EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Veterinary Medicines Division

Overview of comments received on public consultation regarding the request to the European Medicines Agency from the European Commission for a scientific opinion regarding the risks to vultures and other necrophagous bird populations in the Union in connection with the use of veterinary medicinal products containing the substance diclofenac

Table of Contents

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Introduction

On 12 August 2014, the European Commission (EC) presented to the European Medicines Agency a request for an opinion from the Committee for Medicinal Products for Veterinary Use (CVMP), on a scientific matter concerning the risks to vultures and other necrophagous bird populations in the European Union in connection with the use of veterinary medicinal products (VMPs) containing the substance diclofenac, in accordance with Article 30(3) of Regulation (EC) No 726/2004.

In the interest of transparency, and in order to provide stakeholders with the opportunity to input any information or data that they consider may be helpful to the CVMP in reaching its opinion, following the September 2014 CVMP meeting, a public consultation was started on 12 September 2014. The deadline for the provision of information and comments was 10 October 2014

More information about the above public consultation is published on the Agency's website.

I - List of stakeholders who provided comments on Topic 1

Stakeholder no.	Name of organisation or individual
1	Portuguese Association of Zoo and Aquariums (APZA) – Arlete Sogorb
2	• Associazione CERM Centro Rapaci Minacciati ONLUS – Guido Ceccolini • Vulture Conservation Foundation (VCF) - José Tavares • Luca Passalacqua (affiliation not specified) • Società di scienze naturali del Verbano Cusio Ossola - Lucia Pompilio
3	• European Association of Zoos and Aquaria (EAZA) - David Williams-Mitchell • Royal Zoological Society of Antwerp, Antwerp zoo and Planckendael Animal Park - Marleen Huyghe • Danish Association of Zoos and Aquaria (DAZA) - Richard Østerballe • Association Française des Parcs Zoologiques (AFdPZ) - Cécile Erny • Nordens Ark - Emma Nygren • Royal Rotterdam Zoo - Harald Schmidt • The Royal Zoological Society of Scotland - Colin Oulton • Avifauna - Joost Lammers • Beekse Bergen - Lars Versteege • Borås Zoo - Daniel Roth
4	British and Irish Association of Zoos and Aquariums (BIAZA) - Kirsten Pullen
5	• BirdLife International - Iván Ramírez • International Fund for Animal Welfare (IFAW) - Sonja Van Tichelen • Wildlife Conservation Society (WCS) - Janice Weatherley-Singh
6	British Veterinary Association (BVA) and British Veterinary Zoological Society (BVZS) - John Blackwell and Mike Stanford
7	Centre National d'Informations Toxicologiques Vétérinaires (CNITV) - Elodie Adamczyk
8	Copenhagen Zoo - Flemming Nielsen
9	Federation of Veterinarians of Europe - Nancy De Briyne
10	Hawk Conservancy Trust - Campbell Murn
11	IFAH-Europe - David John
12	Società di ecopatologia della fauna - Vittorio Guberti
13	IUCN Vulture Specialist Group - Chris Bowden and Andre Botha

Stakeholder no.	Name of organisation or individual
14	Kalba Bird of Prey Centre - Gerard Whitehouse-Tedd
15	Ministry of Agriculture, Food and Environment of Spain – Carmen Martin Franco
16	Ministry Of Agriculture, Food and Environment of Spain - Miguel Aymerich
17	Parques Reunidos - Maria Delclaux
18	The Peregrine Fund - Richard T. Watson
19	IUCN Species Survival Commission Wildlife Health Specialist Group - Richard Kock
20	Italian Association of Zoos and Aquaria (U.I.Z.A.) - Cesare Avesani Zaborra
21	Zoobotánico de Jerez - Iñigo Sánchez
22	Federazione Nazionale Ordini Veterinari Italiani (FNOVI)

I - Comments received on Topic 1

Procedure of feeding vultures and other necrophagous birds species with animal by-products in and outside feeding stations and measures put in place to mitigate risks related to the potential for the by-products to contain residues of veterinary medicines.

Stakeholder no.	Comments
1	Portugal is an important migration area for vultures. Our Association recognizes that mitigating the risk of ingestion of diclofenac by necrophagous birds is next to impossible outside feeding stations, as the birds will feed opportunistically on dead livestock, often before farmers are aware that their animal is dead. Bearing in mind the terrain in which European vulture populations reside, it would be practically impossible for farmers to locate and dispose of dead livestock prior to those animals being located by necrophagous birds and diclofenac residues being ingested. APZA recognises also that there is no way for feeding stations to know – even with vastly improved labelling and records of prescription – whether the animal products being provided to them contain diclofenac without testing every donation, which would be prohibitive in terms of both human and financial resources; these facilities represent a huge resource in the recovery of vulture populations and a significant investment by donors including the European Union LIFE funds. Separation of animal products that contain diclofenac from those which do not prior to donation to feeding stations would also prove a significant burden to livestock farmers. An alternative veterinary anti-inflammatory solution (Meloxicam) exists which is not toxic to necrophagous birds, not subject to patent, and which would provide a simple and cost effective solution to the issues outlined above. Vultures are some of the only European native species where reintroduction is feasible at this time; however, the investment of resources necessary for this aim to be fulfilled would be essentially rendered meaningless in areas where diclofenac is widely used. Fulfilment of Aichi targets for the protection of biodiversity and vulnerable species – an agreement binding on all EU member states – falls largely on our members and in situ conservationists, and vulture protection is an important part of this work. Licencing of diclofenac for veterinary care therefore essentially prevents the governments of countries that do so from fulfilling their obligations to the Aichi targets with regard to vulture species.
2	**Introduction** Out of the 16 species of old-world vultures, 4 occur regularly and breed in Europe: the globally Endangered Egyptian Vulture (*Neophron percnopterus*), the globally Near-Threatened Cinereous Vulture (*Aegypius monachus*) and Bearded Vulture (*Gypaetus barbatus*), and the globally Least Concern Griffon Vulture (*Gyps fulvus*).

Stakeholder no.	Comments
	Europe is now probably the continent in the old world with most vultures, in absolute numbers, as the vulture populations in South Asia have collapsed totally, while Africa is now facing an unprecedented and large-scale vulture decline due to widespread poisoning (Botha et al., 2012). On the contrary, in Europe three of the four species (only exception is the Egyptian vulture) have been increasing steadily , partly due to the intensive conservation effort funded by European Union budget lines – since 1996 the EU, and national governments, have invested significant financial resources for the conservation of vultures, and there has been at least 67 LIFE projects related with these species – only between 2008 and 2012 9 vulture conservation projects alone received 10.7 million Euro (see here). Several vulture reintroduction projects have also been happening in Europe, notably the reintroduction of the bearded vulture in the Alps (successful, with 30 pairs now breeding in the wild, in one of the most celebrated wildlife comeback stories of our times), in Grands Causses (France) and in Andalusia (Spain). The estimated cost to "produce" a bearded vulture for reintroduction has been put at 70-80,000€ (Frey, 1998) Considering that in the last few years between 9 and 13 birds are released per year in the three on-going bearded vulture reintroduction projects, the yearly costs of bearded vulture reintroduction (not even considering the monitoring) is 650,000-900,000€. Further, black vultures are also being reintroduced in France (with already a very successful wild population established), and griffon vultures in several places in Europe (France, Italy, Bulgaria). All in all, hundreds of millions of Euros have been spent on vulture conservation in Europe in the last 3 decades. The Iberian Peninsula, France and Italy include the bulk of the European vulture populations (VCF data). **Vulture populations in Spain and Italy** Veterinary diclofenac has been made commercially available in two key Vulture countries. Spain: With more than 70,000 griffon vultures (90% of the European population), 5,000 cinereous vultures (97% of the European population), 3,000 Egyptian vultures (85% of the European population) and 300 bearded vultures (67% of the European population) (VCF data), Spain is the most important country on the continent for these species – and for some of them (e.g griffon and cinereous vulture) the most important country in the world. It is also the key country to secure a sustainable recovery of vulture populations across Europe – the healthy populations in Spain have been supporting, through normal dispersion, or through human-induced reintroduction and restocking projects with birds of Spanish-origin, several vulture conservation projects in Europe. Italy: Italy has a small and decreasing population of Egyptian vultures in the south (8 pairs in 2012), a small but increasing population of griffon vultures (92 breeding pairs in 2012 across the country, from Sardinia and Sicily to the Abruzzi and the Alps), and a successfully re-established bearded vulture population (9 territorial pairs, of which 5 started breeding in 2014, fledging 3 young). Italy is also key to restoring the migration flow and connecting the increasing and healthy vulture populations in Western Europe with the small and

Stakeholder no.	Comments
	struggling Eastern Europe/Balkan populations. While Italy has important vulture populations and is a vital connecting country, Spain is no doubt the key in this issue of vultures and diclofenac. **Vulture population feeding and legislative framework (in Europe & in Spain)** In general, vultures in Europe benefited from traditional livestock practices that included abandoning dead animals in the fields. The first sanitation laws forbidding the abandonment of carcasses in the field were approved in Spain in the 1950s, but these were not enforced and implemented (Donázar et al. 2009a), and throughout the 20th century vultures in general could find lots of food in the fields, particularly in countries or regions with extensive livestock systems (southwest Iberia, mountains), and an ages old tradition of leaving carcasses of dead animals in "muladares". Many of these muladares also started to receive carcasses from local intensive livestock farms. In 2000, the appearance of bovine spongiform encephalopathy (BSEs) brought about strict EU legislation (CE 1774/2002) aimed at the elimination of all animal by-products in the fields. As a consequence, state and regional administrations enforced measures requiring farmers to remove or destroy all the remains of dead livestock. This led to the closure of many vulture feeding station and muladares (in Spain in 2006/2007) (Donázar et al., 2010) This inevitably led to a sudden scarcity of once plentiful food, and triggered a change in the foraging behaviour and population of vultures. Faced with a reduced supply of carcasses, vultures moved to exploit garbage dumps for example (a lower-quality food source) (Donázar et al. 2010). The sudden closure of these feeding stations and muladares, in combination with other human-related threats, such as poisoning and wind-farms, caused a decline on the number of breeding pairs by c. 24%, adult survival by 30% and fecundity by 35% (data for Gyps fulvus), as well as an increase in the number of birds entering rehabilitation centers (Martínez-Abraín et al., 2011). In 2009, following lobbying by conservation organisations, and recognising the value and role that vultures play in the ecosystem, the EU has introduced a new regulation (EC No 1069/2009) allowing for the reopening of the vulture feeding stations or muladares, listing a number of exceptions to the compulsory collection of carcasses, directed at supplementing food for scavenging birds in dedicated places. However, carcasses in the fields were still subject of enforced collection. Later, the relevance of vultures for safe, cheap and natural disposal of livestock carcasses has been recognized in the most recent EU Animal by-products regulation (CE 142/2011), which includes specific authorizations for leaving carcasses in nature, in areas frequented by vultures. This regulation has already been transposed to national law in Spain (Real Decreto 1632/2011), and adopted already in 10 Spanish autonomous regions. It includes a number if provisions:

Stakeholder no.	Comments
	- The definition of Protection Areas for birds of prey and/or feeding scavenger species of Community interest. In these areas, where scavenger birds are already present, some free-ranging animals don't need to be recovered when dead and therefore might be available for vultures (except if they die of infectious diseases). Exact definition of what can be left out in the fields varies in different autonomous region, depending mostly on endemic infectious diseases. - The establishment of carrion-dump sites (muladares) for birds of prey and/or feeding scavengers where intensive indoor or free-ranging farmed animals can be disposed, with certain conditions. Some specified risk materials (SRM) are still forbidden, as it is the deposition of animals that died because of certain specified diseases (in this case the whole animal should still be incinerated). The dump-sites are locked enclosures and subject to a certain degree of control, and often receive lots of animal by-products and carcasses from intensive explorations. There are at least 199 official vulture feeding points in Spain, but it is also known that there exist a reasonable number of “illegal” (i.e. not approved) ones. **Patterns of vulture foraging and feeding in nature** It is generally considered that domestic livestock constitute more than half of the biomass eaten by vultures in Europe. The exact figure varies from country to country, and from species to species, but it is generally accepted that domestic livestock are a significant proportion of what vultures eat in Europe. It is also relevant to note that vultures in general, and griffon vultures in particular, identify and start to feed on carcasses very soon after animals die in the fields or are deposited in vulture feeding stations – on average 31 minutes after death/deposition (Cortés-Avizanda et al. 2012, Duriez et al. 2012). So there is solid evidence that vultures prefer to feed mostly immediately after the death of an animal. In Spain, and elsewhere in Europe, vultures feed mostly on two types of situations 1) Using carcasses and other animal products made available to them in registered and custom-built vulture feeding stations. 2) Finding carcasses of dead animals in the field in a more natural foraging and feeding pattern (with more unpredictability, both temporal and spatial) (Monsarrat et al. 2013). Vultures use more or less feeding stations depending on the location, the season and number of these in a specific area, and also the availability of “natural” (in the fields) carcasses. Patterns are extremely variable and cannot easily be characterised – in some regions with lots of feeding stations some vultures feed almost exclusively on feeding stations, in other places with no or few feeding stations they feed mostly on carcasses in the fields. Further, some vultures feed on feeding stations during some part of the year (e.g. in the

Stakeholder no.	Comments
	Spanish pre-Pyrenees where they bred) and may migrate to areas with no or few feeding stations in another season (ex. Extremadura and southern Portugal, where they spend the winter, or Central Pyrenees in summer with extensive livestock farming), making the overall situation rather fluid and variable. In Spain alone there are at least 199 authorized feeding stations, and these vary greatly in size and management. Some are run by local government, some by local NGOs, others by individuals (e.g. farmers and hunters) – some receive many hundreds of kilos of meat-animal by-products every week, others limited amounts more irregularly – again, the situation here is very diverse. The format of meat disposal is also very diverse – in some cases whole carcasses are dumped, while in others only parts of carcasses (bones, organs, viscera, etc.) are given. Again, a very diverse and wide ranging situation. In Spain, the Ministry of Agriculture and Environment (MAGRAMA) keeps a register of all carcasses (and in some cases parts of carcasses) transferred to official and recognized vulture feeding stations. According to their data, the following are sent to vulture feeding stations across the country in one year: 345 carcass-equivalents of cattle 38,413 carcass-equivalents of intensive-reared pork 259 carcass-equivalents of horses (sheep and goats are not mentioned here because they are not susceptible to be treated with veterinary diclofenac – but please note that given the convenience of administration, veterinary diclofenac would appear to be a very convenient Non-steroid anti-inflammatory drug to be administered by shepherds without veterinary supervision!). (Data taken from the Spanish government report “Análisis del riesgo de uso de medicamentos veterinarios con diclofenaco sobre las populaciones de buitres en España – recomendaciones de actuación y escenarios potenciales de afección”, July 2014, MAGRAMA (Direcciones Generales de Calidad y Evaluación Ambiental y Medio Natural (DGCEAMN), Sanidad de la Producción Agraria (DGSPP)) and the Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)). These numbers are certainly underestimated, as our experience suggests that not all apportions are logged in. But even considering these as a good estimation of order of magnitude, we can see that as an absolute minimum circa 40,000 cows/pigs/horses are deposited in vulture feeding stations across Spain per year. Regarding carcasses left out in the fields, according to MAGRAMA´s own data, based on the official census of the livestock in the country,

Stakeholder no.	Comments
	the average mortality rate, and the data from the companies that collect carcasses from the fields (from 2011), the estimation of number of carcasses left in the fields is the following: 7,365 free ranging cattle 18,881 free ranging pork (sheep and goats are not mentioned here because they are not susceptible to be treated with veterinary diclofenac) Data taken from the Spanish government report "Análisis del riesgo de uso de medicamentos veterinarios con diclofenaco sobre las populaciones de buitres en España – recomendaciones de actuación y escenarios potenciales de afección", July 2014, MAGRAMA (Direcciones Generales de Calidad y Evaluación Ambiental y Medio Natural (DGCEAMN), Sanidad de la Producción Agraria (DGSPP)) and the Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)). This is likely to be a gross underestimates as this data is from 2011, when the sanitary regulation was not yet transposed and the collection of carcasses was supposedly enforced everywhere. Now that it is actually allowed, the number of carcasses left out in the fields is certainly considerably higher, but this estimate gives us an order of magnitude for carcasses of free ranging cattle and pork available to vultures per year in Spain – circa 30,000. There is solid scientific evidence that almost all of the carcasses that are left out in the fields (i.e. not collected) are consumed by vultures where these occur- Cortés-Avizanda et al. 2012 has suggested that 89,1% of carcasses observed registered vultures coming to feed. We are therefore talking about an absolute minimum of 70,000 carcasses of cattle, pork and horses consumed by vultures in Spain, both in vulture feeding restaurants and in the fields. This is certainly a lot of carcasses to control for presence of veterinary diclofenac! In Italy too many tens of thousands of animals are left to die in the fields every year. According to the Banca Dati Nazionale dell'Anagrafe Zootecnica (BDN), between October 2013 and September 2014 at least 19,000 heads of animals were lost/unaccounted for (see table 1 below). Interesting, the Italian database also points out to another potential problem with livestock that will make effective control extremely difficult – stealing! In the last year, more than 9,000 heads of livestock in Italy have been stolen, and thus eventually slaughtered without proper control. Italy does not have the vulture populations that live in Spain, and many of these lost heads would not be consumed by vultures, but these figures serve to show that hundreds of thousands of livestock carcasses are left out in the fields across Europe every year – this increases the risk that a few of them do include some toxic levels of diclofenac.

Stakeholder no.	Comments					
	DATI AL 1/10/14 SUI 12 MESI PRECEDENTI	NUMERO ALLEVAMENTI BOVINI E BUFALINI IN CUI SONO AVVENUTI FURTI/SMARRIMENTI Stolen/lost	NUMERO CAPI OGGETTO DI FURTO/SMARRIMENTO Stolen/lost	- di cui oggetto di FURTO Stolen	- di cui oggetto di FURTO/SMARRIMENTO Stolen/lost	- di cui oggetto di SMARRIMENTO Lost
	PIEMONTE	175	382	207	1	174
	VALLE D'AOSTA	33	42	3	38	1
	LOMBARDIA	158	605	230	0	375
	TRENTINO PROVINCIA TRENTO	9	9	0	1	8
	VENETO	65	178	178	0	0
	FRIULI	21	45	20	8	17
	LIGURIA	78	175	74	3	98
	EMILIA ROMAGNA	177	475	180	31	264
	TOSCANA	171	505	249	10	246
	UMBRIA	152	336	147	12	177
	MARCHE	79	206	3	29	174
	LAZIO	824	2972	801	78	2093
	ABRUZZO	216	1001	584	0	417

MOLISE	127	304	206	0	98
CAMPANIA	702	1784	485	63	1236
PUGLIA	622	2265	784	46	1435
BASILICATA	282	893	17	2	874
CALABRIA	1376	3789	1736	348	1705
SICILIA	2965	9442	2603	264	6575
SARDEGNA	676	4273	868	142	3263
TOTALE ITALIA	8908	29681	9375	1076	19230

Day to day operations of vulture feeding stations

Our practical experience in the field, coming from many years of observations and management of vulture feeding stations, suggests that currently there is no individual veterinary control over every single animal coming in to the vulture feeding stations. Crucially, veterinary control and monitoring, and decisions on what to send to the vulture feeding stations, are separate in time and done by different people, so the risk that a treated animal with veterinary diclofenac reaches the vulture feeding chain is real and exists.

While all industrial exploitations sending carcasses to vulture feeding stations need to be registered and are controlled by veterinarians, the day to day decisions to send animals or parts of animals to the local vulture feeding station is often done by farmhands and/or slaughterhouses. Theoretically, there are ways to prevent this (strict isolation of all animals treated with veterinary diclofenac), but this would certainly entail significant costs for the livestock farmer, that may be unrealistic (see below).

Below you can find a simple description of three typical vulture feeding stations, illustrating the scale of the issue

Case study 1

Feeding station in NE Italy run by local NGO. Feeding station used by 200+ griffon vultures, some black vultures that have started to summer in the Alps, and more irregularly by Egyptian vultures.

On table 2 below you can see the total apportions of meat to that feeding stations last year. Pigs is from intensive pork farms, bovine

mostly from intensive cattle farms, but includes some rests from slaughterhouses.

2013	Roe Deer		Red Deer		Wild Boar		Pigs		Bovine	Other
	Kg	N°	Kg	N°	Kg	N°	Kg	N°	Kg	Kg
January	230	11	670	9	200	2	1470	21	250	20
February	620	30	1020	15	500	6	720	10		
March	660	37	1590	22	120	2	940	12		60
April	1690	89	2490	45	150	3	870	12		20
May	580	35	180	2	110	2	3660	55		
June	95	7	270	4	40	4	5370	86		
July	530	41	340	5	210	4	3682	43	245	5
August	295	22	280	2	175	5	3350	53		15
September	260	16	50	1	30	1	3520	58	760	15
October	270	18	550	5	250	4	1790	42	700	
November	290	17	460	5	530	8	1600	21		
December	1095	49	770	8	530	13	480	10		
TOT	6.615	372	8.670	123	2.845	54	27.452	423	1.955	135

In Italy, all farmers must have a REGISTER where they have to write all the medicines used. In theory all dead animals treated with veterinary drugs must be destroyed after death. While carcasses of Category 1 animals (potentially subject to Bovine Spongiformis Encephalopathy) must be checked by a veterinarian first and only then destroyed, animals of category 2 (pigs, horses), that have died and were being treated, can be destroyed from the farmer but there is no direct veterinary control.

Stakeholder no.	Comments
	So in this case, if any of those pigs from industrial explorations that usually supply the feeding station had been treated with diclofenac, and died, the only way to prevent it from entering the vulture food chain would be for the farmer to identify treated animals, isolate them and destroy the carcasses without giving them to the feeding station. **Case study 2** Feeding station in Southwest Spain run by a regional government. Feeding station used by hundreds, sometimes 1000 griffon vultures that breed nearby, some black vultures in dispersion-winter, and a few of the reintroduced nearby bearded vultures. Data for 2013 – average of 1,600 kg of meat and animal by-products deposited every month, mostly pigs from intensive farms. All carcasses and animal by-products deposited come from slaughterhouses, and are thus animals that in principle are suitable for human consumption. However, there is no routine diclofenac analysis being done in Spain, so levels of diclofenac on those carcasses unknown. Decision on what goes to the vulture feeding station is often taken by slaughterhouse staff. **Case study 3** Feeding station in the Pyrenees run by conservation foundation. Feeding station used by 250-300 griffon vultures that breed nearby, 10 Egyptian vultures, 20-25 red kites, 30 black kites and 2 pairs of bearded vultures. Data for 2013 – A total 104 depositions (approximately 2 every week) were made, totalling 15,600 kg, all parts of sheep, goats and cows (including viscera), from the local slaughterhouse. The animals there are subject to the normal veterinarian control for human consumption, but again diclofenac is not specifically tested for. Viscera and other animal parts are usually gathered in common pile and then given to the foundation staff that take it to the vulture feeding station. **Day to day operations of extensive systems** The recent report prepared by Spanish government agencies to evaluate the risk of veterinary diclofenac to vultures in Spain suggests that “in extensive systems it is expected that this type of veterinary agents usage is almost zero, because livestock suffers less from this type of diseases, and has much less management”. With an absence of detailed data on usage of veterinary diclofenac in Spain, it is impossible to assume that free ranging cattle are not treated with veterinary diclofenac in Spain – on the contrary, the precaution principle would recommend we do consider it may be used. In this case, and unless treated animals are permanently confined, it is virtually impossible to guarantee that a treated animal may not be available to vultures if it dies in the fields. Griffons usually eat 90% of dead carcasses, and they reach normally less than 1 hour after death, often well before the farmer.

Stakeholder no.	Comments
	Our experience from the field suggests that often shepherds and farm hands administer anti-inflammatory medicines ad-hoc when they detect some of the ailments. Please note that in many extensive systems animals are still stabled during some periods (night/season). **Risk-assessments done** The general risk assessment for veterinary diclofenac in Spain were done by the Agencia Española de Medicamentos y Productos Sanitarios (AEMPS), that has concluded that "the risk-benefit profile for the target species is favourable, and that the quality and biosecurity of the drug for humans and the environment is acceptable". No mention of their well-known impact on vultures (See Green et al. 2004; Green et al. 2006; Prakash et al. 2012 for well documented and dramatic impact on Indian vultures) is ever made in the risk assessments. On the contrary, on page 4 of the risk assessments, it is written that "the drug is safe for the people administering it, for the consumers of animal products from treated animals, and for the environment, when recommendations are used". In relation to ecotoxicity, the manufacturer has only presented a phase I report, which dismissed the need for a phase II report, according to directive CVMP/VICH/592/98 (see here). The authority responsible for its control in Spain (AEMPS) has not carried any pharmacological, toxicological or residues studies for the drug's impact on scavenging species. This is so because, according to Spanish legislation (article 7 of the Real Decreto 1246/2008 of 18 July), this is not necessary when the drug is for a bioequivalent of a generic medicine with reference values established. There is, for the case of the Spanish products, a simple statement in its technical dossier stating "do not administer to animals susceptible to enter wild animals food chain". Given the known effects of diclofenac on vultures and the major depletion of their population caused by this drug in Asia, the eco-toxicity of this and other NSAIDs should always be strictly evaluated. **Potential Measures to mitigate risks from veterinary diclofenac** First, it must be noted that there are currently no measures in place to test the presence of diclofenac in tissues of dead animals. Neither the Spanish drug-alert system (VIGIAVET) nor its European equivalent (EudraVigilance Veterinary) have ever registered an alert for intoxication of vultures by this drug. There is therefore no system in place to routinely detect veterinary diclofenac in tissues of animal by-products. Further, testing for diclofenac is very expensive, and can be done only in handful of laboratories – none in Spain. Given all the above, and in order to minimize the risks from veterinary diclofenac to vultures, this would require a complex set of additional controls and practices that are not only extremely expensive, but counterproductive, complex and not necessary – given that

Stakeholder no.	Comments
	there is an alternative readily available, equally cheap, and with the same therapeutic properties (Meloxicam, Swan et al 2006). In order to minimise risk to vultures if veterinary diclofenac is allowed to continue to be marketed across Europe one would need, as an absolute minimum, to - Establish a system to routinely test tissues of animals for this drug, within the EudraVigilance Veterinary programme framework. Analysis for veterinary diclofenac are expensive. - Establish additional control mechanisms in all livestock explorations. This would need to secure that all extensive livestock treated with diclofenac should be isolated and kept indoors for at least 7 days (and not 2 as the MAGRAMA report suggests – see below) after treatment; and that in the intensive operations cattle and pork treated with veterinary diclofenac should also be separated from the rest, controlled regularly by a veterinarian, and not sent to the vulture feeding stations in case of mortality - In case any of the diclofenac treated animal dies, the carcass should be collected by a specialized company and destroyed, so as not to enter the vulture food chain, with all the corresponding costs. These are also the measures identified in the Spanish government report published recently (page 7). These measures entail considerable costs, regulation and red tape. Given the proven and dramatic impact on vultures (see also below), the status of vultures in Europe, the considerable investment done so far for their protection, and the existence of a generic, similar and readily available alternative, our opinion is that these potential measures that would need to be set up and enforced to minimise risk are too costly, complicated and unnecessary. It should also be taken into account that in most counties in southern Europe, including Spain and in Italy, the current austerity policies have resulted in severe budgetary cuts that have significantly reduced the capacity of the regional governments, public veterinary agencies, and enforcement agents to monitor and enforce legislation and regulations across the country. Further, there are lots of examples suggesting that even the most strict veterinary controls are not 100% failsafe because somewhere, sometime, someone will fail the rules. The recent spread of African Swine in Latvia has been linked to the illegal disposal of offal in the forest from an authorized slaughterhouse, even though a strict system was in place to prevent this situation happening (Vittorio Guberti, pers. comm.). We thus need to choose between implementing more measures and regulations that are expensive, complicated, and add up to the red tape, and that are not 100% effective 100% of the time, to try to minimise proven risks to vultures, or to simply ban the drug, when an alternative that is equally cheap, readily available and with the same therapeutic properties exist (Meloxicam – see Swarup et al. 2007).

Stakeholder no.	Comments
	Precedent and possibility of expansion to other markets Finally, one aspect often overlooked but very important. The EU is often regarded as the leader in civilization-setting procedures and principles, that often have a significant influence and impact elsewhere in the world as principles, laws and regulations are considered best practice and examples to follow. Legalising the use veterinary diclofenac would send the signal to others that it is ok to use it – also probably creating an export market from Europe to other regions. We all know that control systems and procedures elsewhere are substantially weaker than in Europe, so even if billions of Euros were spent in setting up the new mechanisms described above in the EU, these would not certainly be followed through in other places, where veterinary diclofenac could continue to kill/start to kill vultures. Availability of diclofenac in Europe would mean worldwide availability, with significant impacts on vultures everywhere.
3	EAZA members are responsible for much of the captive breeding of vultures in Europe, and provide animals for release on a regular basis. EAZA recognizes that mitigating the risk of ingestion of diclofenac by necrophagous birds is next to impossible outside feeding stations, as the birds will feed opportunistically on dead livestock, often before farmers are aware that their animal is dead. Bearing in mind the terrain in which European vulture populations reside, it would be practically impossible for farmers to locate and dispose of dead livestock prior to those animals being located by necrophagous birds and diclofenac residues being ingested. EAZA recognises also that there is no way for feeding stations to know – even with vastly improved labelling and records of prescription – whether the animal products being provided to them contain diclofenac without testing every donation, which would be prohibitive in terms of both human and financial resources; these facilities represent a huge resource in the recovery of vulture populations and a significant investment by donors including the European Union LIFE funds. Separation of animal products that contain diclofenac from those which do not prior to donation to feeding stations would also prove a significant burden to livestock farmers. An alternative veterinary anti-inflammatory solution (Meloxicam) exists which is not toxic to necrophagous birds, not subject to patent, and which would provide a simple and cost effective solution to the issues outlined above. EAZA further notes that a major aim of vulture European Endangered Species programmes at our member institutions is to provide animals for re-introduction. Vultures are some of the only European native species where reintroduction is feasible at this time; however, the investment of resources necessary for this aim to be fulfilled would be essentially rendered meaningless in areas where diclofenac is widely used. Fulfilment of Aichi targets for the protection of biodiversity and vulnerable species – an agreement binding on all EU member states – falls largely on our members and in situ conservationists, and vulture protection is an important part of this work. Licencing of diclofenac for veterinary care therefore essentially prevents the governments of countries that do so from fulfilling their obligations to the

Stakeholder no.	Comments
	Aichi targets with regard to vulture species.
4	BIAZA strongly believes that the mitigation of the risk of diclofenac ingestion by necrophagous birds both inside and outside the feeding stations is unachievable. Necrophagous birds are opportunistic and will often feed on dead stock before the farmer has recognised the death of the stock animal. There are many situations across Europe, particularly in moorland or mountainous areas where it is unfeasible to ask the farmers to locate and remove dead stock before necrophagous birds have fed, resulting in the ingestion of diclofenac residues. The level of ingestion necessary to have an extreme impact on the health of the necrophagous birds, particularly in the case of vultures, is so small that even short term exposure to carcasses containing diclofenac residue can have significant impacts. Within the provision of feeding stations, it is unfeasible to expect a detailed enough knowledge of the carcasses provided to ensure there is no risk of diclofenac poisoning. It is not feasible in terms of time and costs to test each carcass donation for the presence of diclofenac, and the separation of diclofenac treated stock would place an undue burden on the farmers providing that fallen stock. The feeding stations represent an invaluable resource in the protection of these threatened European species and have been the recipient of European Union LIFE funds. Although much of the work around diclofenac has centred on vulture species, recent evidence has demonstrated its potency in other necrophagous species. We don't yet know the extent of necrophagous bird species that can be impacted on by diclofenac residues in fallen stock. Many members of BIAZA work closely with the European Association of Zoos and Aquaria to achieve the captive breeding of populations of necrophagous birds, in particular threatened European vulture populations. These breeding programmes will often be the source of birds for release to boost the surviving populations. Staff from BIAZA zoos also participate with the IUCN vulture species survival group. Much of the work undertaken here contributes significantly to the achievement of the goals of the Aichi targets for the protection of biodiversity and vulnerable species – an agreement binding on all EU member states. Licensing of diclofenac for veterinary care can be seen to prevent the government of countries that do so from fulfilling their obligations to the Aichi targets. Where there is a veterinary anti-inflammatory solution (Meloxicam) which is not toxic to threatened bird species, not subject to patent and gives a simple cost effective alternative, this would seem like the optimum mitigation to the risks of diclofenac.
5	**Introduction** BirdLife International is the official IUCN Red List Authority for birds. It is also one of the most experienced organisations in the field of

Stakeholder no.	Comments
	diclofenac contamination and its effects to wild fauna. We draw on our ten years of experience dealing with diclofenac contamination of domesticated ungulate carcasses in South Asia to comment on this and the following two topics. Our comments focus largely on how diclofenac can impact on Spanish vultures. We do this because we are familiar with diclofenac use, livestock disposal and vulture feeding in Spain. Spain also holds the vast majority of vultures in Europe (>95%), including the Eurasian Griffon (Gyps fulvus), which we know is intolerant to diclofenac (Swan et al., 2006a); and the Spanish Imperial Eagle (Aquila adalberti), which is Endangered and we suspect is intolerant to diclofenac (SHARMA et al., n.d.). There are three types of site where European vultures can consume diclofenac-contaminated tissue from domesticated ungulate carcasses: 1) vulture feeding stations (i.e., vulture restaurants: sites designed for vulture benefit); 2) carcass disposal sites (i.e., Spanish muladares: sites designed for both vulture and human benefit); and 3) fallen livestock in the field. EMA's Public Consultation outcomes will have an immediate and direct impact on all European vulture populations. We believe that, before addressing your 3 main Topics, a brief analysis of the vulture conservation status in Europe is needed: • Out of the 16 species of old-world vultures, 4 occur regularly and breed in Europe: the globally Endangered Egyptian vulture (Neophron percnopterus), the globally Near-Threatened Cinereous vulture (Aegypius monachus) and Bearded vulture (Gypaetus barbatus) and the globally Least Concern Griffon vulture (Gyps fulvus). We already know that Gyps fulvus is intolerant to diclofenac. • Europe holds the healthiest vulture populations in the old world, as the vulture populations in South Asia have collapsed totally due to diclofenac use, while Africa is now facing an unprecedented and large-scale vulture decline due to widespread poisoning (Botha et al., 2012). In Europe, three of the four species (except Egyptian vulture) have been increasing steadily, partly due to the intensive conservation effort funded by European Union budget lines – since 1996, the European Union and national governments have invested significant financial resources for the conservation of vultures, and there have been at least 67 LIFE projects related to these species – only between 2008 and 2012, nine vulture conservation projects alone received 10.7 million Euro (see here). • Beyond their historical breeding grounds, and because of the local extinctions that happened during the past century, the European Union has funded vulture reintroduction projects in many European areas. The reintroduction of the Bearded vulture in the Alps (with 30 pairs now breeding in the wild) and in Andalusia (Spain) and the various reintroduction programmes of the Griffon vulture in France, Italy and Bulgaria, totalling hundreds of millions of Euros, give an idea about the size and importance of such biodiversity investment in Europe • Spain, Portugal, France and Italy hold the bulk of the European Union vulture populations (BirdLife International, 2004)

Stakeholder no.	Comments
	Vulture populations in Spain and Italy: Veterinary diclofenac has been made commercially available in two key vulture countries. Spain: More than 70,000 Griffon vultures (90% of the European population), 5,000 Cinereous vultures (97% of the European population), 3,000 Egyptian vultures (85% of the European population) and 300 Bearded vultures (67% of the European population). Spain is the most important country on the continent for these species – and for some of them (e.g. Griffon and Cinereous vultures) the most important country in the world. It is also the key country to secure a sustainable recovery of vulture populations across Europe, which the healthy populations in Spain have been supporting, both through normal dispersion, and through human-induced reintroduction and restocking projects with Spanish-origin birds. Italy: Italy has a small and decreasing population of Egyptian vultures in the south (8 pairs in 2012). The estimated breeding population of Griffon vultures is about 90 breeding pairs, but the total population in summer, when immature birds arrive from either France or Spain, boosts the population up to 300-400 individuals. There is also a small but stable Bearded vulture population (20 individuals). The most important areas for vultures in Italy are Sardinia and the Abruzzo region. Italy plays also a fundamental role in the migration routes followed by other vulture populations in Western Europe on their way to the Eastern/Balkan regions. **Vulture population feeding and legislative framework** The availability of food for scavengers in Western Europe during recent decades permitted the existence and growth of huge vulture populations. This is the result of both legal protection and high food availability. During the second half of the 20th century, food availability was well above that required to maintain the scavenger populations, leading to a spectacular increase in population size, especially that of the Griffon vulture. This situation was exacerbated by a failure to comply with sanitation laws introduced in the 1950s, which forbade the abandonment of carcasses in the field (Donázar et al., 2010) In 1999, bovine spongiform encephalopathy (BSEs) brought about strict EU legislation (CE 1774/2002) aimed at the elimination of animal by-products. As a consequence, state and regional administrations enforced measures requiring farmers to remove or destroy the remains of dead livestock. In 2006 / 2007, these feeding stations were closed as part of BSE control measures (Donázar et al., 2010). Food scarcity after the BSE crisis triggered a change in the foraging behaviour of vultures. Faced with a reduced supply of carcasses, many individuals moved to exploit garbage dumps, a lower-quality food source, not exploited previously. The closure of these feeding stations, in combination with other human-related threats, such as poisoning and wind-farms, caused a decline in the number of breeding pairs by c. 24%, adult survival by 30% and fecundity by 35% (data for Gyps fulvus), as well as an increase in the number of birds

Stakeholder no.	Comments
	entering rehabilitation centres (Martínez-Abraín et al., 2011). The relevance of vultures for safe, cheap and natural disposal of livestock carcasses has been recognized in the most recent EU Animal by-products regulation (CE 142/2011) , implementing Regulation (EC) No 1069/2009, which includes specific authorizations for managing “carrion-dumps” and leaving carcasses in nature, in areas frequented by vultures. This regulation, adopted in Spain since 2011 (Real Decreto 1632/2011, de 14 de noviembre) with a number of provisions, includes: • The definition of Protection Areas for birds of prey and/or feeding scavenger species of Community interest. In these areas, where scavenger birds are already present, free-ranging animals don't need to be recovered when dead and therefore might be available for vultures (except if they die of infectious diseases). According to data provided by SEO/BirdLife, 15 Spanish autonomous communities have approved such areas while 2 haven’t. These areas cover most or all the surface in some regions • The establishment of carrion-dump sites (muladares) for birds of prey and/or feeding scavengers where intensive indoor or free-ranging farmed animals can be disposed of, with certain conditions: if they die because of disease, specified risk materials (SRM) should be removed, and for certain death causes, the whole animal should be incinerated. The dump-sites are locked enclosures and the items disposed should also be controlled. SEO/BirdLife data confirms that 11 autonomous communities have established these muladares, totalling 199 “official” sites in Spain. **BirdLife International experience from Asia and comparison with the European scenario** In Nepal, we manage vulture feeding stations. Old, ailing and unwanted cattle are donated to the site by local communities and cared for until their natural death by our staff. Only cattle that die after 10 days in our care are provided to vultures. In this way we can ensure that any diclofenac that these cattle may have been treated with previously has been fully metabolised (see our response to Topic 2). vulture feeding stations in Spain, France and other European countries largely obtain abattoir by-products (mostly viscera). Diclofenac is more slowly depleted from viscera and withdrawal periods are only designed to protect human health (see our response to Topic 2). Any given quantity of by-product obtained by feeding stations is likely to come from multiple individual animals and often-different species. Therefore, European wildlife managers presently rely on livestock owners not using diclofenac 10 days prior to slaughter. In Spain, withdrawal periods for cattle and pigs are both greater than 10 days, but no withdrawal period exists for horses because they are not slaughtered for human consumption. Yet, horses are often slaughtered and processed at the same abattoirs as cattle. Our data from South Asia shows a very high proportion of horses (33.3%), higher than for cattle, are treated with diclofenac before death (Taggart et al., 2007). This is possibly a welfare measure that is likely to be similar in Europe. Thus, the by-products of a horse treated with

Stakeholder no.	Comments
	diclofenac prior to slaughter can be supplied to a vulture feeding station in an indistinguishable and contaminated mix. In India, we survey carcass disposal sites to determine diclofenac prevalence in vulture food. Despite the ban on veterinary diclofenac in 2006, we still find diclofenac-contaminated carcasses. This is because Indian pharmaceutical companies are circumventing the ban by producing human diclofenac in the vial size adequate for treating cattle and distributing these to veterinary pharmacies. However, it is veterinarians and livestock owners that are purchasing and administering diclofenac in South Asia. We are currently advocating a ban on all diclofenac in vials larger than 3 ml (adequate for human treatment), which is expected to occur in India later this year. We do not think pharmaceutical companies, pharmacists and veterinarians will circumvent laws in Europe as they have in South Asia; but this scenario highlights the sometimes irresponsible attitude of veterinarians and livestock owners to environmental issues. This bears on the large network of managed carcass disposal sites in Spain, which were re-established to prevent vulture declines as a result of a lack of food. These muladares also provide livestock owners, who are responsible for these sites, an easy and inexpensive means of carcass disposal. Our colleagues in Spain have received reports of poorly or badly managed muladares. In the worse cases, chemicals, including vials of veterinary medicine, are discarded among carcasses. While it is therefore likely that vultures can be exposed to diclofenac by consuming tissue doused in discarded diclofenac, we are more concerned that these same irresponsible livestock owners will dispose of carcasses contaminated with diclofenac at sites where vultures have access. **Patterns of vulture foraging and feeding in nature** Vultures have evolved to be nature's most efficient undertakers. Vultures can see for vast distances while soaring. In addition, they monitor their soaring neighbours' behaviour and, in this way, vultures work together to scan vast areas of countryside for fallen livestock. Further, vultures are adapted to quickly and effectively consume a carcass. We have seen first-hand, in South Asia, 20 vultures consume a cattle carcass in less than 1 hour. Given the tendency for animals to die at night and the many responsibilities of livestock owners, a wake of vultures could locate and consume a contaminated carcass before many livestock owners could organise its retrieval. Further, in mountainous areas of Spain, livestock owners are exempt from retrieving carcasses. In these cases, livestock could be treated with diclofenac during round-ups. It is generally considered that domestic livestock constitute more than half of the biomass eaten by vultures in Europe. Scientific data confirm that vultures, and Griffon vultures in particular, can identify a dead animal much quicker than any other necrophagous species. An average of 31 minutes has been established for Griffon vultures, reinforcing the idea that vultures will be ready to feed on recently dead animals (Cortés-Avizanda et al., 2012; Duriez et al., 2012). All livestock are rounded up once or more during their lives, and diclofenac may be used to treat ailments at these times. If these

Stakeholder no.	Comments
	animals are released and then die within 10 days of treatment, they could in turn kill vultures. In fact, the stress and physical nature of a round-up itself may increase the likelihood that an animal might die. As explained before, vultures feed mostly on: a) Carcasses and other animal products made available to them in registered and custom-built vulture feeding stations b) carcasses of dead animals found in the field in a more natural foraging and feeding pattern (with more unpredictability, both temporal and spatial). Feeding patterns are extremely variable and cannot be characterised – in some regions with lots of feeding stations, some vultures feed almost exclusively at feeding stations, while in other places with no or few feeding stations they feed mostly on carcasses in the field. Further, some vultures feed at feeding stations in some parts of the year and may migrate to areas with no feeding stations in another season, making the overall situation rather fluid and variable. In Spain alone, there are approximately 200 authorized feeding stations, and these vary greatly in size and management. Some of the "muladares" are managed by the local authority, city council, county council or even by conservation NGOs. There are also cases of legal muladares run by birdwatching companies or individuals that will receive donations of dead animals or meat by-products and will leave them in a specific semi-controlled area. Only considering the 10 autonomous communities that provided data, these muladares receive about 2.700 tonnes of carrion per year. As to which parts will be left out for vultures to feed, there is a great variability, from whole animals to bones, organs or muscle tissues. In Spain, the Ministry of Agriculture and Environment (MAGRAMA) keeps a register of all carcasses (and in some cases parts of carcasses) transferred to vulture feeding stations. Data provided indicates that, approximately, 345 and 38,500 carcasses of indoor raised cattle and pig, respectively, could be left out in muladares per year. This constitutes a very important food-resource for the wild vulture populations. Further, there is solid scientific evidence suggesting that almost all of the carcasses that are left out in the fields and are not collected, following the new sanitary regulations, are consumed by vultures - Cortés-Avizanda et al. 2012 has suggested that 89% of observed carcasses attracted vultures to feed. Beyond those carcasses left at specifically opened muladares, data from MAGRAMA suggest there will be another 27,000 carcasses left out yearly in the open fields and therefore accessible for vulture consumption in the scavengers' protection areas. Thus, summing all muladares and "open field" available carcasses, there would be, on average, 66,000 dead animals available for vultures per year. There is no such data available for Italy, but LIPU (BirdLife Partner in Italy) informs that a few thousands of carcasses are also left out for

Stakeholder no.	Comments
	vultures to feed in Sardinia and the Abruzzo region. **Potential measures to mitigate risks from veterinary diclofenac** Despite the measures put in place by regulation CE 142/2011, there are currently no measures in place to test for the presence of diclofenac in tissues of dead animals. Neither the Spanish drug-alert system (VIGIAVET) not its European equivalent (EudraVigilance Veterinary) have ever registered an alert for necrophagous-birds intoxication by this drug. There is therefore no system in place to routinely detect veterinary diclofenac in tissues of animal by-products. Further, testing for diclofenac is very expensive, and can be done only in handful of laboratories – none of which is in Spain. BirdLife International has been unable to get a solid estimate of the current usage of veterinary diclofenac in either Spain or Italy. This is of critical importance, given the large numbers of carcasses referred in the previous paragraphs. Local access to the drug, despite being limited to veterinarians, seems to be far easier and uncontrolled than it should (data from SEO/BirdLife), and neither the governments nor us can present accurate data for this report. The Spanish Government recently released a risk-assessment report for veterinary diclofenac in Spain (MAGRAMA, 2014) where three scenarios are given. In this report they estimate that only 1-2% of all the carcasses available to vultures may have been treated with diclofenac. BirdLife International cannot agree with such a conservative estimate, because of the absolute lack of field-data and detailed information about diclofenac availability around vulture strongholds. **Day to day operations for animals left out in the field (either open field or muladares)** Data from our partners in Spain and Italy confirm that the control measures in place are weak and rarely followed for the vast majority of the animals left in the open. A better enforcement does occur in muladares, given their more regulated functioning and intrinsic value both as research stations or bird watching spots. The chances that a diclofenac-treated carcass is left out in the open are high and could already be happening. It should be taken into account that in most Spanish regions, budgetary cuts have been very serious on environmental issues, and that surveys and monitoring by environmental law enforcement officers, in particular forest and rural rangers, have been restricted, and available budgets for such testing have decreased dramatically over the past decade. It is therefore impossible to assume that free ranging cattle are not treated with veterinary diclofenac in Spain – on the contrary, the precautionary principle would recommend we do consider it may be used. In this case, and unless treated animals are permanently confined, it is virtually impossible to guarantee that a treated animal may not be available to vultures if it dies in the fields. Griffon

Stakeholder no.	Comments
	vultures usually eat 90% of dead carcasses, which they normally reach less than 1 hour after death, often well before the farmer. **Day to day operations of intensive farming** As for the case of penned animals, such as pig farms, veterinarians do not supervise directly the disposal of dead animals. On most occasions, veterinarians will only visit the farm when called by stockbreeder and will not be present if a diclofenac-treated animal dies. To believe those cattle-owners, on top of their daily responsibilities, will ensure adequate separation and disposal of these animals is, to say the least, a very risky judgement to be made. Addressing the risks posed by the mere commercial availability of veterinary diclofenac in Spain and Italy would require a complex set of additional controls and practices that are not only extremely expensive, but complex and even counterproductive– given that there is an alternative readily available (meloxicam), equally cheap, and with the same therapeutic properties. Some of the steps that would need to be incorporated would include: • Establish a system to routinely test tissues of animals for this drug, within the EudraVigilance Veterinary programme framework • Establish additional control mechanisms in all livestock explorations. This would need to secure that all extensive livestock treated with diclofenac should be isolated and kept indoors for at least 7 days (and not 2 as the MAGRAMA report suggests) after treatment: and that in the intensive operations cattle and pigs treated with veterinary diclofenac should also be separated from the rest, checked regularly by a veterinarian, and not sent to the vulture feeding stations in case of mortality • In case any of the diclofenac treated animals die, the carcass should be collected by a specialized company and destroyed, so as not to enter the vulture food chain These measures entail considerable costs, regulation and red tape. Given the proven effects on vultures, the status of the birds, the considerable investment made, our opinion is that the alternatives are too costly, complicated and unnecessary, when there is an alternative readily available. **Risk assessment carried out to date** In Spain veterinary diclofenac is marketed under two brand names, Diclovet and Dolofenac, (registered by FATRO Iberica SL). In Italy, Italy, veterinary diclofenac is commercialised under the name Reuflogi (registered by FATRO S.p.A.). As per the three drugs risk assessment, general conclusion is that “the risk-benefit profile for the target species is favourable, and that the quality and biosecurity of the drug for humans and the environment is acceptable”. No mention of their well-known impact on

Stakeholder no.	Comments
	vultures is made. On the contrary, on page 4 of the risk assessments for Diclovet, it is written “the drug is safe for the people administering it, for the consumers of animal products from treated animals, and for the environment, when recommendations are used”. In relation to Eco-toxicity, the manufacturer has only presented a phase I report, which dismissed the need for a phase II report, according to Directive CVMP/VICH/592/98. The authority responsible for its control in Spain (Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) has not carried any pharmacological, toxicological or residues studies for the drug’s impact on necrophagous species. This is because, according to Spanish legislation (article 7 of the Real Decreto 1246/2008 of 18 July), this is not necessary when the drug is for a bioequivalent of a generic medicine with reference values established. There is, for the case of the Spanish products, a simple statement in its technical dossier stating, “ Do not administer to animals susceptible to enter wild animals food chain”. Having in mind that recommendations of medicines are not always respected, even for human consumption, we are convinced that a significant amount of corpses will be disposed of, disregarding this statement. BirdLife International believes that given the known effects of diclofenac on vultures and the major depletion of their population caused by this drug in Asia, this and other NSAIDs should always be evaluated against secondary poisoning by scavenger birds. Yet, monitoring and tracing all the animals that could have been treated, or exposed to this drug, would require additional resources, both to public administrations responsible for the monitoring, and cattle-owners. This, according to data provided by BirdLife partners in Spain and Italy, would be prohibitively expensive. It would also be an illogical measure, considering that vulture-safe alternatives exist (Meloxicam). **Vultures are already being poisoned by NSAIDs in Europe** We know that Spanish vultures are exposed to NSAIDs, because we have found flunixin in the tissue of a dead Griffon vulture from southern Spain with severe visceral gout (paper in press to appear soon in Biological Conservation). We are confident that flunixin poisoning caused renal failure and death in this vulture. How this wild bird consumed flunixin is unknown but it had to be via one of ways described in this report. At least in Spain, diclofenac and flunixin are recommended for treatment of the same livestock species and for similar ailments (actually, diclofenac is recommended for more types of ailments than flunixin). Further, both drugs have similar withdrawal periods. Therefore, the flunixin case provides indisputable evidence that Spanish vultures are exposed to diclofenac. It is very important to remember that only a small number of carcasses contaminated with diclofenac are needed to cause serious declines in vultures. Modelling our data from India and Pakistan indicate as few as 1 in 760 domesticated ungulate carcasses

Stakeholder no.	Comments
	contaminated with lethal levels of diclofenac caused declines in the Oriental White-backed vulture (Gyps bengalensis) of about 50% per year (GREEN et al., 2004). There is no reason to think that the closely related European Griffon vulture would differ greatly in response, given it too is intolerant to low concentrations of diclofenac (Swan et al., 2006b). From our observations and calculations, we can say with high confidence that even if only 1 in every 2000 carcasses available to Europe's vultures were contaminated with lethal levels of diclofenac, their populations could be halved in six years (Margalida et al. 2014 submitted).
6	We wish to advise that we broadly support the comments submitted by BirdLife International, which we have had sight of. However, we would like to stress the importance of NSAIDs in general, and their therapeutic indication, which impact on the welfare of animals. In principle, a wide choice of active products is desirable for veterinary surgeons to choose the most appropriate treatment for the specific case, but all veterinary products, including NSAIDs must be safe for target species and for wildlife. Their conditions of use should also take special risks for endangered species into account. This has long been applied in the environmental assessments on molecules such as *ivermectin*, where environmental risk mitigation measures are applied across Europe, and also specific measures are applied in some special areas, such as National Trust land in the UK, where rare species such as the Chough or the Horseshoe bat are found. We are seriously concerned about the impact that the use of diclofenac could have on the European vulture population, concentrated in Italy and Spain, and have previously called for the EMA to undertake an in-depth Environmental Risk Assessment. The role of the legal use of veterinary diclofenac in the decline of vultures in India is well recognised, where numbers fell by 99% in the early 2000's, leading to the Indian government to ban veterinary diclofenac as an anti-inflammatory treatment for livestock in 2006. Although we understand that veterinary regulations are relatively strict in Europe when applied to safety of licensed medicines to the target species, the user/consumer and the environment, the evidence is clear that even a very small proportion of contaminated carcasses exposed through the environment would have a very serious impact on vulture populations because of the high toxicity of diclofenac in these birds. We recognise that EU regulations prohibit the illegal disposal of carcasses. However, disposing of carcasses at feeding stations is a permitted and recognised means of disposal in Spain and therefore provides a serious risk of exposure to diclofenac residues for these birds in animals treated with the product. There is also a risk that some European zoos may take fallen stock to feed their captive raptors, vultures or cats etc., which could contain diclofenac. Even in the UK, there remains some confusion as to the adequacy of the environmental risk assessment in this particular context. In a recent response to a question from Professor the Lord Trees in the House of Lords on this issue, the DEFRA minister Lord de Mauley

Stakeholder no.	Comments
	stated that the environmental risk assessment (ERA) looks first at the exposure to assess the hazard and whether it becomes a risk, but then went on to say that there is no exposure in the case of diclofenac. Clearly there is which is why birds have died in such worrying numbers outside the UK. Recent work with Steppe eagles suggests there is a risk, not just to European endangered vulture populations, but also to other scavenging raptors. The environmental risk assessment for NSAIDs for livestock must address the risk to vultures and similar cases, and recommend suitable risk mitigation measures, including warnings and restrictions on use where appropriate. There is a precedent on the SPC for barbiturate euthanasia products, which specifically warns against feeding euthanased carcases to other animals. The final risk-benefit analysis must balance the risk to endangered wild fauna against animal welfare for livestock, in a scientific and reasonable way, based on evidence. It should be noted that alternative veterinary medicines, for example meloxicam, as generic and affordable preparations, are available for use in livestock which are safe for vultures and have replaced diclofenac in India. (Although we recognise that meloxicam is a poor analgesic in horses). Though the finding of flunixin in a Griffon vulture carcase (as highlighted in the BirdLife International response) cannot provide evidence of exposure to diclofenac, it does demonstrate that veterinary NSAIDs can be found in wildlife. The assumption must be that diclofenac could follow a similar route, despite instruction and user guidance. It may also be prudent to monitor raptor carcases to determine the impact of flunixin.
7	The National Centre for Toxicological Information Veterinarians (CNITV) is an animal poison control centre. In contrast with environmental and vulture protection associations, we have no legitimacy to comment this topic. See topic 3 for specific scientific argumentation.
8	Lots of cases from the third world shows that uncontrolled disposal of animal carcasses in dumps with access for scavenging birds like vultures will course poisoning by diclofenac to these birds and they will die.
9	We are very grateful that EMA is taking this issue serious as this has been a point of concern for the veterinary profession since recently diclofenac came on the market in Italy and Spain. The main possible route for vultures to come in contact with meat or animals containing residues of diclofenac seems to be: 1. via the vulture feeding stations (can be animals who lived outside or indoors);

Stakeholder no.	Comments
	2. via eating animals who are treated by diclofenac and live outdoors (e.g. horses, sheep and goats, cattle in the mountains, etc.). A third scenario, however unlikely, is for vultures to come into contact with diclofenac used in human medicines (the much sold 'Voltaren or Voltarol'). FVE also received anecdotal evidence from several state veterinary officers who told us that occasionally they receive reports saying that vultures attacked weak animals, such as newly born foals or calves and sometimes even the mothers who just gave birth. Spain and Italy both have rules in place to control disposal of carcasses and to control the feeding stations, however control is difficult as: 1. detection methods for residues of diclofenac are very expensive and can only be done by a very limited number of diagnostic laboratories; 2. diclofenac is very effective in killing birds. Only very small amounts are necessary; 3. especially if livestock die in open fields, the carcass is likely to be eaten before the farmer notices it. Some studies also show that diclofenac is not only toxic for vultures but also for eagles (Sharma et al, Diclofenac is toxic to the Steppe Eagle). This suggests that it most likely is toxic and deadly to a greater number of birds of prey. Veterinarians in Spain and Italy are very well aware of the toxicity of diclofenac to vultures. We do not know if this is also the case of animal owners.
10	1. Eliminating or even reducing the risk of ingestion of diclofenac or other veterinary medicine residues by wild vultures is impossible outside feeding stations. Our own research (Murn, C. P. & Anderson, M. D. (2008). *Ostrich* 79: 191-198; Martin, G. R., Portugal, S. J. & Murn, C. P. (2012) *Ibis* 154: 626-631) and the research of many others has shown conclusively that the highly efficient foraging behaviour of vultures means that these birds regularly find fallen carcasses many hours and sometimes days before farmers, livestock owners or carcass disposal units. The rugged terrain in which most European vulture populations reside emphasises this point. 2. Even with improved labelling and prescription of veterinary products containing diclofenac it is impossible for the prescribing veterinarian to oversee the stock disposal process and impossible in some cases for even the farmer (cf. Point 1 above). 3. Reducing the risk of carcasses used at feeding stations containing diclofenac or other veterinary medicine residues is highly

Stakeholder no.	Comments
	problematic. Feeding station operators cannot know what residues a carcass may contain without testing each carcass, which is extremely expensive. Even with testing in place, carcasses with diclofenac residues would need to be disposed of separately – at additional cost. Furthermore, routine testing for diclofenac is not available. These three points, among many others, highlight that it is impossible to secure zero (or even reduced) risk of vultures and other necrophagous birds ingesting carcasses that have been treated with diclofenac or other veterinary medicine products.
11	By-products are regulated by Regulation 1069/2009/EC which specifies exceptions regarding carcasses for carrion feeding, which is also handled by Regulation 142/2011/EU. Specifically for Spain, Royal Decree 1632/2011 addresses the matter of feeding certain wildlife species with animal by-products. In fact, this is the appropriate legislation, in place already, that deals with conditions of feeding animal by-products/carcasses to wildlife including vultures.
12	In Italy we have strict procedures for the “feeding stations” and the probability that a diclofenac contaminated animal will be used is – probably – very low. Even if a proper quantitative assessment has never been done. Whereas we would like to point the attention on the number of animals that die or disappear in the rural areas. According to the official statistics (Ministry of Health, animal register) during the past 12 months in Italy a total of 29 681 bovines (twenty-nine thousand six hundreds eighty-one) have been cancelled from the national database. Again, according to the official database, 19 230 of them have been lost in the field. Almost 80% of them are concentrated in areas with great bio-diversity. We do not have official statistics for pigs, sheep and goats. Consider also that we have an overlapping distribution of vultures and wolves. Most of the wolf’s attack to livestock results in few dead animals and several wounded dispersed animals. Find a wounded animal is time consuming and often difficult. Most of the wounded animals are not retrieved at all. In real life, in many Italian rural areas the number of “lost” animals is very high. Many wounded/dead animals are left in the field where they soon die. We feel it will be almost inescapable that diclofenac will be ingested by some susceptible species. Finally let us underline that Italy represents a migration bridge between Africa and Europe during spring migration when a population of more than 100 000 individuals belonging to migrating raptor species feeding on carrions is estimate to fly across Italy.
13	We draw on the advice and experience of a network of experts with more than ten years of experience dealing specifically with the issue of diclofenac contamination of domesticated ungulate carcasses in South Asia to comment on this and the following two topics. Our comments focus largely on how diclofenac can impact on Spanish vultures. We do this because we are familiar with diclofenac use,

Stakeholder no.	Comments
	livestock disposal and vulture feeding in Spain. Spain also holds the vast majority of vultures in Europe (>95%), including the Eurasian griffon (Gyps fulvus), which we know is intolerant to diclofenac (Swan et al. 2006 Biology Letters); and the Endangered Spanish Imperial Eagle (Aquila adalberti), which we suspect is intolerant to diclofenac (see Sharma et al. 2014 Bird Conservation International). There are three types of site where European vultures can consume diclofenac-contaminated tissue from domesticated ungulate carcasses: 1) vulture feeding stations (i.e., vulture restaurants: sites designed for vulture benefit); 2) carcass disposal sites (i.e., Spanish muladares: sites designed for both vulture and human benefit); and 3) fallen livestock in the field. In Nepal, vulture feeding stations are intensively managed. Old, ailing and unwanted cattle are donated to the site by local communities and cared for until their natural death by vulture project staff. Only cattle that die after more than 10 days in the direct care of these centres are provided to vultures. In this way it is ensured that any diclofenac that these cattle may have been treated with previously has been fully metabolised (see our response to Topic 2). Vulture feeding stations in Spain, France and other European countries largely obtain abattoir by-products (mostly viscera). Diclofenac is more slowly depleted from viscera and withdrawal periods are only designed to protect human health (see our response to Topic 2). Any given quantity of by-product obtained by feeding stations is likely to come from multiple individual animals and often different species. Therefore, European wildlife managers presently rely on livestock owners not using diclofenac 10 days prior to slaughter. In Spain, withdrawal periods for cattle and pigs are both greater than 10 days, but no withdrawal period exists for horses because they are not slaughtered for human consumption. Yet, horses are often slaughtered and processed at the same abattoirs as cattle. Data from South Asia shows a very high proportion of horses (33.3%), higher than for cattle, are treated with diclofenac before death (Taggart et al. 2007 Environmental International). This is possibly a welfare measure that is likely to be similar in Europe. Thus, the by-products of a horse treated with diclofenac prior to slaughter can be supplied to a vulture feeding station in an indistinguishable and contaminated mix. In India, carcass disposal sites are surveyed to determine diclofenac prevalence in vulture food. Despite the ban on veterinary diclofenac in 2006, diclofenac contaminated carcasses are still being found. This is because Indian pharmaceutical companies are circumventing the ban by producing human diclofenac in the vial size adequate for treating cattle and distributing these to veterinary pharmacies. However, it is veterinarians and livestock owners that are purchasing and administering diclofenac in South Asia. We are currently advocating a ban on all diclofenac in vials larger than 3 ml (adequate for human treatment), which is expected to occur later this year. We do not think pharmaceutical companies, pharmacists and veterinarians will circumvent laws in Europe as they have in South Asia; but this scenario highlights the sometimes irresponsible attitude of veterinarians and livestock owners to environmental issues. This bears on the large network of managed carcass disposal sites in Spain, which were re-established to prevent vulture declines as a result of a lack of food. These muladares also provide livestock owners, who are responsible for these sites, an easily and inexpensive means of carcass disposal.

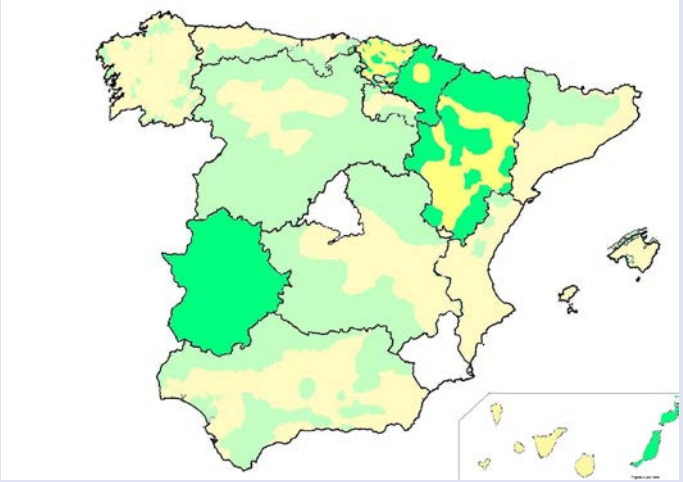
Stakeholder no.	Comments
	Our colleagues in Spain have received reports of poorly or badly managed muladares. In the worst cases, chemicals, including vials of veterinary medicine, are discarded among carcasses. While it is therefore likely that vultures can be exposed to diclofenac by consuming tissue doused in discarded diclofenac, we are more concerned that these same irresponsible livestock owners will dispose of carcasses contaminated with diclofenac at sites where vultures have access. A proposed warning label on diclofenac products in Europe will not prevent this behaviour. We would point out that large and graphic warning labels on tobacco products clearly stating “smoking kills” do not stop smokers smoking; so we are sceptical that a warning label on veterinary diclofenac would stop irresponsible livestock owners dumping contaminated carcasses in muladares. An animal can die in the field and, if it does so in an area where vultures range, vultures are likely to find it before the owner does. Vultures have evolved to be highly efficient carcass consumers. Vultures can see for vast distances while soaring. In addition, they monitor their soaring neighbour’s behaviour and, in this way, vultures work together to scan vast areas of countryside for fallen livestock. Further, vultures are adapted to quickly and effectively consume a carcass. In South Asia, a flock of vultures consume a cattle carcass in less than 1 hour. Given the tendency for animals to die at night and the many responsibilities of livestock owners, a flock of vultures could locate and consume a contaminated carcass before many livestock owners could organise the retrieval of the carcass. Further, in mountainous areas of Spain, livestock owners are exempt from retrieving carcasses. In these cases, livestock could be treated with diclofenac during round-ups. All livestock are rounded-up once or more during their lives and diclofenac may be used to treat ailments at these times. If these animals are released and then die within 10 days of treatment, they could in turn kill vultures. In fact, the stress and physical nature of a round-up itself may increase the likelihood that an animal might die. Importantly, we know that Spanish vultures are exposed to NSAIDs, because flunixin has been detected in the tissue of a dead vulture from southern Spain, also with severe visceral gout. We are confident that flunixin poisoning caused renal failure and death in this vulture. How this wild bird consumed flunixin is unknown but it is almost certainly via one of the three sites described above. At least in Spain, diclofenac and flunixin are recommended for treatment of the same livestock species and for similar ailments (actually, diclofenac is recommended for more types of ailments than flunixin). Further, both drugs have similar withdrawal periods. Therefore, the flunixin case provides indisputable evidence that Spanish vultures will be exposed to diclofenac. In the above scenarios perhaps only a small number of carcasses contaminated with diclofenac may be available to vultures. However, it is very important to remember that only a small number of carcasses contaminated with diclofenac are needed to cause serious declines in vultures. Modelling our data from India and Pakistan indicate as few as 1 in 760 domesticated ungulate carcasses (0.13%) contaminated with lethal levels of diclofenac caused declines in the Oriental white backed vulture (Gyps bengalensis) of about 50% per year (Green et al. 2004 Journal of Applied Ecology). There is no reason to think that the closely related Eurasian griffon would differ

Stakeholder no.	Comments
	greatly in response given it too is intolerant to low concentrations of diclofenac (Swan et al. 2006 Biology Letters). From our observations and calculations, we can say with high confidence that even if only 1 in every 2000 carcasses available to Europe's vultures were contaminated with lethal levels of diclofenac, their populations could be halved in six years (Margalida et al. 2014 in review with Science). Such declines would reduce Europe's vulture populations below viable levels and lead to multiple local extinctions and eventually regional extinctions. Finally, we consider that the precedent of allowing diclofenac use by veterinarians in Europe is a very dangerous one for vultures worldwide. The fact that South Asian countries have taken major steps to prevent this could be undermined, as well as the more practical risks that the drug will be exported to neighbouring Africa and Asia. We therefore consider that vultures will be seriously threatened across the world unless immediate steps are taken to prevent licensing in Europe.
14	Feeding stations of animal by-products are an important component in the management and recovery of endangered free-ranging necrophagous bird populations. Within these managed feeding stations, the detection of veterinary medicine residues prior to feeding of carcasses would not be feasible, given the cost of screening all products. Even with improved labelling or disclosure requirements for animal prescription history, feeding stations would not be able to guarantee that animal products used were free of veterinary medicine residues that pose a significant risk to bird health. Outside of feeding stations the problem is exacerbated to the point of being impossible, since necrophagous birds will utilise any and all animal carcasses or animal products in a highly efficient and opportunistic manner. In many cases these birds locate a carcass before the land owner or farmer are aware of the animal's death, particularly in the more remote and poorly accessible areas in which European vultures reside. An alternative veterinary anti-inflammatory solution (Meloxicam) exists which is not toxic to necrophagous birds, not subject to patent, and which would provide a simple and cost effective solution to the issues outlined above.
15	The feeding of vultures and other necrophagous birds species is covered by National Regulation RD 1632/2011, this regulation establish the proceed for the authorization and register of the feeding stations and the proceed for the feeding of animals outside the feeding stations, this regulation can be found on the following link: http://www.boe.es/buscar/doc.php?id=BOE-A-2011-18536 There are 235 feeding stations in Spain.
16	Situación actual: la nueva legislación Listado de normas aplicables a la alimentación de especies necrófagas con subproductos animales no destinados a consumo humano Ámbito europeo

Stakeholder no.	Comments
	1. *Reglamento CE 1069/2009, del Parlamento Europeo y del Consejo de 21 de octubre*, por el que se establecen las normas sanitarias aplicables a los subproductos animales no destinados a consumo humano, y por el que se deroga el Reglamento CE 1774/2002. Este Reglamento establece el tipo de gestión de los subproductos animales y determina los aspectos más importantes de cara a la gestión de la alimentación de las especies necrófagas. No resulta de aplicación a los subproductos animales derivados de especies silvestres, incluidos los sometidos a explotación cinegética, que no sean manipulados o comercializados para consumo humano. Permite establecer excepciones a la recogida de cadáveres para la alimentación de especies necrófagas en peligro o protegidas, siempre que se asegure la ausencia de riesgos para la salud pública y la sanidad animal. 2. Reglamento CE 142/2011, de la Comisión, de 25 de febrero, por el que se establecen las disposiciones de aplicación del Reglamento (CE) n o 1069/2009 del Parlamento Europeo y del Consejo por el que se establecen las normas sanitarias aplicables a los subproductos animales y los productos derivados no destinados al consumo humano. Este Reglamento regula las normas de aplicación de las actuaciones de alimentación de las especies necrófagas. Determina las posibilidades de alimentación tanto en muladares como fuera de ellos. Ambas vías de actuación se especifican en el anexo VI, tal y como se recogen en el texto legal aprobado. 3. *Reglamento 999/2001 del Parlamento Europeo y del Consejo, de 22 de mayo de 2001*, por el que se establecen disposiciones para la prevención, control y la erradicación de determinadas encefalopatías espongiformes transmisibles Ámbito estatal 1. Real Decreto 1632/2011, de 4 de febrero, por el que se regula la alimentación de determinadas especies de fauna silvestre con subproductos animales no destinados a consumo humano. 2. Ley 42/2007, de 13 de diciembre, del Patrimonio Natural y de la Biodiversidad. Esta ley establece el marco general de gestión de las especies amenazadas en relación, entre otras cuestiones, al establecimiento de estrategias de conservación (Art. 57. Estrategias de Conservación de Especies Amenazadas). 3. Real Decreto 3454/2000, de 22 de diciembre, por el que se establece y regula el Programa Integral coordinado de vigilancia y control de las encefalopatías espongiformes transmisibles de los animales. 4. Orden PRE/1431/2009, de 29 de mayo, por la que se modifica el Anexo II del RD 3454/2000. 5. Real Decreto 1911/2000, de 24 de noviembre, por el que se regula la destrucción de los materiales especificados de riesgo en relación con las encefalopatías espongiformes transmisibles.

Stakeholder no.	Comments
	6. Orden PRE/156/2009, de 30 de enero, por la que se modifica el Anexo IV del RD 1911/2000. Contenido de la legislación más importante para la alimentación de especies necrófagas El nuevo Reglamento (CE 1069/2009) derogó el de 2002 y en su desarrollo se aprobó el Reglamento (UE) 142/2011, de 25 de febrero de 2011. Su transposición a la normativa española se produjo a través del Real Decreto 1632/2011, mediante la incorporación de las nuevas posibilidades que permite la normativa comunitaria y regula los mecanismos que permiten su desarrollo en el ámbito español, contemplando tanto las competencias sobre gestión de la fauna silvestre y como las de gestión de la sanidad animal. Además, las excepciones contempladas en el RD 1632/2011 son compatibles con la Ley 8/2003 de sanidad animal, que señala como norma general, que para prevenir las enfermedades de los animales hay que eliminar o destruir los cadáveres y demás productos de origen animal en la forma y condiciones que señalen las normas de sanidad animal, salud pública y protección del medio ambiente (artículo 37). Con anterioridad a la aprobación del RD 1632/2011, la Conferencia sectorial de Medio Ambiente aprobó el 13 de julio de 2011 las *Directrices técnicas para la gestión de la alimentación de especies necrófagas en España*. La finalidad de las directrices fue proporcionar unos criterios consensuados para la gestión de los recursos tróficos, dirigidos a evitar que la escasez, la mala calidad y la alteración de la distribución del alimento afectasen negativamente a las poblaciones españolas de especies necrófagas, con el fin último de mejorar el estado de conservación o mantener un estado de conservación favorable de estas especies. El Real Decreto contempla dos sistemas de aporte de alimento para las necrófagas: 1. En muladares vallados, gestionados por la administración o por particulares. Están recomendados para alimentación de rapaces en programas específicos de alimentación suplementaria o cuando se constate la falta de alimento en determinadas zonas (las condiciones se establecen en el art. 4 del RD 1632/2011). 2. Alimentación fuera de muladares. Este sistema se autorizará en lo que el RD 1632/2011 (art. 2) define como Zonas de protección para la alimentación de necrófagas de interés comunitario, que serán delimitadas por el órgano competente en gestión de fauna silvestre, e incluirán los espacios Natura 2000 definidos por presencia de necrófagas de interés comunitario, los ámbitos de aplicación de los planes de recuperación o de conservación para necrófagas de interés comunitario aprobados y las áreas prioritarias para la alimentación de necrófagas de interés comunitario, cuando no estén representadas en los apartados anteriores. Las explotaciones ganaderas, rebaños o espacios naturales acotados de este supuesto deben cumplir unas condiciones específicas recogidas por el RD 1632/2011 (art. 5.3). Cómo se aplica la alimentación de especies necrófagas en España

Stakeholder no.	Comments
	¿Qué objetivo tiene el nuevo Real Decreto 1632/2011? Trasponer la normativa europea de gestión de subproductos animales no destinados a consumo humano en lo relativo a la alimentación de especies de fauna silvestre, y contribuir a mejorar el estado de conservación de las especies necrófagas españolas en cumplimiento de los requisitos de seguridad alimentaria y sanitaria. El Reglamento (UE) 142/2011, de 25 de febrero de 2011, incorpora novedades respecto a la normativa vigente española (Real Decreto 664/2007) en relación a las posibilidades de exceptuar el régimen de gestión general de los subproductos animales con fines de alimentación de especies necrófagas silvestres. En concreto, amplía las posibilidades y circunstancias en que puede llevarse a cabo la alimentación de las especies necrófagas silvestres más amenazadas, de forma compatible con las necesarias garantías de seguridad alimentaria y sanitaria. De este modo, se contribuye a paliar un problema de conservación de determinadas especies amenazadas para las que España alberga sus poblaciones más importantes a nivel mundial, causado por las disposiciones del Reglamento CE 1774/2002, actualmente derogado, que redujo y alteró la disponibilidad de alimento en forma de carroñas de especies silvestres y de ganado. ¿Que novedades contempla para la alimentación de las especies necrófagas? Además de la alimentación en comederos vallados (ya prevista en la anterior normativa), este nuevo real decreto contempla la posibilidad de alimentar a más especies necrófagas y sin previa retirada del terreno de los animales muertos en unas zonas de protección. ¿A que especies necrófagas se puede aplicar? Al buitre leonado, el buitre negro *(Aegypius monachus),* el alimoche , el quebrantahuesos *(Gypaetus barbatus),* el águila imperial ibérica, el águila real, el milano real *(Milvus milvus)* y el milano negro *(Milvus migrans),* además de cualquier especie del orden Falconiformes y del orden Strigiformes incluidas en el anejo I de la Directiva Aves en las ZEPA y alguna de las especies del orden Carnivora: Oso pardo (*Ursus arctos*) y Lobo (*Canis lupus*), incluidas en el anejo II de la Directiva Habitats en LIC y ZEC. ¿Cuáles son las zonas de protección autorizadas para la alimentación de especies necrófagas? a) Los espacios Natura 2000 definidos por la presencia de las especies necrófagas de interés comunitario. b) Los ámbitos territoriales de aplicación de los planes de recuperación o de conservación para las especies necrófagas aprobados por las comunidades autónomas. c) Áreas prioritarias para la alimentación de las especies necrófagas cuando éstas no estén representadas en los apartados anteriores, y

Stakeholder no.	Comments
	aquellas otras que las CCAA estimen ¿Donde se sitúan estas zonas de protección? Figura 1. Mapa de las zonas de protección declaradas por las Comunidades Autónomas en septiembre de 2014 (en color verde claro, las declaradas antes de 2014, las verde fuerte son las zonas declaradas en 2014 –Extremadura aún no ha sido publicado-, en blanco las regiones sin declaración de zonas de protección)  ¿Qué materiales pueden utilizarse para la alimentación de especies necrófagas sin la recogida previa de los cadáveres? Los cadáveres de ganado en régimen extensivo de equino, porcino, bovino menor de 36 meses y ovino y caprino menor de 18 meses (categoría 2), cuando procedan de animales que no se hayan sacrificado ni hayan muerto como consecuencia de la presencia real o sospechada de una enfermedad transmisible a los seres humanos o los animales. Los restos de animales que se encuentran en buenas condiciones sanitarias y que no se destinan a consumo humano por motivos comerciales (categoría 3). En este caso se incluirían, por ejemplo, los subproductos resultantes de la actividad cinegética en la que las canales y restos de los animales cazados se destinaran a consumo humano. Los cuerpos enteros o partes de animales muertos que contengan MER en el momento de la eliminación (categoría 1), siempre y cuando se compruebe la ausencia de EET. Para ello, es preciso hacer un análisis previo de los bovinos mayores de 36 meses y del 4% de los

Stakeholder no.	Comments
	ovinos/caprinos mayores de 18 meses que mueran en una explotación, como paso previo para poder dejar in situ el 96% restante de cadáveres de ovino y caprino. ¿Cuál es el número de cadáveres que se debe aportar en cada *zona de protección*? En base a la información de la biomasa anual requerida por las especies objetivo en cada *zona de protección*, se puede realizar una conversión de esa cantidad al número equivalente de cadáveres de cada especie (principalmente en tres categorías: ovino, caprino, muflón, rebeco, corzo y gamo -40 kg-, cerdo, jabalí, cabra montés y ciervo -70 kg-, bovino y equino -400 kg-). De este modo, se puede calcular con un margen de error variable el número de cadáveres que se debe aportar en cada *zona de protección.* Es recomendable incrementar un 10% la biomasa a ofrecer en relación a los requerimientos tróficos estimados, por las posibles alteraciones en el consumo de los cadáveres o por cambios en alguna de las variables que intervienen en el proceso natural de aprovechamiento de carroñas. ¿Dónde puede realizarse la alimentación de especies necrófagas sin la recogida de los cadáveres? En terrenos dedicados a la ganadería extensiva (explotación privada cercada, pastos comunales, pastos privados, baldíos o cualquier otro), cuyo aprovechamiento principal sea el pastoreo extensivo por las especies ovina, caprina, porcina, bovina y equina, y a la caza mayor (cotos, reservas de caza o cualesquiera otras figuras oficiales en las que exista un aprovechamiento cinegético de ungulados silvestres). Las explotaciones ganaderas pueden acogerse voluntariamente al programa, en base a los criterios sanitarios siguientes. ¿Qué explotaciones ganaderas pueden acogerse a la alimentación sin recogida de los cadáveres? Las que se encuentren en zonas de protección. Las que se dediquen al aprovechamiento ganadero no intensivo para las especies ovina, caprina, porcina y bovina. Las que cuenten con la calificación sanitaria que establezca el órgano competente en relación a las enfermedades sometidas a Programas Nacionales o de las comunidades autónomas de Vigilancia, Control y Erradicación de Enfermedades, o en su caso existencia de ptuar de este requisito en función de un análisis de riesgo. Estar bajo la vigilancia periódica de los servicios veterinarios oficiales respecto de la prevalencia de las EET y de enfermedades transmisibles a personas o animales. ¿Quién autoriza? El órgano competente en materia de sanidad animal, a propuesta del órgano competente en gestión de fauna silvestre.

Stakeholder no.	Comments
	¿Qué debe cumplir una explotación o espacio natural acotado si es autorizada? Mantener un sistema de registro con, al menos, la identificación y el peso estimado de los animales muertos que son usados para la alimentación de las especies necrófagas de interés comunitario. ¿Se puede suspender o retirar la autorización de la alimentación?. Sí, se pueden suspender o retirar cautelarmente las autorizaciones si se sospecha o confirma la posibilidad de transmisión de EET o un brote de una enfermedad grave transmisible a personas o animales en una explotación ganadera, rebaño o espacio natural acotado que sea establecimiento de procedencia para dicha autorización, hasta que pueda descartarse el riesgo. ¿Como puede realizarse en la práctica la alimentación de especies necrófagas sin retirada de cadáveres? Los cadáveres generados de las explotaciones autorizadas no pueden trasladarse a otras explotaciones y se podrían dejar en el mismo lugar en que aparecen para su eliminación natural por las especies necrófagas. No obstante, es necesario desplazar los cadáveres de su emplazamiento –hacia otros de la finca- si aparecen a menos de aproximadamente las siguientes distancias: • 200 m de los puntos de alimentación suplementaria de ganado y ungulados silvestres, evitando, en la medida de lo posible, su depósito en zonas cultivadas. • 200 m de vallados propios de la explotación, • m de tendidos eléctricos y 4.000 m de aerogeneradores. • 200 m a láminas de agua superficial permanentes o estacionales y manantiales. • 200 m de carreteras,caminos transitados y construcciones humanas no habitadas, y a más de 500 m de viviendas humanas y establos de animales. Es necesario también establecer una distancia de seguridad adecuada en relación a la presencia de aeropuertos y aeródromos para evitar riesgos en relación con la seguridad aérea. Los responsables o titulares de la explotación deben trasladar el cadáver fuera de estas distancias por medio de los vehículos propios de gestión existentes en la explotación, realizando los desplazamientos en todo caso a través de la misma explotación. ¿Cómo se garantiza que los cadáveres no recogidos son consumidos por las especies necrófagas?

Stakeholder no.	Comments
	Los estudios existentes nos indican que en el caso de las aves necrófagas estas consumen los cadáveres con una alta probabilidad si estos se hallan: • disponibles en áreas próximas a zonas de reproducción y en el ámbito de zonas de campeo (equivalentes a las zonas de protección) • en zonas despejadas sin vegetación arbórea ni arbustiva densa y fuera de emplazamientos de difícil acceso para la llegada y el despegue de las aves (barrancos, laderas muy pronunciadas y con vegetación, etc.) • fuera de la proximidad al ser humano, de zonas transitadas (caminos transitados, carreteras) o de presencia estable (casas, elementos de gestión, naves, pueblos). • alejados de potenciales molestias o riesgos para las aves (paso de vías de transporte de vehículos, zonas de gestión activa del territorio –zonas de extracción de madera, períodos de gestión del monte y de terrenos agrícolas-, zonas con tendidos eléctricos y aerogeneradores) ¿Existen riesgos sanitarios al alimentar a las especies necrófagas sin recogida de los cadáveres? No existen riesgos sanitarios derivados de la no recogida de cadáveres en las explotaciones y espacios naturales acotados. Las aves necrófagas consumen las partes no duras de los cadáveres (salvo huesos y cueros que son consumidos por los carnívoros), de forma que se eliminan rápidamente sin riesgos para la salud pública y la sanidad animal los materiales potencialmente más delicados. Por otro lado, al garantizar previamente el buen estado sanitario de los restos se descarta que éstos puedan ser un foco de infección en el lapso de tiempo hasta que las especies necrófagas los consumen. Además los cadáveres no recogidos destinados a la alimentación de las necrófagas al no salir en ningún caso de la explotación de origen y al ser, en su caso, su desplazamiento dentro de la explotación con vehículos de gestión de la propia explotación, se eliminan los riesgos. Conclusiones sobre posibilidades legales 1. La principal novedad incorporada en el RD 1632/2011 es la posibilidad de aportar cadáveres o restos de cadáveres afectados por la normativa SANDACH –no las pequeñas cantidades de caza ni las piezas abatidas que no se recojan después de matado- fuera de muladares vallados, siempre que se cumplan una serie de pasos: • Se delimiten oficialmente las zonas de protección para la alimentación por la administración autonómica. • Se determinen las condiciones sanitarias y técnicas de las explotaciones no intensivas o acotados que pueden integrarse en los

Stakeholder no.	Comments

programas de alimentación de necrófagas por parte de la administración autonómica.

- Se solicite, por parte del responsable de la explotación ganadera o espacio natural acotado, la participación voluntaria en los programas de alimentación de especies necrófagas.
- Se reciba autorización oficial, con condiciones de actuación y desarrollo de la actuación de alimentación.
- En el caso de explotaciones ganaderas acogidas a estos programas, al no resultar obligatoria la retirada de los cadáveres que irían destinados a alimentación de necrófagas, se articularán fórmulas para reducir o eliminar los costes derivados de la suscripción de seguros agrarios de retirada de cadáveres.

2. Se podrán seguir empleando los muladares vallados como técnica de alimentación, tal y como ocurría previamente, y bajo las condiciones establecidas en el RD 1632/2011.

<u>Desarrollo de la legislación sobre alimentación de especies necrófagas en España</u>

Con la información proporcionada por las Comunidades Autónomas al Ministerio de Agricultura, Alimentación y Medio Ambiente, de acuerdo al artículo 8 del R.D 1632/2011, se ha elaborado el siguiente informe de evaluación del grado de cumplimiento del contenido del R.D.

1. Delimitación de zonas de protección

   Diez de las 17 comunidades autónomas (Andalucía, Aragón, Canarias, Cantabria, Castilla-La Mancha, Castilla y León, Cataluña, Comunidad Valenciana, La Rioja y Navarra), han aprobado y publicado oficialmente sus zonas de protección, lo que supone un porcentaje de cumplimiento del 58%.

2. Número de comederos autorizados.

Las 11 comunidades autónomas que se reseñan en la tabla han remitido información actualizada respecto a los comederos autorizados para el año 2012 o 2013. El resto de comunidades autónomas también tienen puntos oficiales autorizados para desarrollar la práctica de alimentación de especies necrófagas, pero no han remitido datos.

Comunidad Autónoma	Nº de comederos autorizados	Kg. Aportados al año	Nº explotaciones que aportan cadáveres

Aragón	51	1.449.554	1.920
Asturias	1	0	0
Castilla-La Mancha	39	320.265	19
Castilla y León	49	612.340	381
Cataluña	19	6.835	sin datos
Comunidad Valenciana	4	114.013	25
Extremadura	15	51.367	sin datos
Galicia	0	0	0
La Rioja	5	123.629	12
Navarra	15	sin datos	sin datos
País Vasco (Vizcaya)	1	15.990	sin datos

3. Número de explotaciones ganaderas extensivas para el aporte de cadáveres sin su previa recogida

- Cinco comunidades autónomas han concedido autorizaciones a explotaciones ganaderas extensivas para la alimentación de especies necrófagas sin la necesidad de retirada previa de los cadáveres.
- El total de explotaciones en toda España asciende a 4.557, siendo la gran mayoría de las explotaciones autorizadas (>90%) de las cabañas ovina y caprina.
- No existen datos de número de cadáveres aportados anualmente en las explotaciones extensivas autorizadas:
  - Andalucía: 2.439 explotaciones
  - Castilla y León: 628 explotaciones

- Castilla-La Mancha: 977 explotaciones
- La Rioja: 112 explotaciones
- Navarra: 401 explotaciones

4. Requerimientos tróficos de las especies necrófagas a nivel nacional

En la tabla II se expone una estima de las necesidades de biomasa de las especies necrófagas en España, en base a publicaciones científicas y técnicas examinadas por la Subdirección General de Medio Natural del MAGRAMA, sobre los requerimientos individuales diarios, la proporción de carroña en su dieta y el tamaño de población (ver referencias bibliográficas correspondientes a los distintos superíndices enumerados).

Especie	**Requerimientos individuales diarios (kg biomasa)**	**Nº parejas**	**Nº individuos territoriales aprox.**	**Población flotante aprox.**	**Nº total estimado individuos**	**% de carroña en dieta**	**Días al año de presencia**	**Biomasa total (kg/año)**
Quebrantahuesos	0,4[1]	134[8]	290	200	490	1,0	365	71.540
Buitre leonado	0,52[1]	24.609[9]	49.218	15.000	64.218	1,0	365	12.188.576
Buitre negro	0,57[2]	2.068[10]	4.136	1.000	5.136	1,0	365	1.068.544
Alimoche	0,2[1]	1.452[11]	2.904	200	3.104	1,0	200	124.160
Águila imperial	0,26[3]	409[12]	818	300	1.118	0,04[18]	365	5.304
Águila real	0,3[4]	1.553[13]	3.106	600	3.706	0,05[19]	365	20.290
Milano real	0,2[5]	2.176[14]	4.352	800	5.152	0,05[20]	365	18.804
Milano negro	0,17[5]	10.300[15]	20.600	1.500	22.100	0,1[21]	200	75.140

Lobo ibérico	1,7[6]				2.000[16]	0,4[22]	365	496.400
Oso pardo	15[7]				275[17]	0,07[23]	310[24]	90.750
Total								**14.159.508**

Según la anterior tabla la estima de las necesidades de biomasa de las especies necrófagas en España, estarían en torno a las 14.000-15.000 TM/año.

De acuerdo con la distribución de la población reproductora de especies necrófagas entre las comunidades autónomas, en la tabla III se expone una propuesta de reparto de requerimientos tróficos anuales. En función de la información sobre aportes de subproductos animales realizados por las 10 comunidades autónomas que han remitido información, en la tabla se ha realizado una valoración del nivel de adecuación de los requerimientos de biomasa de estas especies. En este sentido, es preciso tener en cuenta que las especies necrófagas consumen carroña procedente de otras fuentes distintas a las derivadas de los programas oficiales de alimentación, tanto de ganado doméstico (aproximadamente un 65-80%, 40%, 25-43% y 28% para el buitre leonado, buitre negro, alimoche y quebrantahuesos respectivamente) como de presas silvestres (35-20%, 60%, 75-57% y 72% para buitre leonado buitre negro, alimoche y quebrantahuesos respectivamente[2, 24, 25, 26, 27, 28]), por lo que los datos de cobertura de necesidades han de ser evaluados con cautela.

Tabla III. Reparto de requerimientos tróficos de las especies necrófagas por comunidades autónomas

Comunidad autónoma	Necesidades de biomasa (kg)	% del total de necesidades	Kg. aportados	% necesidades cubiertas
Andalucía	1.635.006	11,5	sin datos	sin datos
Aragón	2.515.901	17,8	1.449.554	57,6
Asturias	233.070	1,6	0	0
Baleares	136.484	1,0	sin datos	sin datos
Canarias	2.483	0,0	sin datos	sin datos
Cantabria	142.877	1,0	sin datos	sin datos

Castilla-La Mancha	1.459.375	10,3	654.795	44,8
Castilla y León	3.344.842	23,6	612.340	18,3
Cataluña	526.712	3,7	6.835	1,3
Extremadura	1.497.755	10,6	51.367	3,4
Galicia	131.117	0,9	0	0
Madrid	304.640	2,2	sin datos	sin datos
Murcia	1.157	0,0	sin datos	sin datos
Navarra	1.361.407	9,6	sin datos	sin datos
País Vasco	372.027	2,6	15.990	4,3
La Rioja	369.559	2,6	123.629	33,4
Com. Valenciana	125.096	0,9	114.013	91,1
Total España	14.159.508		3.028.523	21,4

Como conclusión de la tabla anterior, se observa que Aragón, Castilla-La Mancha, La Rioja y Comunidad Valenciana son las comunidades autónomas que mayor grado de cumplimiento han alcanzado con la aplicación de programas de alimentación respecto a las necesidades de biomasa de las especies necrófagas a través de puntos de alimentación suplementaria en comederos (y en el caso de Castilla-La Mancha también con explotaciones extensivas autorizadas).

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Stakeholder no.	Comments
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17	Mitigate the risk of ingestion of diclofenac by necrophagous birds is next to impossible outside feeding stations, as the birds will feed opportunistically on dead livestock, often before farmers are aware that their animal is dead. Bearing in mind the terrain in which European vulture populations reside, it would be practically impossible for farmers to locate and dispose of dead livestock prior to those animals being located by necrophagous birds and diclofenac residues being ingested. There is no way for feeding stations to know –

Stakeholder no.	Comments
	even with vastly improved labelling and records of prescription – whether the animal products being provided to them contain diclofenac without testing every donation, which would be prohibitive in terms of both human and financial resources; these facilities represent a huge resource in the recovery of vulture populations and a significant investment by donors including the European Union LIFE funds. Separation of animal products that contain diclofenac from those which do not prior to donation to feeding stations would also prove a significant burden to livestock farmers. An alternative veterinary anti-inflammatory solution (Meloxicam) exists which is not toxic to necrophagous birds, not subject to patent, and which would provide a simple and cost effective solution to the issues outlined above.
18	I refer you to our paper: MARTIN GILBERT, RICHARD T. WATSON, SHAKEEL AHMED, MUHAMMAD ASIM and JEFF A. JOHNSON. 2007. Vulture restaurants and their role in reducing diclofenac exposure in Asian vultures. Bird Conservation International (2007) 17:1–16. doi: 10.1017/S0959270906000621 **From methods**: A supplementary feeding site (vulture restaurant) was established close to the densest area of the Toawala colony (30.50802° N, 71.72487° E), 3.8 km from the harmonic mean center (the point where the inverse reciprocal mean distance to all active nests is a minimum) and 1.4 km from the closest active nest. The site consisted of an open rectangular field (67 m x 45 m) that was visible from the nearest nesting trees and with no overhead wires or similar aerial obstacles for at least 500 m. A 1 m high perimeter fence was erected around the field to exclude dogs and was reinforced with Acacia spp. branches. There were few trees in the immediate vicinity of the vulture restaurant, so four perches were erected to discourage birds from perching on nearby farm houses. A concrete pool was built during early April to provide a reliable supply of water during the hot and dry summer months. All feed animals were locally purchased donkeys and these were marked and held for a period of at least 1 week to ensure that any residues of diclofenac administered prior to purchase were eliminated from their tissues before slaughter. Although no published studies have described the pharmacokinetics of diclofenac in equines, work in humans has shown that 90% of diclofenac administered at therapeutic doses is eliminated by 96 hours (Reiss et al. 1978 cited in Todd and Sorkin 1988). **Conclusion:** This study has demonstrated that during the cool winter breeding season it was possible to modify vulture foraging behaviour and reduce mortality by provisioning a vulture restaurant with uncontaminated food. However, the restaurant was only able to modify the behaviour of vultures with home-ranges centered close by. The restaurant did not attract vultures during the non-breeding season when other factors, such as high ambient temperatures, may influence soaring behaviour and movement over large areas in which food was abundant and exposure to diclofenac-contaminated carcasses could occur. Even under optimum conditions it is not possible to eliminate diclofenac exposure entirely where alternative carcass sources are readily available. Supplementary feeding may prove to be a useful management tool for slowing declines locally in the short term. However, extinction is inevitable in all populations

Stakeholder no.	Comments
	foraging in areas where diclofenac is in veterinary use and treated carcasses become vulture food at sufficient frequency to cause deaths and negative population growth. Elimination of diclofenac in veterinary use is the most certain way to prevent vulture deaths from diclofenac exposure, although education of veterinarians and livestock owners to avoid treatment of terminally ill livestock, or to bury or burn carcasses of recently treated livestock, may also be helpful.
19	The IUCN WHSG has been involved in dialogue relating to the diclofenac poisoning of vultures for over a decade – this includes visits to vulture feeding sites in India and Nepal, and consultations with a variety of groups involved in this area and with its membership which covers most IUCN member countries and all regions of the world. The main area of concern relates to the extensive livestock systems in Spain where animals die in the field and are not detected for some days or at all. These animals if recently treated with diclofenac pose a grave risk to vultures. Further to this the method of control of residues in meat and offal are not likely to stop occasional contaminants reaching vulture feeding stations and given the extraordinarily low dose required to cause death poses a significant risk that current rules and regulations will not prevent. In fact inspection processes in slaughterhouses are heading for less supervision under proposed legislation in some European countries under pressure from the industry to cut costs in face of competition from outside the EU and risks are likely to increase. Our knowledge of vulture movements in the region of vulture feeding station shows that the birds will and can travel many hundreds of kilometres increasing risk of exposure over a vast area where any measures to reduce risk are impractical. Management of some vulture restaurants (e.g. some *muladares* in Europe) appears to be inadequate and we would expect this to again increase risk in the European context. It is after all a cheap way to dispose of carcasses and any regular attempt to reduce risk through labelling etc is not likely to affect behaviour of the people involved in a purely commercial and waste disposal activity. The recent publication of an NSAID poisoned carcass in Spain simply confirms the suspicion that this will be a risk with diclofenac – it is likely to be much more so as it is a very cheap product unlike many NSAIDs. Flunixin is widely used in horses and this may have been the route of contamination.
20	UIZA members are responsible of the captive breeding of many vulture species, which are highly endangered in Italy and in Europe. Some of these animals are also provided for release in the wild. Italy has important vulture populations and it is a vital connecting country. Its Griffon vulture populations are increasing, even if they are still small, and a bearded vulture population has been successfully re-established. Italy is also key to restoring the migration flow and connecting the increasing and healthy vulture populations in Western Europe with the small and struggling Eastern Europe/Balkan populations. The use of veterinary medicinal products containing the substance diclofenac create a great danger for these European endangered birds. Moreover, a recent scientific study, published on 27th

Stakeholder no.	Comments
	May 2014 in the journal of Bird Conservation International, confirms that also eagles are susceptible to veterinary diclofenac. In fact, tests carried out on two steppe eagles (Aquila nipalensis), found dead at a cattle carcass dump in Rajasthan (India) and showing the same clinical signs of kidney failure as seen in vultures, indicate they had diclofenac residue in their tissues. The authors suggest that all the 14 eagle species in the genus Aquila are also probably susceptible to diclofenac. This means a tremendous threat for the European biodiversity. The Italian Association of Zoos and Aquaria entirely agrees with the comments that the European Association of Zoos and Aquaria (EAZA) has provided to EMA on this topic and it also confirms the precious information provided by the Vulture Conservation Foundation. Mitigating the risk of ingestion of diclofenac by necrophagous birds is next to impossible outside feeding stations, as the birds will feed opportunistically on dead livestock, often before farmers are aware that their animal is dead. Bearing in mind the terrain in which European vulture populations reside, it would be practically impossible for farmers to locate and dispose of dead livestock prior to those animals being located by necrophagous birds and diclofenac residues being ingested. There is no way for feeding stations to know – even with vastly improved labelling and records of prescription – whether the animal products being provided to them contain diclofenac without testing every donation, which would be prohibitive in terms of both human and financial resources; these facilities represent a huge resource in the recovery of vulture populations and a significant investment by donors including the European Union LIFE funds. Separation of animal products that contain diclofenac from those which do not prior to donation to feeding stations would also prove a significant burden to livestock farmers.
21	We the European zoos are responsible for much of the captive breeding of vultures in Europe, and provide animals for release on a regular basis. We recognize that mitigating the risk of ingestion of diclofenac by necrophagous birds is next to impossible outside feeding stations, as the birds will feed opportunistically on dead livestock, often before farmers are aware that their animal is dead. Bearing in mind the terrain in which European vulture populations reside, it would be practically impossible for farmers to locate and dispose of dead livestock prior to those animals being located by necrophagous birds and diclofenac residues being ingested. We recognise also that there is no way for feeding stations to know – even with vastly improved labelling and records of prescription – whether the animal products being provided to them contain diclofenac without testing every donation, which would be prohibitive in terms of both human and financial resources; these facilities represent a huge resource in the recovery of vulture populations and a significant investment by donors including the European Union LIFE funds. Separation of animal products that contain diclofenac from those which do not prior to donation to feeding stations would also prove a significant burden to livestock farmers. An alternative veterinary anti-inflammatory solution (Meloxicam) exists which is not toxic to necrophagous birds, not subject to patent,

Stakeholder no.	Comments
	and which would provide a simple and cost effective solution to the issues outlined above. Our zoo coordinate the European Studbook for the Eurasian griffon vulture and presently the major aim of this programme is to provide animals for re-introduction. Vultures are some of the only European native species where reintroduction is feasible at this time; however, the investment of resources necessary for this aim to be fulfilled would be essentially rendered meaningless in areas where diclofenac is widely used. Fulfilment of Aichi targets for the protection of biodiversity and vulnerable species – an agreement binding on all EU member states – falls largely on our members and in situ conservationists, and vulture protection is an important part of this work. Licencing of diclofenac for veterinary care therefore essentially prevents the governments of countries that do so from fulfilling their obligations to the Aichi targets with regard to vulture species.
22	In Italia sono note le seguenti stazioni di alimentazione (Vultur restaurants) che utilizzano carcasse di animali domestici (*) : 1. Riserva Cornino Friuli per Grifone e Aquila reale 2. Parco Regionale Velino Sirente CFS Abruzzo per Grifone e Aquila reale 3. Parco Nazionale Pollino per Grifone e Aquila reale 4. Parco Regionale Nebrodi Sicilia per Grifone 5. Parco Nazionale Gran Sasso Laga, carnai volanti con controllo veterinario 6. Parco Nazionale Montio Sibillini sta per partire il carnaio autorizzato dall'Ispra Il Parco naturale delle Dolomiti Bellunesi ha bandito e assegnato un progetto sull'argomento. *fonte Jacopo Angelini organizzatore del convegno "Applicazione del regolamento 142/2011 sulle stazioni di alimentazione degli uccelli necrofagi minacciati di estinzione in Italia e la problematica dell'avvelenamento da piombo" Parco Gola Rossa e Frasassi 23 maggio 2013 Dall'intervista del Veterinario Ufficiale la stazione n.1 utilizza, sottoprodotti di origine animale specialmente di specie suina; la n.5 (com. personale CFS) carni ovi-caprine regolarmente macellate. E' documentato il decesso per gotta viscerale di 2 esemplari tra quelli presenti nella stazione n.1. (ZUCCA P., Genero F., Costantini F. 2003 Gotta viscerale in due Grifoni (Gyps fulvus) stabulati in cattività. Avocetta 27, 1: 148. Atti del primo convegno nazionale sui Rapaci Treviso).

II - List of stakeholders who provided comments on Topic 2

Stakeholder no.	Name of organisation or individual
1	• European Association of Zoos and Aquaria (EAZA) - David Williams-Mitchell • Portuguese Association of Zoo and Aquariums (APZA) – Arlete Sogorb • British and Irish Association of Zoos and Aquariums (BIAZA) - Kirsten Pullen • Royal Zoological Society of Antwerp, Antwerp zoo and Planckendael Animal Park - Marleen Huyghe • Danish Association of Zoos and Aquaria (DAZA) - Richard Østerballe • Association Française des Parcs Zoologiques (AFdPZ) - Cécile Erny • Nordens Ark - Emma Nygren • Parques Reunidos - Maria Delclaux • Royal Rotterdam Zoo - Harald Schmidt • The Royal Zoological Society of Scotland - Colin Oulton • Italian Association of Zoos and Aquaria (U.I.Z.A.) - Cesare Avesani Zaborra • Zoobotánico de Jerez - Iñigo Sánchez • Avifauna - Joost Lammers • Beekse Bergen - Lars Versteege • Borås Zoo - Daniel Roth
2	• BirdLife International - Iván Ramírez • International Fund for Animal Welfare (IFAW) - Sonja Van Tichelen • Wildlife Conservation Society (WCS) - Janice Weatherley-Singh
3	British Veterinary Association (BVA) and British Veterinary Zoological Society (BVZS) - John Blackwell and Mike Stanford
4	Centre National d'Informations Toxicologiques Vétérinaires (CNITV) - Elodie Adamczyk
5	IUCN Vulture Specialist Group - Chris Bowden and Andre Botha
6	Kalba Bird of Prey Centre - Gerard Whitehouse-Tedd
7	IUCN Species Survival Commission Wildlife Health Specialist Group - Richard Kock
8	• Vulture Conservation Foundation (VCF) - José Tavares • Luca Passalacqua (affiliation not specified) • Società di scienze naturali del Verbano Cusio Ossola - Lucia Pompilio • Associazione CERM Centro Rapaci Minacciati ONLUS – Guido Ceccolini
9	• Fatro S.p.A. and Fatro Ibérica S.L. - Beata Truszkowska and Eugeni Castells

II - Comments received on Topic 2

Depletion of diclofenac residues in food-producing species.

Stakeholder no.	Comments
1	Green et al, "Diclofenac poisoning as a cause of vulture population declines across the Indian subcontinent" (Journal of Applied Ecology 2004) is the definitive study of the population collapse in India and Pakistan, a decline of 99% over a 10 year period from 1993-2003. The study demonstrated that even in cases where the proportion of ungulate carcasses available to vultures was in the range of only 0.1%, vulture population decline was at over 5%, suggesting strongly that depletion of the drug in treated animals is rarely fast enough to render their consumption by necrophagous birds harmless. In addition, it is worth noting that each carcass will be consumed by many birds (often 100+ when including feeding of chicks by adults), and that all (100% according to the same study) of these animals will be poisoned – each tainted carcass therefore represents a threat to a large proportion of each vulture population.
2	BirdLife International has carried our detailed analysis on *diclofenac* depletion for Indian cattle (*Bos indicus*) and goat (*Capra hircus*) (Taggart et al., 2007). The EMA has data on *diclofenac* depletion for European cattle (*Bos taurus*) and pig (*Sus scrofa*) (EMEA 2003 *diclofenac* summary report). Both studies followed similar methods. A key difference, however, between the two is the dose of *diclofenac* given to the two species of cattle. Specifically, we used 1 mg/kg doses while the EMA used 2.5 mg/kg doses. The dose used by the EMA is the recommended dose per day for veterinary *diclofenac*. In both studies, *diclofenac* depleted from the cattle species slower than from the smaller-bodied animals (e.g. *diclofenac* was undetectable in goats after 26 hours). Our results show that *diclofenac* was detectable after 167 hours (~7 days) in cattle viscera. The true concentration of *diclofenac* in this tissue was below our level of quantification at 10 µg/kg. The EMA results show that *diclofenac* was detectable after 144 (6 days) in cattle liver (27 µg/kg) and muscle (5 µg/kg). The experiment conducted by (Oaks et al., 2004) shows that a dose as low as 7 µg/kg can kill an Oriental White-backed vulture (*Gyps bengalensis*; there is no reason to think that Griffon vulture (*Gyps fulvus*) would differ greatly from this response given it too is intolerant to low concentrations of *diclofenac*). In addition, among the carcasses of cattle that we sample in India, we have found some that appear to have been treated with double the recommended dose (Taggart et al., 2007). Larger doses would increase the time needed for *diclofenac* depletion. It is possible that *diclofenac* will be misused in this way in Europe, just as it is in India. Therefore, cattle tissue may be lethal to vultures for more than 1 week after *diclofenac* treatment. This is why we only use cattle that have lived longer than 10 days in our care at vulture Safe Feeding Sites in Nepal; to ensure that they have metabolised all *diclofenac* that they may have been treated with. In Europe, withdrawal periods of greater than 10 days for cattle should ensure *diclofenac* is sufficiently

Stakeholder no.	Comments
	depleted for vulture consumption as well. But vultures can consume carcasses of animals not for human consumption, like horses (Spain). These animals can be slaughtered without prior withdrawal periods. Further, we do not know the time needed for *diclofenac* depletion in horses, but it is likely to be greater in these larger-bodied animals. There are four obvious problems associated with withdrawal periods in general: 1) it is up to the livestock owner to adhere to withdrawal periods; 2) what happens to animal products that are found to be within the withdrawal period; 3) withdrawal periods are designed to protect humans not vultures; and 4) withdrawal periods are only relevant to slaughtered animals – not to fallen stock. Despite good regulation, European laws are not immune to human cheating; therefore, it is fair to assume that on occasion withdrawal periods are not adhered to. A livestock owner can be found to be breaching the withdrawal period, through either inspection of veterinary treatment logbooks, which can be incorrectly filled, or tissue sampling, which leads to tissues requiring disposal. Where do scraps, like intestines, from carcasses with *diclofenac* levels above the maximum residue level, and tissues that fail maximum residue level tests, end up? Some may be supplied unknowingly to feeding stations and irresponsibly dumped in *muladares*. Even if tissues considered unsafe for humans are not provided to vultures, the maximum residue level for *diclofenac* in beef muscle in Spain is 5 µg/kg, which is associated with a 27 µg/kg level of *diclofenac* in the liver of the same animal (EMA results above) and a similar concentration of *diclofenac* in intestines (Taggart et al., 2007). There is no maximum residue level for intestines in Spain, suggesting this tissue is not tested, and therefore, intestines containing lethal levels of *diclofenac* can be provided to vultures from cattle considered "safe" with maximum residue levels lower than 5 µg/kg. Finally, where do fallen, sick or diseased carcasses (i.e., those considered unfit for human consumption) end up? Quite often in *muladares* and it is highly likely that many of these would have been treated with drugs in the days prior to death, precisely because they were ailing. We reiterate, only a very small proportion of carcasses contaminated with *diclofenac* can cause massive declines in vulture populations. In this way, a more precautionary approach is needed to protect Europe's vulture than simple relying on measures designed to protect humans.
3	According to the European Agency for the Evaluation of Medicinal Products Committee for Veterinary Medicinal Products' MRL public summary report on Diclofenac (http://www.ema.europa.eu/docs/en_GB/document_library/Maximum_Residue_Limits_-_Report/2009/11/WC500013751.pdf), high levels of residues occur in pigs and cattle. The report notes (paragraph 17, page 7) that the data from radiometric studies in cattle and pigs indicate that a non-extractable residue was formed through interaction of diclofenac and liver and kidney tissue. It was found that 30 to 40% of the residues were practically irreversibly bound. This evidence therefore suggests that a significant portion of the residues of diclofenac, and or its metabolites, are extremely persistent in treated animals. We therefore believe that regardless of any withdrawal period required in the SPC, however long and even if correctly complied with, these residues in

Stakeholder no.	Comments
	discarded carcasses of treated animals present a very dangerous and toxic threat to scavenging vultures.
4	Depletion of diclofenac residues in cattle and pig (when used at recommended dose) was previously debated at EMA (Committee for Veterinary Medicinal Products, Diclofenac, Summary Report, September 2003). These data are summarized by the Spanish Medicines and Health Products Agency in their document "Análisis del riesgo de uso de medicamentos veterinarios con diclofenaco sobre las poblaciones de buitres en España, Recomendaciones de actuación y escenarios potenciales de afección". Taggart *and al.* (2007) provide information about depletion of diclofenac for goat. Our comments on these data are detailed in Topic 3.
5	Data is available on diclofenac depletion for Indian cattle (*Bos indicus*) and goat (*Capra hircus*) (Taggart et al. 2006 Environmental Pollution). The EMA has data on diclofenac depletion for European cattle (*Bos taurus*) and pig (*Sus scrofa*) (EMAE 2004 diclofenac summary report). Both studies followed similar methods. A key difference, however, between the two is the dose of diclofenac given to the two species of cattle. Specifically, 1 mg/kg doses were used in India while the EMA used 2.5 mg/kg doses. The dose used by the EMA is the recommended dose per day for veterinary diclofenac. In both studies, diclofenac depleted from the cattle species slower than from the smaller-bodied animals (e.g. diclofenac was undetectable in goats after 26 hours). Results for Indian cattle show that diclofenac was detectable after 167 hours (~7 days) in cattle viscera. The true concentration of diclofenac in this tissue was below our level of quantification at 10 µg/kg. The EMA results show that diclofenac was detectable after 144 (6 days) in cattle liver (27 µg/kg) and muscle (5 µg/kg). The experiment conducted by Oaks et al. (2004, Nature) shows that a dose as low as 7 µg/kg can kill an Oriental white backed vulture (*Gyps bengalensis*; there is no reason to think that Eurasian griffon (*Gyps fulvus*) would differ greatly from this response given it too is intolerable to low concentrations of diclofenac; Swan et al. 2006, Biology Letters). In addition, among the carcasses of cattle that we sample in India, we have found some that appear to have been treated with double the recommended dose (see Taggart et al. 2006 Environmental Pollution). Larger doses would increase the time needed for diclofenac depletion. It is possible that diclofenac will be misused in this way in Europe, just as it is in India. Therefore, cattle tissue may be lethal to vultures for more than 1 week after diclofenac treatment. This is why only cattle that have lived longer than 10 days in our care are used at Vulture Safe Feeding Sites in Nepal; to ensure that they have metabolised all diclofenac that they may have been treated with. In Europe, withdrawal periods of greater than 10 days for cattle should ensure diclofenac is sufficiently depleted for vulture
6	The role of diclofenac in causing the vulture population declines across India has been definitively determined. Over a decade, vulture populations in this region declined by 99% as a direct consequence of diclofenac poisoning. Even in areas where carcasses were minimally

Stakeholder no.	Comments
	available to vultures, a > 5% decline in the vulture population was recorded. The scale of the impact that diclofenac has had on vultures in India demonstrates unequivocally that depletion of its residues in animal carcasses after death is too slow to render the feeding of exposed animal carcasses to necrophagous birds as harmless. Moreover, multiple birds will be affected by exposure to a single carcass. In some cases over 100 birds have been seen to feed from one carcass. The feeding ecology of these necrophagous birds therefore represents a key mechanism in the ability of only a single carcass to have rapid and devastating impacts on entire populations.
7	The discussion on depletion is not in our opinion relevant, as not all carcasses will be inspected (and certainly not those most available to vultures) and withdrawal times are not monitored officially – the adherence is effectively voluntary and unenforceable. The low dose toxicity means zero use for zero risk is the only justified approach. Whatever the systems put in place by veterinary authorities they cannot be 100% and more likely these measures are virtually worthless with respect to influencing the people and ensuring no risk from the animals that are likely to be sources of diclofenac. There can only be one way to reduce risk, by banning it in the veterinary field. The very fact these questions are being asked reflects a weak understanding about the realities of drug use, disposal and abuse, in the domestic animal environment, even in European Union countries. Recent scandals about meat product description and actual content shows that highly bureaucratic procedures designed to protect consumers are easily circumvented by criminal elements. Attempting to justify diclofenac use behind a screen of legislation, safety measures such as warning labels, unenforceable regulations at slaughterhouses and other systems is a grave error and potentially catastrophic for several species. Extinction is permanent and there is no justification for allowing this to happen in an unnecessary introduction of a redundant pharmaceutical on to the European market, simply for a small profit to be made.
8	**Depletion of diclofenac residues in food producing species** We have data on *diclofenac* depletion for Indian cattle (*Bos indicus*) and goat (*Capra hircus*) (Taggart et al. 2006). The EMA has data on *diclofenac* depletion for European cattle (*Bos taurus*) and pig (*Sus scrofa*) (EMAE 2004 *diclofenac* summary report). Both studies followed similar methods. A key difference, however, between the two is the dose of *diclofenac* given to the two species of cattle. Specifically, we used 1 mg/kg doses while the EMA used 2.5 mg/kg doses. The dose used by the EMA is the recommended dose per day for veterinary diclofenac. Disposition of residues of Diclofenac in Indian cattle (*Bos indicus*) Cmax (1.0 mg/kg i.m., (= recommended dose in India) 4.0 mg/ml at tmax 0.5 hours post inj. Tissue levels at 20h: 30-1000 microgram/kg in muscle, liver, intestine and kidney, etc. time course of data similar to those published in EMEA documentation for 2.5 mg/kg in *Bos taurus* see below (Taggart et al. 2007). In *Bos taurus* EMEA Summary Report (2004) cattle dosed with ^{14}C diclofenac, 2.5 mg/kg i.m. daily for 3 days sacrificed at 3 days post appl. had 0.623, 0.324, and 0.04mg equivalents per kg in liver, kidney and fat, respectively. In non-radiometric depletion studies performed in European calves

Stakeholder no.	Comments
	dosed with 6x 2.5mg/kg (=recommended dose in Europe) resulted in tissue concentrations 3h p.appl. of 3.7, 2.6 ,0.43 and 0.19 mg/kg of diclofenac (incl. 2 major hydroxymeta-bolites) in liver, kidney, skin &f at and muscle, respectively. In both studies (Taggart & EMEA), *diclofenac* depleted from the cattle species slower than from the smaller-bodied animals (e.g. *diclofenac* was undetectable in goats after 26 hours). The Taggart study results show that *diclofenac* concentration was detectable after 167 hours (~7 days) in cattle viscera. The true concentration of *diclofenac* in this tissue was below our level of quantification at 10 µg/kg. The EMA results show that *diclofenac* was detectable after 144h (6 days) in cattle liver 27 µg/kg and muscle 5 µg/kg. The experiment conducted by Oaks et al. (2004) shows that a dose as low as 7 µg/kg can kill an Oriental white backed vulture (*Gyps bengalensis*; there is no reason to think that Eurasian griffon (*Gyps fulvus*) would differ greatly from this response given it too is intolerable to low concentrations of diclofenac). In addition, among the carcasses of cattle that are being sampled in India, some that have been found that were treated with double the recommended dose (see Taggart et al. 2006). Larger doses would increase the time need for *diclofenac* depletion. It is possible that *diclofenac* will be misused in this way in Europe, just as it is in India. Therefore, cattle tissue may be lethal to vultures for more than 1 week after *diclofenac* treatment – and not, like the recent report published by the Spanish governments suggests, only 48 hours. This is why the SAVE programme in India uses cattle that have lived longer than 10 days in their care at Vulture Safe Feeding Sites in Nepal; to ensure that they have metabolise all *diclofenac* that they may have been treated with. In Europe, withdrawal periods of greater than 10 days for cattle should ensure *diclofenac* is sufficiently depleted for vulture consumption as well. But vultures can consume carcasses of animals not for human consumption, like horses (Spain). These animals can be slaughtered without prior withdrawal periods. Further, we do not know the time needed for *diclofenac* depletion in horses, but it is likely to be greater in these larger-bodied animals. There are two obvious problems associated with withdrawal periods in general: 1) it is up to the livestock owner to adhere to withdrawal periods; and 2) what happens to animal products that are found to be within the withdrawal period. Despite good regulation, Europe laws are not immune to human cheating. How is a livestock owner found to be breaching the withdrawal period? Either through checking veterinary logbooks, which can be fudged, or tissue sampling, which leads to tissues requiring disposal. Where do scraps from dodgy carcasses and tissue that fail maximum residue level tests end up? Are these supplied to feeding stations and dumped in *muladares*? Withdrawal periods are designed to protect humans, not vultures. We reiterate, only a very small proportion of carcasses contaminated with *diclofenac* can cause massive declines in vulture populations. In this way, a more precautionary approach is needed to protect Europe's vulture that simple relying on measures designed to protect humans.

Stakeholder no.	Comments
	Summary data on the toxicity of diclofenac in vultures Studies performed in European Griffon Vultures & African White-backed Vultures (Swan et al. 2006) calculated LD50 values (the dose at which half of the vultures die) at 0.098 to 0.225 mg p.o.. In other words, half of the average Griffon vultures will die after ingesting less than 1 mg diclofenac. These data are consistent with results from similar studies in Indian *Gyps*-species: Oriental White-back-, Long-billed-, Slender-billed and also Himalayan Vultures (Oaks et al. 2004, Das et al. 2010). In mice, rats, dogs, rabbits and guinea pigs LD50s range between 95 and 1300 mg/kg about 3 log steps higher! (EMEA Summary Report 2004). Reasons for that unusual increase in toxicity to vultures are somewhat elusive. There is, however, evidence that diclofenac metabolism will result in reactive metabolites that can interfere with MRPs and urate transporters, thus causing irreversible damage of proximal tubular cells and irreversible toxicity of a single dose of diclofenac. The NOEL in those acute studies was as low as 30 micrograms/kg (References can be provided on request). So far no repeated dose data/study chronic toxicity data have been available! The EMEA data demonstrate tissue concentrations in liver of 623, 1040 and 150 microgram equivalents at 3, 7 and 14 days following 2.5mg/kg i.m /day for 3 days. Those data would indicate significant risk for a *Gyps*-vulture on days 3 and 7. An oriental White-backed Vulture, weighing about 4.75kg on an average (Del Hoyo et al. 1994) will eat some 1.02 kg every 3 days. If it ate the liver of one of the calves mentioned above, it would take up some 0.8mg/kg, which is 4 to 8 times the LD50 mentioned above. Though those figures would represent a worst case scenario, they clearly demonstrate the risk of diclofenac ingestion for vultures. European Griffon Vultures, that weigh 7,4 kg (Cramp 1998, Donázar 1993) can eat 1,2 kg of meat in a single meal (Donázar 1993). Given the unusually high toxicity to vultures, calculations published by Green et al. (2004) suggest that a prevalence of 0.13 to 0.75% of critically (i.e. containing an LD50 in one meal) contaminated cattle carcasses would suffice to fully explain the observed vulture declines in India. In other words, the modelling done suggest that in India, 1 in 1000 carcasses containing a lethal concentration diclofenac is enough for a significant decline of >5% per year! Needless to say that a chick fed with contaminated food by its parent will die as well. Due to the social feeding behavior of those gregarious vulture species, hundreds of individuals may be killed by ONE critically contaminated carcass. Though there have been no toxicology studies in Egyptian Vultures or Red Headed vultures, population dynamics resemble those of Indian *Gyps*-species, and thus it has been suggested that diclofenac is also toxic to them (Chaudry et al. 2012). This would be very relevant for the Egyptian vulture, a globally endangered species which has in Spain one of its global strongholds. Further, recent evidence surfaced that some steppe eagles (*Aquila rapax*) also died in India because of veterinary diclofenac (Sharma et

Stakeholder no.	Comments
	al, 2014). The authors of this finding suggest that other closely related eagles such as the Spanish Imperial Eagle (*Aquila adalberti*) or the golden eagle (*Aquila chrysaetus*), both partial scavengers, could also be affected.
9	The marketing authorisation holders submitted: - residue study of diclofenac inj. in bovine tissues including statistical evaluation of withdrawal period;, - residue study of diclofenac inj. in swine tissues including statistical evaluation of withdrawal period;, - Expert Report assessing these studies.

III - List of stakeholders who provided comments on Topic 3

Stakeholder no.	Name of organisation or individual
1	Portuguese Association of Zoo Aquariums (APZA) – Arlete Sogorb
2	• Vulture Conservation Foundation (VCF) - José Tavares • Luca Passalacqua (affiliation not specified) • Società di scienze naturali del Verbano Cusio Ossola - Lucia Pompilio • Associazione CERM Centro Rapaci Minacciati ONLUS – Guido Ceccolini
3	• European Association of Zoos and Aquaria (EAZA) - David Williams-Mitchell • Royal Zoological Society of Antwerp, Antwerp zoo and Planckendael Animal Park - Marleen Huyghe • Danish Association of Zoos and Aquaria (DAZA) - Richard Østerballe • Association Française des Parcs Zoologiques (AFdPZ) - Cécile Erny • Nordens Ark - Emma Nygren • Royal Rotterdam Zoo - Harald Schmidt • The Royal Zoological Society of Scotland - Colin Oulton • Avifauna - Joost Lammers • Beekse Bergen - Lars Versteege • Borås Zoo - Daniel Roth
4	British and Irish Association of Zoos and Aquariums (BIAZA) - Kirsten Pullen
5	• BirdLife International - Iván Ramírez • International Fund for Animal Welfare (IFAW) - Sonja Van Tichelen • Wildlife Conservation Society (WCS) - Janice Weatherley-Singh
6	British Veterinary Association (BVA) and British Veterinary Zoological Society (BVZS) - John Blackwell and Mike Stanford
7	Centre National d'Informations Toxicologiques Vétérinaires (CNITV) - Elodie Adamczyk
8	Copenhagen Zoo - Flemming Nielsen
9	Fatro S.p.A. - Beata Truszkowska
10	Fatro Ibérica S.L. - Eugeni Castells
11	Federation of Veterinarians of Europe - Nancy De Briyne
12	Hawk Conservancy Trust - Campbell Murn
13	IFAH-Europe - David John

Stakeholder no.	Name of organisation or individual
14	Società di ecopatologia della fauna - Vittorio Guberti
15	IUCN Vulture Specialist Group - Chris Bowden and Andre Botha
16	Kalba Bird of Prey Centre - Gerard Whitehouse-Tedd
17	Parques Reunidos - Maria Delclaux
18	IUCN Species Survival Commission Wildlife Health Specialist Group - Richard Kock
19	Italian Association of Zoos and Aquaria (U.I.Z.A.) - Cesare Avesani Zaborra
20	Zoobotánico de Jerez - Iñigo Sánchez
21	Federazione Nazionale Ordini Veterinari Italiani (FNOVI)

III - Comments received on Topic 3

Use of veterinary medicinal products containing diclofenac in the field – which species are treated and how often? What measures are taken to ensure that necrophagous birds are not exposed to residues of diclofenac in treated animals either through feeding stations or inadvertent exposure (e.g. death of treated animals in regions where necrophagous birds are present)?

Stakeholder no.	Name of organisation or individual
1	We believe strongly that the only effective measure to eliminate exposure of necrophagous birds to diclofenac residue would be an outright ban on the drug in all areas where susceptible bird populations are present. We are convinced that alternative measures will not be effective due to lack of awareness of the issue among local populations, lack of veterinary oversight and lack of effective enforcement measures. Carrion eating birds are not predatory and will not affect the livelihood of farmers, and that there is therefore no conflict of interest between human and animal populations resulting from a healthy wild population.
2	**Which species are treated and how often** In Spain veterinary diclofenac is marketed under two brand names, Diclovet, and Dolofenac, (registered by FATRO Iberica SL). In Italy, Italy, veterinary diclofenac is commercialised under the name Reuflogi. (registered by FATRO S.p.A). The drug is marketed to treat MMA (mastitis-metritis-agalactia syndrome) on lactating females, respiratory diseases (bronchopneumonia) and pathologies of the muscle-skeleton (tendinitis, myositis, arthritis), on cattle and pigs (destined for human consumption) and horses (not destined for human consumption). It is administered by intramuscular injection, even though with horses it can also be administered by intravenous injection. It should be administered only with veterinary prescription, and by the veterinarian or under the supervision of the veterinarian. Posology suggested requires inoculation of three doses in three consecutive days. Both Diclovet and Dolofenac have already a warning in the technical fiche that “it should not be administered in animals that have the potential to enter wildlife food chains”. While veterinary diclofenac is not indicated for sheep and goats, this does not necessarily mean that sheep or goats are not subject to diclofenac medication! Given the convenience of administration, veterinary diclofenac would appear to be a very convenient NSAID to

Stakeholder no.	Name of organisation or individual
	be administered by shepherds, if they got the drug for other animals. **How much diclofenac has been sold in Spain & in Italy?** Unfortunately, neither the government nor FATRO have given us figures for the current usage of veterinary diclofenac in Spain (or Italy). However, we know that the AEMPS has had access to the number of doses sold in Spain, from May 2013 to May 2014, and has thus calculated the scenarios used in the recent report published in July 2014 based on those figures. According to the AEMPS, and assuming a 5 times increase in the current number of animals treated (data from May 2013-May 2014), the total number of animals considered for the modelling in the report were (scenario 2, page 25): • 11,000-28,000 cattle in intensive regime • 1,000-2,000 cattle in extensive regime • 35,000-58,000 pork in intensive regime • 300-500 horses This suggests that in the first year of the marketing of veterinary diclofenac in Spain the following animals were treated with diclofenac: 2,200-5,600 cattle in intensive explorations, 200-400 cattle in extensive regime, 7,000-11,600 pigs in intensive regime and 60-100 horses. So in total between 9460 and 27,700 animals were treated with diclofenac in Spain during the first year of marketing of this drug. This figure has the potential to increase exponentially, if FATRO succeeds in implementing a good marketing strategy. New drugs exploding in a market are an intrinsic part of the dynamics of the veterinary drug sector. **How many carcasses of animals treated with diclofenac can reach the vulture food chain?** There is no reliable estimate or figure for the mortality rate of diclofenac-treated animals, as the diseases against which diclofenac is used are not liable to official registration. Hence the recent scenarios published by MAGRAMA are thus only estimates. However, they estimate that in the future, and assuming a 5 times increase in the sales of veterinary diclofenac in Spain from first year levels, ca. 0,1-0,2% of all the carcasses available to vultures in Spain may be laced with diclofenac (page 28). In other words, the estimate produced by the Spanish authorities suggests that there is a probability that 1 or 2 carcasses in every 1000 that are consumed by vultures in Spain may include diclofenac. These figures are within the percentages (0,13-0,75%) of cattle carcasses

Stakeholder no.	Name of organisation or individual
	critically contaminated with diclofenac (i.e. containing an LD50 in one meal) and available to vultures that explained the 99% decline in Indian vultures. **General conclusions** Even the report recently produced by the Spanish authorities ("Análisis del riesgo de uso de medicamentos veterinarios con diclofenaco sobre las populaciones de buitres en España – recomendaciones de actuación y escenarios potenciales de afección", July 2014, MAGRAMA (Direcciones Generales de Calidad y Evaluación Ambiental y Medio Natural (DGCEAMN), Sanidad de la Producción Agraria (DGSPP)) and the Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)) recognises that "there is a risk of mortality of vultures in Spain due to the use of anti-inflammatory products containing diclofenac", page 6). Given that • Veterinary diclofenac is extremely toxic to vultures - half of the Griffon vultures will die after ingesting less than 1 mg • In India, it caused a 99% decline of vultures – the decline observed could be explained if only 1 in 1000 carcasses available to vultures contained a lethal concentration of diclofenac • Between 9,460 and 27,700 animals were treated with diclofenac in Spain during the first year of marketing of this drug alone • Tens of thousands, probably hundreds of thousands, of carcasses of cattle, pork and horses are eaten by vultures alone in Spain • Many of those come from intensive explorations where veterinary control is not individualised • Animal carcasses treated with diclofenac can still kill vultures seven days after treatment (thus even more difficult to control) • Vultures are gregarious eaters, with tens, often hundreds of animals eating from a single carcass. One animal carcass treated with diclofenac would be enough to kill dozens of vultures • Day to day decision on what to send to vulture feeding stations remains in the hand of farm managers, not veterinarians • There is risk that treated cattle in extensive systems can die in the fields and are then almost all eaten by vultures within 1 hour of death • The practical measures suggested to minimise risk to diclofenac would be extremely expensive to set up, and would not be 100% safe 100% of the time, due to lack of enforcement, awareness, and veterinary oversight

Stakeholder no.	Name of organisation or individual
	• According to the Spanish government own estimate, between 0,11 and 0,22% of all carcasses available to vultures could include diclofenac in 5 years – close to the 0,13%-0,75% that caused the 99% decline in India! • Legal availability of diclofenac in Europe causes a precedent and a conduit for a global boom in veterinary diclofenac worldwide • There is an alternative drug with the same therapeutic properties and price (Meloxicam) The VCF concludes that the risk to European vultures is unacceptable, and thus veterinary diclofenac should be banned in Europe. References: Botha, A.J., Ogada, D.L., Virani, M.Z., 2012. Vulture Summit 2012. Chaudhry et al. 2012 First evidence that populations of the critically endangered Longbilled Vulture Gyps indicus in Pakistan have increased following the ban of the toxic veterinary drug diclofenac in south Asia Bird Conservation International / FirstView Article / October 2012, pp 1 9. DOI: 10.1017/S0959270912000445, Published online. Cortés-Avizanda, A., Jovani, R., Carrete, M., Donazar, J.A., 2012. Resource unpredictability promotes species diversity and coexistence in an avian scavenger guild: a field experiment. Ecology 93, 2570–2579. Del Hoyo, J., Elliot, A. and Jargatal, J., Handbook of Birds of the World 1994, Vol.2., 127 Donázar, J., Cortés-Avizanda, A. & Carrete, M. 2010. Dietary shifts in two vultures after the demise of supplementary feeding stations: consequences of the EU sanitary legislation. European Journal of Wildlife Research, 56: 613-621 Duriez, O., Herman, S., Sarrazin, F., 2012. Intra-specific competition in foraging Griffon Vultures Gyps fulvus: 2. The influence of supplementary feeding management. Bird Study 59, 193–206. doi:10.1080/00063657.2012.658640 Frey, H. 1998) Estimation of the costs for captive bred bearded vultures within the framework of the European bearded vulture project. Bearded Vulture Reintroduction into the Alps Annual Report, 1998, 75–77. GREEN, R.E., Newton, I., SHULTZ, S., CUNNINGHAM, A.A., GILBERT, M., Pain, D.J., Prakash, V., 2004. Diclofenac poisoning as a cause of vulture population declines across the Indian subcontinent. J Appl Ecology 41, 793–800. doi:10.1111/j.0021-8901.2004.00954.x Green et al. 2006 Collapse of Asian vulture populations: risk of mortality from residues of the veterinary drug diclofenac in carcasses of treated cattle Journal of Applied Ecology 43: 949-956

Stakeholder no.	Name of organisation or individual
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Stakeholder no.	Name of organisation or individual
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3	EAZA understands that diclofenac is used in Spain and Italy on pigs, cattle and horses, and in Czech Republic and Estonia on horses only. For the purposes of EAZA's involvement with reintroduction of vulture species, our focus is principally directed towards use in Spain and Italy. We believe strongly that the only effective measure to eliminate exposure of necrophagous birds to diclofenac residue would be an outright ban on the drug in all areas where susceptible bird populations are present. EAZA is convinced that alternative measures will not be effective due to lack of awareness of the issue among local populations, lack of veterinary oversight and lack of effective enforcement measures. Conservationists have faced significant struggles to ensure sustainability of vulture populations in areas across Europe. Populations have begun to recover, following reintroduction and establishment of feeding stations and other resources; a ban on diclofenac in veterinary use would essentially safeguard these gains, and allow further work to be done which will be impossible if the ban is not enacted. We believe that it is not an exaggeration to state that conservation efforts will fail without immediate action to ban diclofenac for veterinary use in areas where necrophagous bird populations are present. Carrion eating birds are not predatory and will not affect the livelihood of farmers, and that there is therefore no conflict of interest between human and animal populations resulting from a healthy wild population.
4	BIAZA understands that diclofenac is used in Spain and Italy on pigs, cattle and horses, and in Czech Republic and Estonia on horses only. Our greatest concern focusses on the reintroduction of vulture species, and therefore is principally directed towards the use of diclofenac in Spain and Italy. We believe that the only effective means to eliminate exposure of necrophagous birds to diclofenac residue would be an outright ban on

Stakeholder no.	Name of organisation or individual
	the drug in all areas where susceptible bird populations are present. BIAZA is concerned that lack of awareness or consideration of the issue among local livestock holders, lack of veterinary oversight and lack of effective enforcement measures inevitably means that alternative measures will not be effective. Much work has been achieved in recent years with much struggle, to ensure the sustainability of vulture populations in their ranges across Europe. The recent signs of population recovery, boosted by reintroductions, the provision of feeding stations and other resources, would be safeguarded by a ban on diclofenac. Given that these birds are carrion eating and not predatory, there is no conflict of interest between human and animal populations caused by a healthy population of vultures. We believe that the lack of a ban on the use of diclofenac will jeopardise the work that has been so far achieved in maintaining the populations of threatened vultures. We believe that the conservation efforts to save these populations will fail without a ban on the veterinary use of diclofenac in areas where necrophagous birds are present.
5	In Spain veterinary *diclofenac* is marketed under two brand names, Diclovet and Dolofenac, (registered by FATRO Iberica SL). In Italy, Italy, veterinary *diclofenac* is commercialised under the name Reuflogi (registered by FATRO S.p.A.). According to data compiled by BirdLife International, this drug will be particularly used to treat MMA (mastitis-metritis-agalactia syndrome) on lactating females, especially sows, or respiratory diseases, and limps in cattle. Although the drug is probably more used in penned animals, we are aware that unofficial/illegal dumping of corpses is not rare. Official veterinarians interviewed informed that they are not aware by the authorities of any specific measure to deal with corpses treated with *diclofenac*. *Diclofenac* could also be used on extensive livestock, in particular cattle. BirdLife International partners inform that in most cases, dead animals will be discovered first by vultures and later (and not always) by farmers. This has to do with the very particular characteristics of such farms, occupying very large areas with medium to low cattle density. If any of the *diclofenac*-treated animals dies in the open, it will be virtually impossible for the farmer to collect it before vultures gain access to it. According to scientific evidence, a small number of carcasses with *diclofenac* can have a significant impact on vulture populations and not only locally, but in a wide area, as vultures travel and forage far and wide. A *diclofenac*-laced carcass can impact on vultures from a neighbouring region, or even country, hundreds km away. In Spain, cattle, pigs and horses are the only target species. There is extensive horse farming in many regions, especially, but not only, in northern Spain. Free-range cattle farming is common in most regions. Extensive pig farming is common in southwest Spain. Intensive pig farming is extremely regular in Avila and Segovia provinces as well as in Catalonia, but also in other areas. vultures are abundant in all mentioned areas.

Stakeholder no.	Name of organisation or individual
	We were not given access to official data on the use of *diclofenac* on cattle and pigs in Spain. The product has only been available for a short time, and potentially the amount available is relatively low (although even small amounts can have dramatic effects on vultures). Although in some places they still use the same treatments as before, the spread of the use of any product of this kind depends on the experience of neighbouring farmers. Once a new product starts to be used, it spreads very fast. The only measure taken in the *diclofenac* drug package is the inclusion of a technical note in its technical dossier stating "do not administer to animals susceptible to enter wild animals food chain". This is clearly not enough, having in mind the little attention paid to this kind of recommendation by many users. *Diclofenac* is supposed to be administrated under the supervision of veterinary staff, but in practice this means only that the veterinary will prescribe the drug, but is the farmer who treats the animal. **Expansion to other world regions** Legalising the use of veterinary *diclofenac* would send the signal that its use is acceptable – also probably creating an export market from Europe to other regions. We all know that control systems and procedures elsewhere are substantially weaker than in Europe, so even if billions were spent in setting up the new mechanisms described above in the EU, these would not certainly be followed through in other places, where veterinary *diclofenac* could continue or start to kill vultures. Availability of *diclofenac* in Europe would effectively mean worldwide availability, with significant impacts on vultures worldwide. Vultures are already suffering a steep decline in parts of Africa (Botha et al., 2012), and the mere presence of *diclofenac* in the Mediterranean basin threatens even more of these wild vulture populations. **General conclusions** From our work in South Asia, coupled with our work in Southern Africa, we have direct evidence that *diclofenac* kills vultures (Oaks et al., 2004) (Swan et al., 2006a)and indirect evidence that it kills eagles as well (SHARMA et al., n.d.). In fact, we now think that *diclofenac* may threaten more than 30 species of scavenging raptor worldwide ((unpublished data, but see Sharma et al. 2012 Bird Conservation International). Various other commonly used NSAIDs are also problematical. We also have direct evidence that *ketoprofen* kills vultures (Naidoo et al., 2010) Further, we have indirect evidence that *aceclofenac* (Sharma, 2012) *flunixin (*Zorilla et al. in press) and *nimesulide* (Cuthbert et al. in preparation) kill vultures. Note that evidence for *flunixin* comes from Europe *(*Zorilla et al. in press). We are also currently safety-testing *carprofen* and preliminary results suggest that the level of residue of this NSAID (and maybe others) at the injection site is lethal, even if levels in other tissues are not ((RSPB/UP/UHI, unpublished data). The toxicity for some untested NSAIDs, and very small

Stakeholder no.	Name of organisation or individual
	levels of known vulture-toxic NSAIDs, may not be acute, but cumulative – gradual killing individual vultures over a period.) The only NSAID shown to be vulture safe (to date) is *meloxicam* (Swan et al., 2006a). Many other NSAIDs are available globally; the toxicity of which is unknown. We hope that one or more of these may prove to be vulture-safe to give veterinarians and farmers more choice. There is no impetus in South Asia or Europe to test these drugs and all the above knowledge has been gained through the efforts of non-profit organisations and the donations of the global community concerned with vulture conservation. What is more disturbing is that injectable NSAIDs are effectively exempt from Phase II risk assessment in Europe (due to the way the legislation is currently constructed). Therefore, until this present assessment, the portfolio of peer-reviewed evidence complied over the last decade showing, without a doubt, that veterinary *diclofenac* caused unprecedented declines in vulture populations in South Asia, seems not to have been read before FATRO's *diclofenac* products were approved. Most veterinary NSAIDs in Europe are *meloxicam*-based, which is considered to have fewer side effects for both animals and humans. There is no current market need for *diclofenac*-based products in Europe and, had our work been acknowledged, a precautionary decision might have been made. That decision would have ensured the safety of Europe's vultures; not jeopardised Europe's financial investment in the conservation of vultures; and avoided this current assessment. Therefore, we see a greater problem with how pharmaceutical drugs are approved in Europe, particularly NSAIDs, and call for an immediate ban on veterinary *diclofenac* in Europe and a strengthening of the current environmental risk assessment system **References:** **Reports**: Análisis del riesgo de uso de medicamentos veterinarios con diclofenaco sobre las poblaciones de buitres en españa,Julio 2014.MAGRAMA **Papers in scientific journals** BirdLife International (2004). BirdLife Conservation Series no. 12. BirdLife International, Cambridge, UK. Botha, A.J., Ogada, D.L., Virani, M.Z., 2012. Vulture Summit 2012. Cortés-Avizanda, A., Jovani, R., Carrete, M., Donazar, J.A., 2012. Resource unpredictability promotes species diversity and coexistence

Stakeholder no.	Name of organisation or individual
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6	We are not aware for which species diclofenac is authorised for in Spain and Italy but from the MRL public summary report we note that MRLs have been established for pigs and cattle so one can assume these are the target species for which this active is formulated for use.
7	**INTRODUCTION** The National Center for Toxicological Information Veterinarians (CNITV) is an animal poison control center. Its missions include a particular vigilance to animal (domestic and wilf fauna) toxic exposure. Thus, CNITV was and is still actively involved in national and European projects of reintroduction and conservation of wildlife in general and in particular vultures (1). (1): • "Renforcement et conservation du Faucon Crécerellette dans l'Aude (Fr) et l'Extremadure (Es)". N° LIFE 05 NAT/F/000134 (2005-2009) • "Restauration du vautour Percnoptère dans le sud-est de la France". N° LIFE 03 NAT/F/000103 (2003-2008). **I. DICLOFENAC USE IN LIVESTOCK** Diclofenac is a nonsteroidal anti-inflammatory drug (NSAID) used for many years (in human medecine) for its antipyretic, analgesic and anti-inflammatory properties. In the European Union, diclofenac is sold for use in food producing animals in Italy, Estonia, Lithuania, Czech Republic and Spain. Available specialties are injectable solutions for the treatment of cattle, pigs and horses (not for human consumption) for the following indications : • Acute metritis and mastitis;

- Acute respiratory diseases
- musculoskeletal system diseases (lameness ...).

Dosage and treatment time recommended in the Summary of Product Characteristics (SPC) of the two specialties marketed in Spain (DICLOVET® and DOLOFENAC®) are detailed in Table I

Table I Dosage and treatment time recommended in animals for DICLOVET® and DOLOFENAC® (SPC) [1, 2].

Species	**Posology**	**Route**	**Treatment time**
Cattle	2.3 mg/kg	IM	1 to 3 days
Pigs		IM	3 days
Horses (not for human consumption)		IM (or IV)	3 - 5 days

Even if the SPC of the specialties containing diclofenac only mention use of this molecule in cattle, pigs and horses, this does not preclude practical use in other species such as goats and sheep. Indeed, the directive establishing a Community code relating to veterinary medicinal products (Directive 2001/82 / EC of 6 November 2001) defines the **principle of therapeutic veterinary "Cascade"** applicable throughout the European Union. Veterinarians must prescribe primarily a drug that is licensed (marketing authorization, temporary use authorization or ATU, import authorization or registration in the case of homeopathic medicines) in defined animal species, and therapeutic indications. These authorizations are granted following a scientific assessment to ensure quality, safety and efficacy. Thus, the veterinarian can use the drug safely. However, there are diseases or species for which the practitioner faces no authorized veterinary medicinal product. Also, the off-label use of drugs is allowed under pre-defined conditions. When no authorized veterinary medicinal product is available or appropriate, the veterinarian may prescribe :

1. first-line, a veterinary medicinal product authorized for animals of another species in the same therapeutic indication or for animals of the same species in a different therapeutic indication,
2. if such a drug does not exist, he can prescribe a veterinary medicinal product authorized for another species and for another therapeutic indication,
3. if the drugs mentioned above do not exist, then he may prescribe a drug approved for human use;

4. if no previous medication exists, he may prescribe a last an extemporaneous preparation prepared from a veterinarian's prescription (compliant to good practice extemporaneous preparation by a pharmacist or a veterinarian).

So when we search an anti-inflammatory drugs (NSAID) available in France for the treatment of farm animals, there is a lack of specialties with authorization for use in goats (Table II). Only one NSAID, acetylsalicylic acid based, is allowed in sheep for the following indications: "symptomatic treatment of febrile diseases and / or inflammatory for mild to moderate pain".

Table II. Anti-inflammatory drugs authorized in France for the treatment of farm animals (DMV 2013 and ircp (05/21/2014 last visit)) [4, 5].

Trade name	Composition	Target species				
		Horses	Cattle	Pigs	Ovines	Goats
CALMAGINE	Metamizole	X	X	X		
DIPYRALGINE		X	X	X		
VETALGINE	Acetylsalicylic Acid	X	X	X	X	
TOLFINE	Tolfenamic Acid		X			
NOROCARP	Carprofen		X			
RIMADYL			X			
XELCOR			X			
ANTALZEN	Flunixin	X	X	X		
AVLEZAN		X	X	X		
FINADYNE		X	X	X		

FLUNIXINE 5% NORBROOK		X	X	X		
FLUNIXYL		X	X	X		
GENIXINE		X	X	X		
MEFLOSYL		X	X	X		
RESFLOR	Flunixin + florfenicol		X			
COVUNIL	Flunixin + oxytetracycline		X			
FINOXALINE			X			
COMFORION	Ketoprofen	X	X	X		
KETINK		X	X	X		
KETOFEN		X	X	X		
NEFOTEK		X	X	X		
EMDOCAM	Meloxicam	X	X	X		
LOXICOM		X	X	X		
MELOVEM			X	X		
MELOXIDYL		X	X	X		
METACAM 5 mg/mL			X	X		
METACAM 20 mg/mL		X	X	X		

Far from being banned, the use of diclofenac on species not listed in the SPC (such as sheep and goats) is legalized by the application of veterinary therapeutic « Cascade». This use is made especially easier in practice by the fact that in the countries where they are authorized, veterinary drugs containing diclofenac are much cheaper than other NSAIDs such as meloxicam known for its safety on wildlife when used as recommended [9]. For the user (practitioner, breeder…), it is even more tempting to use diclofenac in species of

Stakeholder no.	Name of organisation or individual
	lesser economic value such as sheep and goats. **II. RISK MANAGEMENT MEASURES APPLIED TO REDUCE THE IMPACT OF DICLOFENAC ON WILDLIFE** The term of risk management measure represents the arrangements implemented to minimize the potential risks of the use of diclofenac on wildlife. To our knowledge concerning this issue, a single management measure has been implemented. The following risk phrase appears on the Summary of Product Characteristics: "Do not use in animals which may enter the wildlife feed chain." This sentence, however, should not be considered in itself as constituting an adequate risk management measure. First of all, it should be noted that this sentence appears only on the DICLOVET® SPC [1], not on DOLOFENAC® SPC [2] although these veterinary specialties containing diclofenac are both marketed in Spain. Moreover, if this risk phrase warns the user against a potentially dangerous use of diclofenac for wildlife, no action is proposed to control that this risk management is effective and sufficient. The establishment of a sampling plan for the detection of residues of diclofenac on animal carcasses intended to be laid on the feeding places (plots) could have been (even partially) an answer to this problem. Please note, however, that supplementary feeding provided through the plots do not represent the bulk of feeding for vultures (which find most of their resources on the corpses of animals found in the wild). In this context, no action would indicate whether the risk represented by the use of diclofenac for the vultures is controlled (consider the difficulty of a sampling plan on dead animals in the wild?). Therefore, it is doubtful that the existence of a single risk phrase on the SPC or leaflet of drugs containing diclofenac could represent an adequate risk management measure. The fact that the delivery of injectable veterinary specialties containing diclofenac is authorized only on presentation of a vet prescription cannot be the guarantee of an appropriate use and comply with the recommendations, in particular the risk phrase. In practice, the packaging of these specialties is such that a single vial allows treatment of several animals (eg. vial 250 mL DOLOFENAC® enables 8 injections in one adult bovine of average size, whereas treatment is only 3 days long max). After the first prescription by a vet, breeders provided with this drug in their farm will inevitably be tempted to use the remaining product in self-medication on other animals from the same farm. This second administration will be achieved without the advice/prescription of a veterinarian, without injection traceability and therefore no reminder of the precautions to take to avoid the impact on vultures. In this context, the negligent administration of diclofenac in goats or sheep (which may be laid afterwards on feeding plots) is probable and should be considered. Containment measures of treated animals are sometimes proposed to manage "diclofenac" risk on wildlife. Thus, the Spanish Medicines

and Health Products Agency has proposed, when diclofenac is administered to animals bred in extensive conditions, to keep treated individuals under control within the 48 hours post injection. [3] This can not be an adequate answer for two reasons:

- first, it is inapplicable in practice. Indeed, when a limp (for example) is detected on an animal just before transport to the summer pastures, this would imply that the animal is kept confined during treatment time (3 days) and 48 hours after the last injection and thus only transported to the summer pasture five days after its congeners. In practice, the NSAID is administered before transport and no monitoring of the animal is ever performed.
- secondly, the definition of such confinement time is based on questionable assumptions. Indeed, the Spanish Medicines and Health Products Agency considers three levels of minimal toxicity of diclofenac from vulture, the smallest being 0.1 mg / kg. This is actually a NOAEL dose (No Observable Adverse Effect Level dose) obtained in various experimental animal models. However, Oaks and al. observed lesions of visceral gout induced by oral administration of a much lower dose of diclofenac, around 0.007 mg / kg, in the vultures of Bengali genre. [6] Swan and al. (2006) have also shown that the diclofenac sensitivity of the (european) griffon vulture is at least as important as the vultures of Bengali genre. [8] Therefore, there is no sufficient data to allow to say with certainty that the vultures but also possibly other species of birds (eagles ...) would not be sensitive to extremely low doses of diclofenac. That information provides a new appreciation of the table detailing the residue depletion of diclofenac in livestock carcasses (Table III) : for example, eating a meal of 1.2 kg of offal (kidney and liver) of a dead animal 96 hours after the last injection of diclofenac exposes a medium sized vulture (7.4 kg) at a dose of 0.014 mg / kg of diclofenac, which is twice the minimum toxic dose (estimated at 0.007 mg / kg)

Table III. Diclofenac residues depletion in cattle carcasses (mg/kg) (Spanish Medicines and Health Products Agency, July 2014) [3].

Time from administration	Liver	Kidney	Fat	Muscle
3 h	2,874	3,244	1,270	0,470
12 h	1,232	1,511	0,504	0,172
24 h	0,426	0,423	0,100	0,047
96 h	0,082	0,088	0,055	0,010

144 h	0,027	0,021	0,009	<0,005
176 h	0,025	0,023	0,010	0,005

Note that these measures of diclofenac residue depletion have not been performed on non-target species such as sheep and goats, species that we have shown that they will undoubtedly receive diclofenac-based treatments.

Finally, therapeutic combinations (with other products such as antibiotics) and the changes they may induce in diclofenac bioavailability have not been taken into account in determining the toxicity of carcasses of the treated animals. Yet Rahal and al. (2008) showed that co-administration of diclofenac and enrofloxacin in sheep causes a decrease in the clearence of the diclofenac and increases the AUC (Area Under Curve) hence plamastic concentrations remain high longer [7]. As a consequence, bioavailability of diclofenac could be doubled when administered IM together with enrofloxacin.

Considering the fact that, in animal farms, an anti-inflammatory drug is rarely used alone (most commonly, it is associated with antibiotic treatment), this example illustrates, if necessary, that the carcass of the diclofenac treated animals can be dangerous for the vultures that feed upon them, during a highly variable time, depending on other medications that could be administered concomitantly. Diclofenac bioavailability was not assessed on the basis of all possible combinations with other drugs, making its carcass toxicity very unpredictable.

Considering the elements above, we warn against the lack of reliable risk management plan (no information for practitioners, no training, no control plan…) deployed to prevent that real toxic threat to wildlife.

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Stakeholder no.	Name of organisation or individual
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8	All necrophagous bird species will be effected by diclophenac.
9	Fatro S.p.A. is MAH of VMPs containing diclofenac authorised nationally since 1993: in Czech Republic and Latvia the product is authorised for sport horses, in Estonia for cattle, swine and sport horses, in Italy there is one product for cattle and swine and one for sport horses. The product is primarily sold in Italy (~ 95%). The main use in the field is in cattle (~ 60%), followed by swine (~ 30%) and horse (~ 10%). In cattle about 90% of the product is used for housed animals in intensive farming, while in swine it is used for housed animals in intensive farming only. The product is sold on veterinary prescription only, not repeatable and in three copies for cattle and swine. Since the first authorisation of the product in the 1990's Fatro has never been aware of any incidents involving necrophagous birds linked to the veterinary use of diclofenac in EU Member states. Furthermore, to ensure that necrophagous birds are not exposed to residues of diclofenac in treated animals, the following precautions for use are under authorisation in Italy: • Contraindications The animals treated with the product must not be allocated to wildlife feeding. The animals treated with the product should not be allocated to feeding stations for necrophagous birds authorized under the

Stakeholder no.	Name of organisation or individual
	Regulations (EC) 1069/2009 and (EU) 142/2011. Do not use in other species except those indicated. • Special precautions for use in animals The treated animals may be kept at pasture only at the end of the withdrawal period (15 days for meat and offal of cattle, 12 days for meat and offal of swine). For non-food-producing horses it is recommended to hold the treated animals for at least 28 days before sending them out to pasture. The following sentence will be reported on the outer package: • Special warnings This veterinary medicinal product is extremely toxic to *Vulturidae (vultures): read carefully the package insert*
10	Veterinary medicinal products containing diclofenac have been marketing in Spain since March 2013. The target species are horses not intended for human consumption, cattle and pigs. The percentage of use by species is between 2-10% in horses, 40-60% in cattle and 30-50% in swine, almost entirely sold in intensive farming. The veterinary medicinal product is administered once a day during 3 days to cattle and swine and during 3-5 days to horses. The main use of the product is to treat musculoskeletal disorders. It should be dispensed under veterinary prescription. Administration should be conducted exclusively by the veterinarian (in the case of intravenous administration) or under the vet's supervision. To ensure that necrophagous birds are not exposed to residues of diclofenac in treated animals, the following precaution for use in animals is included in the SPC and package leaflet: *Do not use in animals that can enter the food chain of wildlife.* Since the authorisation of the product Fatro Ibérica has never been aware of any incidents involving necrophagous birds linked to the veterinary use of diclofenac in Spain.
11	NSAIDs are often used to alleviate pain in livestock. Seeing that diclofenac only recently came on the market in Spain (Diclovet and Dolofenac (registered by FATRO Iberica SL) and Italy, Reuflogi (registered by FATRO S.p.A), FVE could not get figures on the exact use of diclofenac in the field, although from the limited number of replies we received it seems to be used not often.

Stakeholder no.	Name of organisation or individual
	The product seems to be used mainly for (beef) cattle and pigs (mma syndrome, musculoskeletal and joint diseases). In seldom cases, it is used in horses as eye drops and for musculoskeletal problems. It is listed in the Controlled Medication Substances of FEI. Some other NSAIDS are also believed to be possibly toxic to necrophagous birds. Alternative NSAIDs are on the market which respondents say are at least equally effective, no more expensive and some safe for the necrophagous birds.
12	In terms of domestic livestock being treated with diclofenac, we refer to the study by Green et al (2004) *Journal of Applied Ecology* 43: 949-956.This is the definitive and well-recognised study that highlights how a very small proportion (<1%) of carcasses containing diclofenac residues will cause a rapid decline in vulture populations. This very small proportion means that the species treated with diclofenac and the frequency at which they are treated is comparatively irrelevant. With respect to inadvertent exposure, we refer to Topic 1 and the highly efficient foraging behaviour of vultures, which means that fallen livestock carcasses are regularly found by these birds first. This means that, at some point, any livestock veterinary treatment system containing diclofenac will expose vultures to these veterinary medicine residues.
13	The company marketing the products containing diclofenac is not a member of IFAH-Europe. However, IFAH-Europe would like to offer the following contribution to this consultation: First of all, the toxicity of diclofenac to raptors is well established and documented in numerous publications resulting from the investigations on vulture population decline in Asia. In view of this inherent toxicity, the protection goals are very clear and should aim at reducing exposure of raptors to this substance to an absolute minimum, be it via carcasses, drinking water or any other means. Regarding the use of diclofenac in veterinary medicine, we would like to highlight the differences in use of this substance between Asia and Europe, since this has a direct influence on exposure: • In Asia, diclofenac has predominantly been used to allow moribund cattle from animal shelters to walk themselves to the vulture feeding locations where the animals subsequently were left to die. It is obvious that this off-label practice results in high and chronic exposure: high because of the short time span between drug administration and death despite the rapid clearance of the substance in ungulates (Taggart et al (2007) Diclofenac disposition in Indian cow and goat with reference to Gyps vulture population declines. Environmental Pollution 147 (2007) 60-65); chronic because of the high proportion of treated animals at these feeding places (Taggart et al (2007). Diclofenac residues in carcasses of domestic ungulates available to vultures in India.

Stakeholder no.	Name of organisation or individual
	Environment International 33 (2007) 759–765). • In Europe (including Spain): in analogy to their use in human medicine, diclofenac and other NSAIDS are used as symptomatic treatment in addition to targeted therapy of conditions for animal welfare reasons to reduce pain and enhance the animal's defence systems in animals which are meant to be cured, not to die. Should the animals die after treatment, then the legislation cited in topic 1 comes into effect, posing very strict rules on how carcasses are handled within the EU. It should be noted that when animals are sick, they are predominantly contained in sick pens rather than dwelling on pastures, since they typically require multiple days of treatment which would not be practically feasible when they would be dwelling on mountain pastures in areas such as the Pyrenees. This entails a fundamental difference in potential exposure of raptors to the substance. While the intrinsic hazard remains the same, the risk is determined by potential exposure. Veterinary medicines, just like or maybe even more than human medicines are regulated very strictly in Europe. Environmental considerations form an integral part of the risk/benefit analysis, which means that authorisation can be refused by regulatory agencies based on environmental grounds. In the case of the diclofenac containing products, a precaution has been included on the label, indicating that animals treated with these products should not enter the wildlife food chain. This is a result of the overall risk/benefit analysis made by the concerned regulatory agency. Notwithstanding that, the EU-citizen has a right to full transparency and therefore IFAH-Europe can only support the present public consultation, and the fact that product labels, SPCs and public assessment reports outlining the rationale followed by the competent authorities to reach a decision are made publicly available.
14	Bovine is the most treated species. FATRO that is the company that own the mark for veterinary use, did not allow to share with us any information regarding the amount of sold product and in which areas. There are no measures in place to reduce the risk of contamination in case of dead animals especially in mountainous areas (Vulture and eagle main habitat). As commented in Topic 1 almost 20.000 bovines/year are lost in the rural areas of Italy. Birds of prey or other scavengers could easily eat all these carcasses.
15	Comments given in Topic 1 above largely apply to this point and are not repeated here; but we add here some relevant additions relating to other scavenging raptors. From work in South Asia, coupled with that in Southern Africa, we have direct evidence that diclofenac is highly toxic to and kills vultures and indirect evidence that it also kills eagles (see Sharma et al. 2014 Bird Conservation International). In fact, we now believe that diclofenac may threaten more than 30 species of scavenging raptor worldwide. We reiterate that we believe that licensing diclofenac for veterinary use in Europe poses severe and avoidable threats not only to all European vulture species, but also to vultures worldwide.
16	Given the relative ease with which only a single carcass can reap significant effects in a multitude of necrophagous birds, it is apparent

Stakeholder no.	Name of organisation or individual
	that the only effective measure to eliminate exposure of these birds to diclofenac residue is a complete ban on the use of the drug in livestock in all areas in which necrophagous bird species are known to reside or migrate through. A lack of awareness, poor dissemination of information, insufficient veterinary supervision, and lack of effective policing or enforcement measures will mean that any other alternative control method will be meaningless. As such, any measure other than an outright ban is considered to confer significant risk to all European populations of necrophagous bird species, many of which are already threatened with extinction. The sustainability of vulture populations in Europe is not yet assured, despite great efforts by conservationists. Although populations have begun to recover in some areas following reintroduction programmes and the establishment of feeding stations, further work is required to safeguard these populations. The continuity of the gains already achieved from these conservation programmes would no longer be possible if a ban on diclofenac was not enacted. Moreover, without an immediate ban on diclofenac, the complete failure of conservation efforts for European vultures is nearly guaranteed. Banning diclofenac therefore represents a critical step in safeguarding the conservation outputs and would allow for important developments and further gains in vulture conservation. Vultures and other carrion-eating birds play a key role in maintaining the health of ecosystems, and represent no conflict of interest with human land use since they are not predatory and pose no threat to livestock.
17	The only effective measure to eliminate exposure of necrophagous birds to diclofenac residue would be an outright ban on the drug in all areas where susceptible bird populations are present. The vulture populations across Europe have begun to recover, following reintroduction and establishment of feeding stations and other resources; a ban on diclofenac in veterinary use would essentially safeguard these gains, and allow further work to be done which will be impossible if the ban is not enacted. We believe that it is not an exaggeration to state that conservation efforts will fail without immediate action to ban diclofenac for veterinary use in areas where necrophagous bird populations are present. Carrion eating birds are not predatory and will not affect the livelihood of farmers, and that there is therefore no conflict of interest between human and animal populations resulting from a healthy wild population.
18	Our deliberations with the PHARMA industry including with their research divisions showed that the industry has no legal obligation to test for toxicity of their products in birds. Minutes of meetings are available if requested. The protocols do not safeguard birds during tier testing candidate products, which explains why no early warning of the potential toxicity of diclofenac was ever available for bird species. In any case even a product that is environmentally toxic, if it can be proven to be valuable to human health, it will likely be licenced. It took 15 years after diclofenac was widely in use to track its use back the catastrophic decline of 3 gyps species. This was

Stakeholder no.	Name of organisation or individual
	after the drug became generic and where recall was impossible and despite its ban in South Asia, it is still widely available and used in animals where human drug remains in pharmacies and controls on prescription are weak. These are all important reasons for use of the precautionary principle on NSAID licencing and use in animals and for stronger environmental protection legislation on pharmaceuticals and for introduction of toxicological testing on birds. The industry resists doing this as the costs are already extremely high to get a product to the market and given the extremely weak legislation to product biodiversity and the environment generally they are not moved to act independently on this matter. The only process that could be employed is the Stockholm convention and this is too cumbersome a process taking 15 years to achieve results in most cases – far too long to prevent this sort of scenario experienced in South Asia.
19	As far as we know, in Italy pigs, cattle and horses are treated with veterinary medicines containing diclofenac. We strongly believe that the only effective measure to eliminate exposure of necrophagous birds to diclofenac residue would be an outright ban on the drug not only in Italy but in all areas where susceptible bird populations are present. UIZA, together with the European Association of Zoos and Aquaria, is convinced that alternative measures will not be effective, due to the lack of awareness of the issue among local populations, lack of veterinary oversight and lack of effective enforcement measures.
20	We understand that diclofenac is used in Spain and Italy on pigs, cattle and horses, and in Czech Republic and Estonia on horses only. For the purposes of our zoo involvement with reintroduction of vulture species, our focus is principally directed towards use in Spain and Italy. We believe strongly that the only effective measure to eliminate exposure of necrophagous birds to diclofenac residue would be an outright ban on the drug in all areas where susceptible bird populations are present. We are convinced that alternative measures will not be effective due to lack of awareness of the issue among local populations, lack of veterinary oversight and lack of effective enforcement measures. Conservationists have faced significant struggles to ensure sustainability of vulture populations in areas across Europe. Populations have begun to recover, following reintroduction and establishment of feeding stations and other resources; a ban on diclofenac in veterinary use would essentially safeguard these gains, and allow further work to be done which will be impossible if the ban is not enacted. We believe that it is not an exaggeration to state that conservation efforts will fail without immediate action to ban diclofenac for veterinary use in areas where necrophagous bird populations are present. Carrion eating birds are not predatory and will not affect the livelihood of farmers, and that there is therefore no conflict of interest between human and animal populations resulting from a healthy wild population.

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21	A. I rapporti ufficiali comunitari sui risultati dei Piani Nazionali integrati dei controlli disponibili dal 2009 al 2012 indicano che la molecola diclofen (diclofenac) appartenente alla categoria B.2.e “Anti infiammatori non steroidei” è riscontrata come non conforme su campioni di varie matrici alimentari umane tra cui le carni di ungulati domestici vedi tabella 1. E’ ragionevole che anche i relativi sottoprodotti contenessero diclofenac. Un’indagine sulle vendite della specialità contenente diclofenac effettuate nel 2013 da parte di 3 grandi distributori di farmaci veterinari (ed 1 piccolo) del nord est dell’Italia ricadente nell’area dove vive una folta colonia di grifoni intorno la stazione di alimentazione n.1, ha portato ai seguenti risultati: localmente quasi sconosciuto: 3 pz da 100ml e 8 pz da 250 ml, Grande distributore X 199 pz da 100ml e 37 pz da 250 ml, Grande distributore Y 20 pz da 100 ml e 59 pz da 250 ml, Grande distributore Z 31 pz da 100 ml e 48 pz da 250 ml. Dai Grandi distributori 2 e 3 il dato specie target: bovini da carne specialmente in alternativa terapeutica ai cortisonici in quanto l’eventuale residuo sulle carni viene trattato dalla legge italiana come trattamento anabolizzante. Il principio attivo è quindi significativamente presente nel territorio, considerato che è stato da poco riautorizzato. B. L’Autorità Competente nazionale ha emanato 2 note (allegato 1 e 2) ma la possibilità di differenziare sottoprodotti provenienti da animali non sottoposti a trattamento terapeutico con diclofenac è inapplicabile specialmodo per la specie suina dove le patologie muscoloscheletriche e articolari sono tra le cause frequenti di conclusione della carriera produttiva. Ad esempio i bovini che non risultano idonei al trasporto per difficoltà locomotorie (zoppie) sono abbattuti in azienda e mandati al macello regolarmente, viceversa i suini con difficoltà di deambulazione (quindi facilmente oggetto di trattamento con anti infiammatori non steroidei) non lo sono e se la terapia non ha successo vanno a finire tra i sottoprodotti dell’allevamento.

IV - List of individuals who provided general comments

Stakeholder no.	Name of organisation or individual
1	Brian Gormley (affiliation not specified)

IV - Comments received

Stakeholder no.	Comments
1	I can see no valid reason why Diclofenac should be licenced for veterinary use in the EU given the overwhelming evidence from the Indian sub-continent of its catastrophic effect on carrion feeding raptors in that region. In India it caused an exceptionally rapid 99% decline of a number of vulture species there. It has since been withdrawn in four countries in the region, including India, as has been well documented. The EU commission naively believes that "conditions differ significantly from those of certain third countries". As the medical prescription regime in Spain and Italy (where Diclofenac is currently authorised) is lax relative say to Ireland, one can only presume that the veterinary prescription system leaves even more to be desired. The EU commission is delusional if it believes that the regulations for the disposal of fallen stock (1069/2009) are adhered to throughout the Union and that there is veterinary oversight of the disposal of all dead animals. A walk across upland, livestock farmland anywhere in the EU should be enough to demonstrate the reality. It has been shown that as little as one in 760 carcasses need contain diclofenac to ensure the virtual extinction of the Indian Vulture for one ***. If the EU still has any aspirations of "high environmental standards" in its agricultural production then an immediate ban on the production, use and export of veterinary Diclofenac should be put in place. *** **IUCN 2014. *The IUCN Red List of Threatened Species.*** *Version 2014.2*. http://www.iucnredlist.org/details/22729731/0 ***Gyps indicus*** This species is classified as Critically Endangered because it has suffered an extremely rapid population decline as a result of mortality from feeding on carcasses of animals treated with the veterinary drug diclofenac. **Major Threat(s):** By mid-2000, *Gyps* vultures were being found dead and dying in Pakistan and throughout India, and major declines and local

Stakeholder no.	Comments
	extirpations were being reported. The anti-inflammatory drug diclofenac, used to treat domestic livestock, has been identified as the cause of mortality, with renal failure resulting in visceral gout in the vast majority of examined vultures (Oaks *et al*. 2004a, Shultz *et al*. 2004, Swan *et al*. 2005, Gilbert *et al*. 2006). Modelling has shown that **to cause the observed rate of decline in the species just one in 760 livestock carcasses need contain diclofenac** residues (Green *et al*. 2004). Despite awareness programmes to educate locals about the association between diclofenac and vulture mortality, a survey in Nepal indicated that the vast majority of people still do not link diclofenac use to a decline in vulture populations (Paudel 2008), potentially leading to a slower uptake of meloxicam (a safe alternative). A second veterinary drug in use in India, ketoprofen, has also recently been identified to be lethal to the species, and measurements of residue levels in ungulate carcasses in India indicates that concentrations are sufficient to cause vulture mortalities (Naidoo *et al.* 2009). Other likely contributory factors are changes in human consumption and processing of dead livestock (which have occurred in response to the collapse in vulture numbers), poison and pesticide use, and possibly avian malaria (Poharkar *et al.* 2009), but these are probably of minor significance.