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<sup>38, 39</sup>. It is clear that the measures employed thus far are not preventing vulture-toxic NSAIDs from entering the food chain of wild vultures<sup>38, 39</sup>.
- The additional three case studies analysed (Cambodia, Oman, Saudi Arabia) cover countries which have more recently engaged in assessing potential effects of NSAIDs on vultures. 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 has considered regulatory action, but whose policymakers are perturbed by the endorsement of veterinary diclofenac in the EU.

## Discussion points

**Policy incoherence.** There is currently a mosaic of licensed, banned and restricted veterinary NSAIDs across the four countries of the Indian subcontinent and among their respective states and provinces (Table 2). The considerable variation among users in which drugs are preferred has led to policy incoherence and downstream ambiguity, as well as particularly challenging conditions in border regions where drugs banned in one country are crossing the border from another.

**Transparency.** There is substantial variation among Indian states in awareness of NSAID policy<sup>16</sup>. This is in contrast to the examples of successful community initiatives elsewhere: Nepal's 'vulture safe zone', 'vulture restaurants' and 'diclofenac-for-meloxicam' schemes have engaged and educated livestock owners, citizens and officials about the risks to vultures from the use of these drugs<sup>35</sup>. 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<sup>40, 41</sup>. This conflict has led to a rise in targeted attacks on vultures using deliberately set poison-baits and in turn, weakens the case put forward by organisations advocating for vulture conservation in Spain, including efforts to ban veterinary diclofenac.

**Bindingness.** Countries on the Indian subcontinent have published National Vulture Conservation Action Plans detailing their goals for vulture conservation going forward. While comprehensive and far-ranging, these plans are each published or endorsed by a single government department and have no legal power to bind other departments or wider stakeholders. This severely limits their prospects of successful implementation and has led to ambiguity over the roles of various actors. Furthermore, levels of enforcement of NSAID bans and restrictions remain low, with only one clear example from Tamil Nadu<sup>42</sup>.

**Precautionary principle.** Based on the EU's guidelines for the application of the precautionary principle, 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<sup>43</sup>, it would seem the vulture-NSAID debate should warrant a precautionary approach. On examination of the EU's handling of other diffuse

ecotoxic chemical policy, such as neonicotinoid pesticides or antibiotic growth promoters, it can be argued that such consistency should but does not yet extend to veterinary NSAIDs. This is in contrast to the direct citation of the precautionary principle as a reason to uphold the restriction in India on multi-dose vial sizes of diclofenac labelled for human use. A case at Madras High Court cited the precautionary principle as a well-established principle of Indian law in its reasoning to uphold the restriction in the face of opposition from pharmaceutical companies<sup>44, 45</sup>. Furthermore, the pre-emptive bans on veterinary diclofenac in both Oman and Cambodia are similar, albeit less explicit, examples of a precautionary approach.

**Safety testing.** The licensing processes in South Asia and Europe do not require that prospective veterinary NSAIDs be tested on vultures or on any other secondary or tertiary species<sup>32,35</sup>. Instead, distantly-related avian test subjects with incomparable susceptibilities (domestic chickens, for example) continue to be used, if at all<sup>46, 47</sup>. It is important that any future safety testing procedure is retrospective as well as prospective: testing drugs which are already licensed as well as those under consideration<sup>4</sup>. Furthermore, it is argued the burden of proof for such testing should be shifted to the licence applicant<sup>4</sup>.

**Does veterinary diclofenac pose a risk to Spanish vultures?** Overall, populations of Eurasian griffon vulture are substantial and showing positive trends<sup>32</sup>, and only four NSAID-related vulture deaths have been confirmed (with only one involving diclofenac)<sup>38, 39, 48</sup>. However, it is likely the true number of casualties is higher than those published. Furthermore, the annual use of veterinary diclofenac in Spain continues to rise<sup>32</sup> and evidence of carcass contamination exists from the very limited sampling performed at vulture feeding sites<sup>38, 49</sup>. The use of another vulture-toxic NSAID – flunixin – is also a potential threat<sup>38</sup>. There remains significant uncertainty over the magnitude and extent of risk posed to Spanish vultures from the use of veterinary NSAIDs. 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?

**Does the EU have a duty to ban vulture-toxic NSAIDs?** Regardless of the differences in cultural background and

case specifics between South Asia and Europe, it can 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. The progress of a ban on veterinary diclofenac in other range states may be being impeded by the EU's decision not to ban the vulture-toxic drug, as is the case in Saudi Arabia<sup>35</sup>.

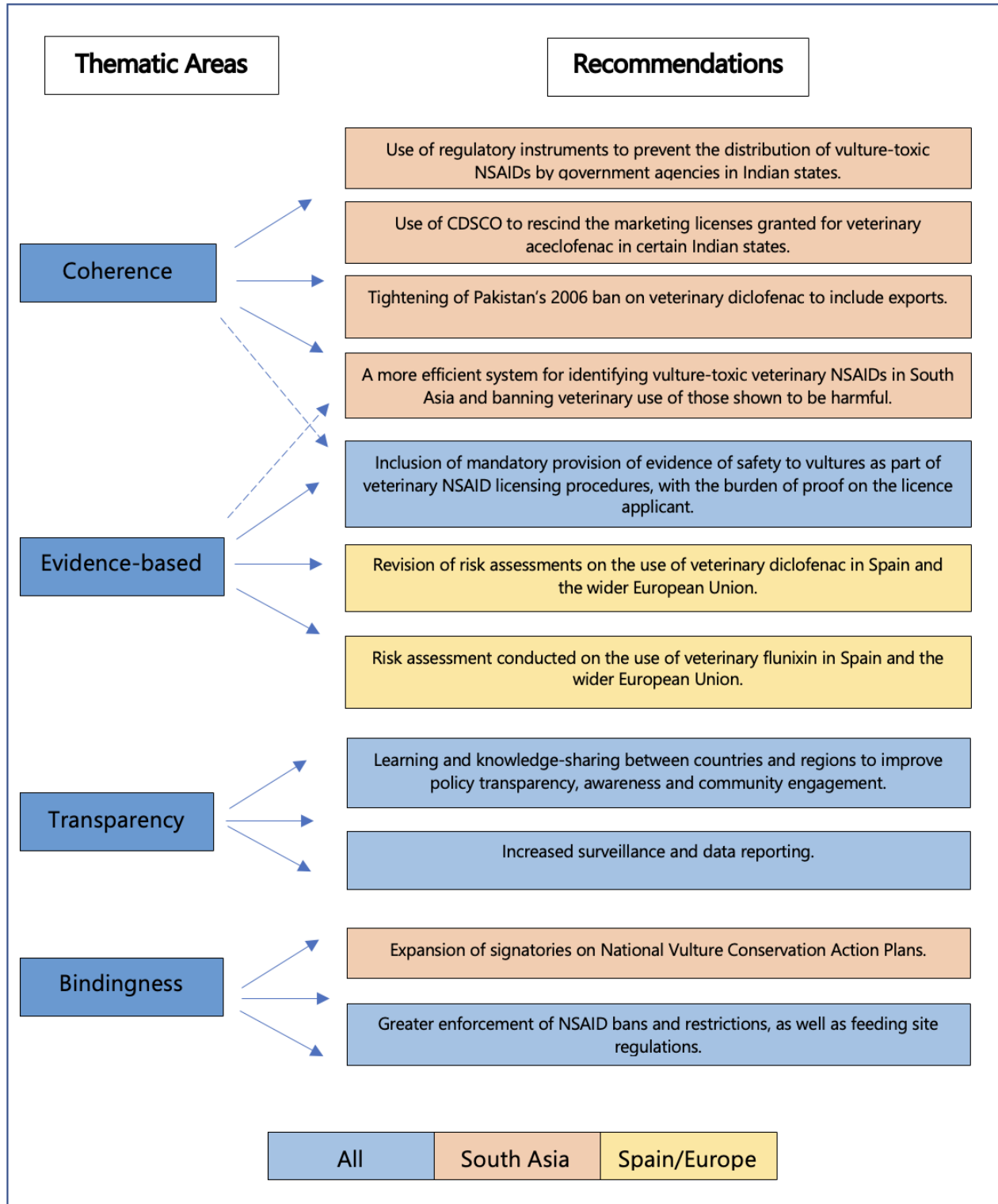
### Box 3: Time lag

The life-history characteristics of vultures – namely their long lifespans, slow maturation and low fecundity – make their population size and trend especially vulnerable to additional adult mortality and hence dramatic population declines<sup>33, 50</sup>. The population halving time for white-rumped vultures under the influence of veterinary diclofenac was found to be just one year in India and Pakistan<sup>51</sup>, while the maximum doubling time for a vulture population under ideal conditions is at least ten years<sup>52</sup>. As a result, each year that passes without effective diclofenac (and wider NSAID) regulation prolongs population recovery of a susceptible species by at least a decade. It can 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.

### Conclusion

The bans on veterinary diclofenac in the early 2000s across the Indian subcontinent were swift, coordinated and well supported by robust regulatory instruments. 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 there is a similar picture: a powerful pharmaceutical industry with resources that outstrip those of conservation NGOs, and government actors balancing multiple conflicting pressures as they navigate this problem. These differences are more pronounced in India and Spain, while relationships between actors in Nepal and Bangladesh appear more conducive to cooperation thanks to their smaller pharmaceutical industries and closer NGO-government relationships.

## Summary of Recommendations



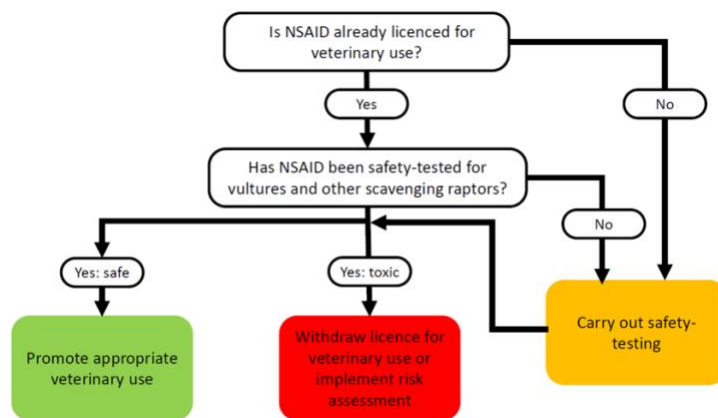
**Figure 1:** Summary of recommendations to facilitate legitimate and evidence-based policymaking.

## General Recommendations for All Vulture Range States

In addition to the country and region-specific recommendations arising from conclusions drawn from this research, CMS provides general recommendations for policymakers in all states home to Old World vultures.

CMS [Resolution 11.15 \(Rev.COP13\)](#) urges Parties and Non-Parties to:

- Ensure safety testing on vultures of existing veterinary NSAIDs.
- Withdraw licensing of vulture-toxic NSAIDs (including diclofenac) for veterinary use; or,
- Implement adequate risk assessment for known threats to vultures and other scavenging raptors.
- Ensure safety testing of new veterinary NSAIDs as part of the standard protocol of research and development departments of, or financed by the pharmaceutical industry, making licensing conditional on the results of these tests.
- Contribute to the identification and promotion of safe alternative drugs.



**Figure 2:** Recommended decision-making process for market authorisation of veterinary NSAIDs<sup>53</sup>.

Further information can be found in the CMS [Vulture Multi-species Action Plan](#) and their [Guidelines to Prevent the Risk of Poisoning to Migratory Birds](#).

*Thanks and acknowledgement must go to all interviewees and collaborators involved in this project, without whom this research would not have been possible. In addition, thanks to all who helped review this document: Chris Bowden (RSPB), Umberto Gallo-Orsi (Raptors MOU), Vicky Jones (BirdLife International), Roger Safford (BirdLife International).*

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