Diclofenac in Europe – an update

✓ Diclofenac: non-steroidal anti-inflammatory substance
✓ Vet *diclofenac* caused 95-99% decline in Indian Gyps vultures in 20 years
✓ Vet *diclofenac* in Europe
✓ Safe alternative exists
✓ Legal availability of *diclofenac* in Europe causes a precedent and a conduit for a global boom in veterinary *diclofenac* worldwide
Diclofenac kills vultures

- Kidney failure
- Death within two days
- LD50 (dose at which half of the vultures die): 0.098-0.225 mg p.o.
- Toxicity up to 1 week after diclofenac treatment
- Withdrawal periods for diclofenac: 12 days for pigs & 15 days for cattle.
Diclofenac in Europe

- Manufactured by Italian company (FATRO)
- Used in cattle, pigs and horses, subject to veterinary prescription, and application by veterinaries (intravenous) or under vet supervision (intramuscular)
- Used to treat mastitis-metritis on lactating females, respiratory diseases (bronchopneumonia) and pathologies of the muscle-skeleton (tendinitis, myositis, arthritis)
- First authorised in 1993 (Italy)
- Since 2009 in a number of countries (Estonia, Czech Republic, Latvia)
- 2013 in Spain
Diclofenac in Europe

- Between **9,460** and **27,700** animals were treated with *diclofenac* in Spain during the first year of marketing of this drug alone
- 10% of diclofenac used in animals in extensive pastures
- Spanish gov. estimated: **15 – 39** Eurasian griffon vultures will die /year
- Green & Margalida (2014): **683-4792*/year
Diclofenac in Europe – time line

2009 - Approved in Italy (Reuflogin)
2013 - Approved in Spain (Diclovet & Dolofenac)
Dec 2013 – VCF informed
Jan 2014 – VCF and other conservation organisations write and meet EU Commission and ask for banning of diclofenac
Mar 2014 - VCF & others contact FATRO and asks for voluntary withdrawal of the market – refused
2014 - VCF & others campaign. Press work. Petition (50,000 signatures). IUCN, CMS, WCS, EAZA, SCB, OIE all support campaign
Den Geiern droht Gefahr

Eine Armee für Kinder hat die Geierpopulationen Iberiens fast ausgerottet. Nun kommt sie auch in Spanien auf den Markt, wo 80 Prozent der europäischen Geier leben. Von Hansjakob Baumgartner

TIER UND MENSCH

Das Sterben der Totengräber

Ein unverhältnismäßig hohes Medikament für Nutzfütter gefährdet Ausmaße - Vor allem in Spanien könnten Geier und Adler deshalb sogar aussterben

Midi Libre

Troubles de l’équilibre: les kinés peuvent aider

En Lozère, la professionnelle estime que la rééducation est bénéfique pour les patients et les personnes âgées. [Page de Midi Libre] F.3

Faune Un médicament met en péril tous les vautours

Syté Un des otages libérés raconte leur détention

Font-Romeu Martin Fourcade ou le retour de l'entraîneur biologique

VULPINAIRE

Le coup de fond de d'Aubert pour Houellebecq

Fragonard

VULTURE CONSERVATION FOUNDATION

Vulture Conservation Foundation
Vulture culture at threat from diclofenac

VULTURE (Vulturinae), the only known obligate vulture species, has been an endangered species for the last 20 years.

The decline of vulture species can affect diversity, development and conservation of various species, as well as the potential consequences of this phenomenon. In the future, we need to think about how to protect these species from diclofenac.
Diclofenac in Europe – time line

Aug 2014 - EU Commission asks the European Medicine Agency (EMA) for scientific opinion
Oct-Nov 2014 – public consultation and hearing. VCF contributes
Dec 2014 - EMA decision
EMA Decision

✓ Confirmed risk for vultures and other necrophagous birds in the European Union

✓ Risk identified at two exposure scenarios - feeding stations from non-slaughterhouse material and fallen stock
EMA Decision

✓ Considers that further regulatory action is needed (e.g. implementation of additional risk management measures)
✓ These are wide ranging, from banning the drug to labelling
✓ EMA could not evaluate the effectiveness of all of the proposed measures as several of them cannot be quantified at present or do not fall within its remit. Therefore, it did not make a recommendation on which of them would be most appropriate.
EMA Decision

Annex I

Summary of considered risk management measures

✓ Information to veterinarians
✓ Warnings in the product literature
✓ Change in the administration pattern of the VMP
✓ Changes in the food chain information
✓ Increase controls in farms intentionally leaving dead animals in the field
✓ Accompanying of document for by-products
✓ Sampling scheme
✓ Withdraw diclofenac products from the EU market

In conclusion, the EMA was of the opinion that additional risk management measures are needed and efforts should focus on determining the most suitable and effective ones to ensure that contaminated carcasses do not end up in the food chain of vultures and other necrophagous birds.
Diclofenac in Europe – time line

Dec 2014 - EMA decision
Feb 2015 – EU Commission decides, after consulting with member states (MS), NOT ban the drug, and asked MS to develop mitigation plans, to submit by April
Jun 2015 – National action plans submitted to the EU
National Mitigation Action Plans

1. Information to veterinarians - BG, CZ, LI, PL, ES, SE, IT
2. Warnings in the product literature - BG, CZ, EE, IT, ES, SE, IT
3. Changes in the administration pattern of the VMP - BG, CZ, EE
4. Changes in the food chain information - PT, IT
5. Increase controls in farms intentionally leaving dead animals in the field - PT, IT
6. Accompanying of document for by-products - PT
7. Sampling scheme - HR, CY, ES
8. Withdraw diclofenac products from the EU market - AT, SE
National Mitigation Action Plans - Italy

Italy takes almost no measures. They have amended the labelling – indicating that animals treated cannot be fed to wild fauna and not put on feeding stations, and that animals can only be sent out grazing after the withdrawal period. They also previously send out note to feeding stations and veterinarians.
Spain takes even less measures. They have amended the labelling – a general sentence indicating that Diclofenac should not be administered to animals that will be eaten by wild fauna. They send out a note to veterinarians. They are planning to set up a scheme to test sick and dead vultures, but at first will rely on the wildlife rescue centres to provide them with information.

Spain explicitly decides not to change the prescription method, as they claim it is not practically possible. They also will not change the Food Chain information and the documentation of byproducts.
Last year’s meeting

✓ Implement public campaign to detect head dropping birds – not done - capacity
✓ Explore diclofenac in water in farms in Spain line – cost!!!
✓ Continue work in press, work with vets and advocacy - ongoing
Diclofenac in Europe – future options

Lobbying/Advocacy
Member states to improve action plans
Continue to battle for ban
Press work

Sampling in the field
In Andalucia, only 15% of all tissue vulture corpses taken to centers were tested against diclofenac presence (5 griffons in 2014-2015)
Beyond Diclofenac

✓ Vet drugs (NSAIDs, euthanasia agents, antibiotics) - probably a bigger threat than we think or know – Fluxininin, anti-parasitics

✓ EU risk assessment guidelines + testing toxicity of existing and new drugs on vultures