

Legal Battle to Protected Vultures from Diclofenac Poisoning

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Abstract:

The drug controller general, government of India had banned the veterinary use of diclofenac in way back in July 4th, 2008. It sparked fresh hopes for the survival of the critically-endangered vulture species, the nature's clean-up crew! But the drug was still available in large multi- dose vials of 30 ml labelled '*not for veterinary use*', facilitating the illegal veterinary use of the drug, which caused further decline in vulture populations. To avoid this, the Ministry of health and family welfare, Government of India, passed a blanket ban on multi-dose vials (MDV) of diclofenac, through a notification issued on July 17, 2015. But, this ban was challenged by a pharmaceutical company and the stay was issued on 29th December, 2017 by the Madras High Court. It took 2 years for the hearings to be completed and a judgement for upholding the ban was passed by the High Court in 23rd October, 2017 which reinstated the sense of hope to vulture conservation.

Keywords:

Vulture, multi-dose vials of diclofenac, impugned provision, petition, affidavit, critically endangered, conservation

Introduction:

A notification issued on July 17, 2015 by the union health ministry states that the diclofenac formulation for human use will henceforth be available only in a single dose pack. This brought a relief to vulture conservationists, but that relief was short lived.

While I made a casual visit on the early morning of 29-12-2015, to meet Dr. Vijaykumar, a veterinary doctor, he showed me the news item titled "High Court Stays the prosecution over the ban of Multi Dose Vials of diclofenac".

It was a shock and I was speechless for a moment Then I shared the sad news with fellow conservationists and they expressed their concern over the news.

. I was started thinking, "Large organizations can engage in court proceedings against large drug companies, but what I can do in this situation? The task was humungous - limited resources, lack of legal expertise, the urgency of conservation of vultures all in front of me and a formidable adversary in the form of the pharma companies.

Finally, I decided to face the situation head-on.

First of all, I wanted to collect the case details based on this news but I had no previous experience in court proceedings.

Way forward overcoming constraints

I contacted Lajapathirai , an Environmentalist Advocate known to me. Since he is practising in the Madurai High Court, he directed me to contact an Advocate *Thilakeswaran*, who practises in the Madras High Court.

When I contacted him, he asked me to come in person. I travelled to Chennai (Madras) the very next day and explained to him about vultures and the urgent need to save them. He wanted to know the details of the writ petition filed by the drug company for preparing a petition for impleading and said that this might take a few weeks and he would call me after collecting the details. His words encouraged me when he said, he would not demand fees, and accept what I can afford, as he wanted to be part of this good cause.

He called me within a week and informed that he had collected the case documents. He also informed me that the document copy could be collected from his office before 6pm. It was already 5pm then.

I called *Nagaraj*, my friend, who was near the advocate's office and I requested him to collect the documents. He collected the documents within an hour and called me. After that, I contacted another one friend *Britto* to scan and send the documents to my mail id. It was already 8pm and he could not do it. Then I contacted *Ragunath Krishna*, a volunteer of Arulagam. He agreed to help and sent the scanned copy to me by email the same night.

I went through the details. But, I was not able to grasp most of the points raised by the petitioner. I was kept on reading and got some idea. Following points were noted from the affidavit filed by the company.

The Details of the Case

The writ petitioners attacked the provision in the ban of Diclofenac injections and its formulations in animal use on various grounds and they can be summarized as follows:

- a) The basis for introduction of the ban is not supported by any systematic, scientific and long duration study and the same has not been documented by any Governmental Agency.
- b) The ban has been brought in, not on account of misuse on human beings, but on suspicion that vultures die on feeding on carcasses of animals, which were administered the Drug, i.e., Diclofenac 72 hours before their death;
- c) Diclofenac injections in 30 ml multi dose packs are supplied only to specialty hospitals and Nursing Homes, besides registered Medical Practitioners. They are economical and efficacious;
- d) MDV of Diclofenac injection are absolutely essential for treatment as an analgesic i.e., as an NSAID for various conditions in human beings.
- e) There are malafides behind the introduction of the ban as the same has been brought in to promote one particular pharmaceutical company.
- f) There is no evidence on record to show that Diclofenac has been misused and diverted in large scale for use in animals.
- g) The ban was issued prior to conclusion of Drugs Technical Advisory Board (DTAB) constituted for this purpose which held its 63rd and 64th meetings held on 16.05.2013 and 19.07.2013 respectively.
- h) If the diclofenac drug for human use is used illegally to treat animals, there are many ways to control the misuse.
- i) The drug was manufactured prior to the ban order and distributed all over India and it is not possible to withdraw all of them. Hence, action on pharmacists by authorities should be stopped immediately.

Experts' Role

Due to my knowledge is limited, I shared the case details with experts in this field namely *Vibhu Prakash*, *Sashikumar*, *Chris Bowden* and *Toby Galigan* and requested them to send scientific details to respond to this writ petition. They sent all scientific documental evidences published in international journals and ban orders on diclofenac in Nepal, Bangladesh, Pakistan and Iran issued in their official gazettes. We attached the proven claim by Professor *Rhys Green* of University of Cambridge that just 1% of diclofenac residue in a carcass is sufficient to kill thousands of vultures.

Then, I also shared the details with *K. Mohanraj*, volunteer, Arulagam, Homi RSK of Bombay Natural History Society) and *Devendra Swaroop* of Indian Veterinary Research Institute. I collected their views and submitted all the above documents to the advocate, but he expressed his time constraints to read all the research papers and requested us to highlight the relevant sections. *Sasikumar* of Malabar Natural History Society helped in this exercise and attached remarks, which were submitted to the advocate.

The advocate wanted to include the details such as my background and what motivate me to show interest in this case. I provided him the details that I have been working for 25 years in environmental conservation and I have been working to conserve vulture species in Tamil Nadu

during the past five years. Besides, I have written 3 books and more than 200 articles in Tamil language on wildlife and environmental issues. He included those details and submitted the impleading petition.

Our Response to the petition

Our submissions can be broadly summarized and encapsulated as below:

- a) Vultures play the critical role of sanitizing the ecosystem as a keystone species. They are irreplaceable.
- b) There is enough statistical and scientific proof to show the decline in vulture population and that diclofenac is the major cause.
- c) Since they are critically endangered, and wiped out from most of its earlier home range and hence collecting carcasses of vultures for testing diclofenac residue is very difficult.
- d) The ban was introduced in public interest on the basis of sanctified precautionary principle.
- e) People prefer to use diclofenac as it is cheaper than the alternate safe drug.
- f) 3 ml vial is enough for human use. Repeatedly using 30 ml vials on a single individual may cause contamination.
- g) Since it is people that purchase drugs for both cattle and themselves, it is difficult to know who they are purchasing them for.
- h) The judgement given by Justice *K. S. Radhakrishnan* on “Protection of Wild Buffalo” is a precedent where the judgement was given without full scientific evidence considering the gravity of the situation.
- i) India is a signatory to the 1992 Biodiversity Convention and therefore should not allow the decline of vulture population, as the objective of the biodiversity convention is that, wherever there is threat of reduction or loss of biological diversity, lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimize such a threat.

The day arrived

18-02-2016, It was the first time I entered the court proudly for a public interest case.

There were a lot of cases to be heard on that date and I was eagerly waiting. Our case was taken only in the late afternoon session for hearing. Our advocate felt that it would be more appropriate if senior advocate *Radhakrishnan* appeared for this case and requested him to do so.

So, *Radhakrishnan* appeared and pleaded that, banning the MDV pack is the policy decision taken by government of India. And, there are strong evidences available on diclofenac is the cause for reduction in vulture population and even though the drug is banned but the pilferage is continuing. Hence the stays order to be vacated to save the endangered vulture species.

The Objections by the Pharma Companies

The advocate appearing for the Pharma Company objected my intervention stating that I don't have a scientific background and I have no rights to respond. And that only the union government should respond. Moreover, all the information that I submitted were downloaded from the internet. Hence my impleading petition to be dismissed.

Intervener

However, the honourable judge allowed me to continue as an intervener and my advocate as an amicus curie. This gave me an opening to witness and get periodic updates on about what is going on in the hearings. Vibhu prakash and Sashikumar gave me a moral support by joining me couple of time during the hearings.

Judge remarks

The honourable judge questioned the urgency of announcing the ban without waiting for the DTAB report. The Ministry of health and family welfare, Government of India responded stating that the ban was not on the drug itself, but only on the size of the vials and hence there was no need of waiting for the expert opinion. But the honourable judge did not accept this argument. He ordered to form a committee and submit a report.

Another threat

Based on the traction that *Laborate* got from this case, another company named *Alpa* joined as a second petitioner, whereby they would benefit from the proceedings.

Court order

Since there was no progress in forming a committee until the next hearing, the honourable high court in its hearing dated 17th June, 2016 directed: “minutes of DTAB dated 16th May 2013 should be given affect to and committee of the persons mentioned aforesaid stands constituted to submit its report to the DTAB with a copy to be placed before us. The committee may also obtain the opinion of the petitioner”.

Meanwhile, *Seshan*, a wildlife enthusiast, joined as an impleader and advocate *Yogeshwaran* appeared for him.

The Committee Report

The hearings were repeatedly postponed for the next 6 months due to non-receipt of the expert committee report. Finally, the committee submitted their report during January 2017 after sitting through as many as 9 meetings.

In that report, committee pin pointed out that, “the decision of DTAB was minuted in 2013 but the notification was issued two years later. The reasons for this gap were not clear”.

Questions to the petitioner

As per the direction of the court, the committee also tried to obtain the petitioner’s view by raising the following questions

- a. Production data of diclofenac injection of all pack sizes manufactured by you year wise since 2008 till date.
- b. Market share of your formulations of diclofenac injections
- c. Financial loss suffered due to the restriction of pack size of diclofenac injection
- d. Number of other manufactures of MDV of diclofenac

The Petitioner’s Response:

Financial Year	30 ML	3 ML
2007 - 08	3321180	2817500
2008 - 09	7868970	3246000
2009 - 10	10532225	2301550
2010 - 11	6243384	4095194
2011 - 12	7624220	4755000
2012 - 13	8566180	8753500
2013 - 14	10065550	13554050
2014 - 15	17029175	9321750
2015 - 16*	18929070	5840650

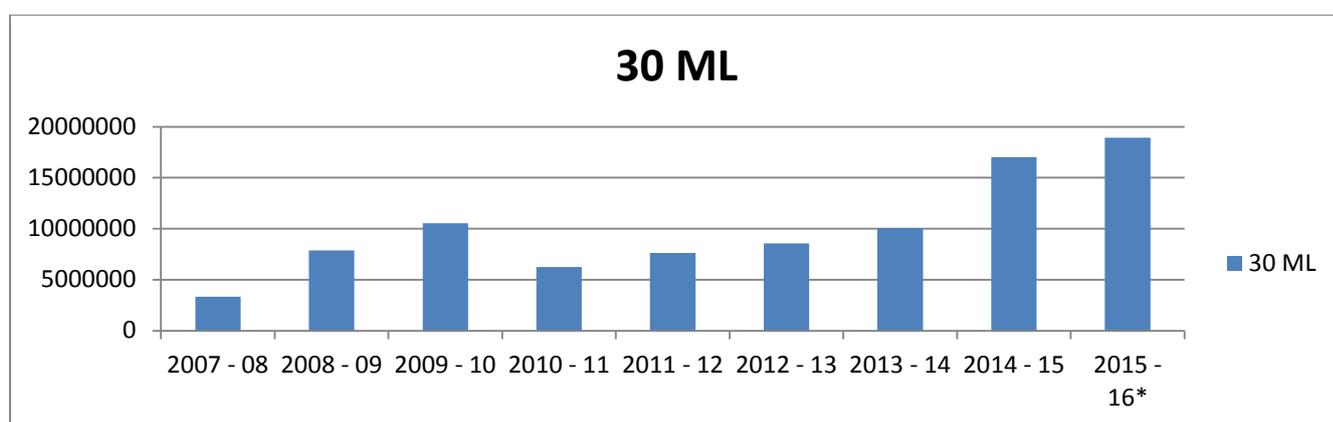
Table 1

The petitioner responded only for the production details of year-wise production. They have not responded to the rest of the questions. From the figures we can deduce that they have not faced any financial loss, but substantial increase in the sale of 30 ml and 3 ml vials. The figures clearly say that the company income become manifold.

**Our visualisation based on figures provided by the petitioner can be seen below in figures 1 & 2.*

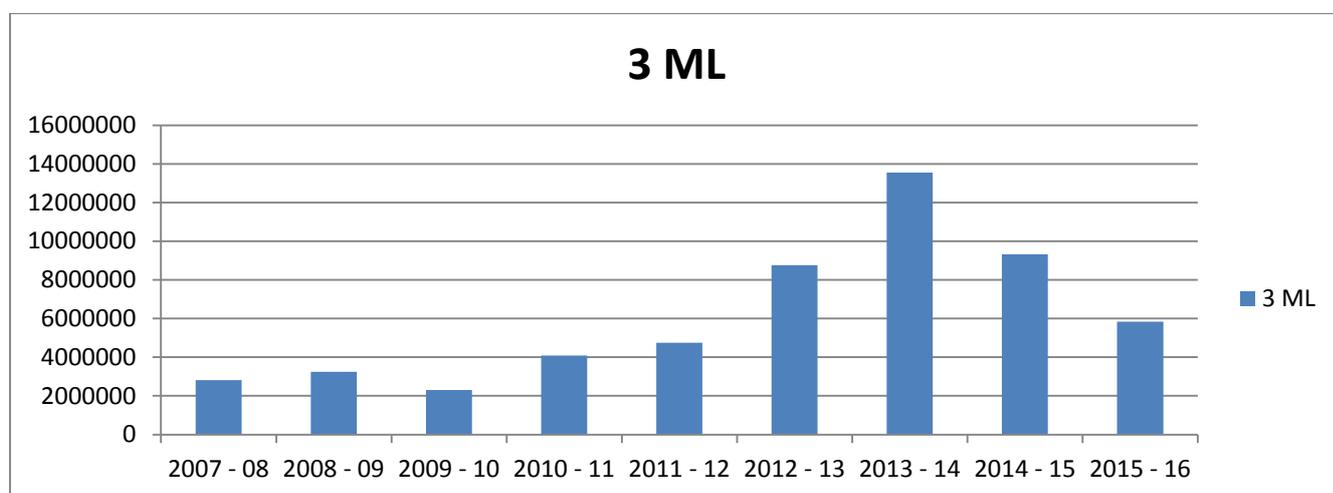
This showed the production grew significantly (25 times increase) when there was an expectancy of ban coming through. This seemed to have been deliberate.

Figure 1



*It is to be noted that the figures pertaining to 2015 – 16 only shows their production from April to June 15th (just 75 days). This is only in the case of the 30 ml vials.

Figure 2



3ml production chart

Recommendations by the Expert Committee

The expert committee also obtained the views of the Ministry of health and family welfare, Environment and Forest (MoEF & CC), Animal Husbandry, Government of India and scientist Dr.Vibu Prakash of BNHS. Based on those, the committee recommended as below.

- 1) The prohibition of diclofenac resulted in significant reduction rate of death of vultures as demonstrated by modelling studies. This justifies the continued prohibition of use of diclofenac in animals. Further, additional measures of reducing the environmental contamination of diclofenac and other pharmaceutical products namely other NSAIDs, antibiotics, anticancer drugs etc. be enforced. This can be done by a synergy and

comprehensive approach by regulatory bodies, pharmaceutical industry, public awareness, stringent enforcement of biomedical waste regulations etc..

- 2) Although the correlation of diclofenac residue has been shown with reduction in vulture population, still stronger evidence is required. Therefore, continued adequately powered well-structured epidemiological studies and casualty studies are required.
- 3) As far as the MDV pack size of diclofenac injection meant for human use is concerned, there is no strong evidence of its pilferage leading to its misuse in animals, which is sufficient to cause significant adverse impact in vulture population. However, the possibilities of its misuse in animals as **alleged by NGO's cannot be ruled out**.
- 4) The committee is of the opinion that no disadvantage to the patient community will occur by withdrawing the MDV of diclofenac as a precautionary approach. More evidence based data and not the opinion or perception is required to take a considered view on withdrawal of MDV of diclofenac for human use. This also includes feedback from practising physicians, clinics, nursing homes and hospitals.

Though the report was unbiased, it was a double-edged sword and we could not make much headway with the same. But honourable judge drew valid point from the report like ...'misuse of the drug cannot be ruled out'

Response from the Ministry of Health and Family Welfare, Gol

On behalf of the Ministry of Health and Family Welfare, Gol, Dr. Manivannan, Deputy Drug Controller, CDSO, submitted the counter-affidavit to the petition with passion and enthusiasm. This was a shot-in-the-arm to our case. It can be broadly crystallized and summarized as follows:

- a) Vultures are universally accepted as Natural Scavengers and absolutely essential for environmental and ecological balance. Therefore, preservation of vulture population is non-negotiable.
- b) The ban has been introduced in public interest.
- c) The ban has been introduced after taking into account the views of stakeholders. Views of stakeholders were obtained by publication of draft rules and inviting objections and suggestions from the stakeholders and public on the proposed impugned provision.
- d) The possibility of misuse of 30ml packs in animals and the possibility of diversion for use in animals cannot be ruled out even according to the report of the Expert Technical Committee appointed by this Court.
- e) As a corollary to the preceding point, Government of India would submit that they have brought in the ban on the basis of the sanctified precautionary principle impelled by public interest.
- f) The pharma companies seem to have just their commercial interest, without social responsibility.

Argument by senior Government Counsel

Senior Government Counsel *Rajagopalan* refuted the argument from the petitioner that the government institutions have not done any study on the role of misuse of diclofenac and their impact on vulture population. In support of this, he quoted a study done by the Indian Veterinary Research Institute (IVRI), where it has been clearly documented how the drug was being misused with state-wise data. He also brought the judges' attention the judgement against Macleods Pharmaceuticals Limited, which was given on the basis of precautionary measures without sufficient scientific evidence.

Summary of discussions and judgement

On patient hearing of both parties, the Hon'ble Ms. Indira Banerjee, Chief Justice and The Hon'ble Justice Mr. M. Sundar delivered their historic milestone judgement.

One of the highlight in the verdict was the court chose to use the term '**Natural Sanitary Worker**' instead of the term 'Natural Scavenger'.

- Vultures are universally accepted as sanitary workers, which clear carcasses of domestic livestock/cattle and thereby protect ecological balance. 'Vulture population in India is on the decline, it has an adverse impact on the ecological balance / environment and therefore, such decline in vulture population needs to be arrested' - this is the central theme of the genesis of this lis.
 - There is no dispute amongst the parties to the lis before us that the aforesaid vultures are critically endangered species and the nucleus is a pharmaceutical product, which goes by the name Diclofenac.
 - The expert committee filed its detailed report in this Court on 01.02.2017. The findings returned by the expert committee to the effect that the possibility of misuse of Diclofenac in animals has, as urged by Non-Governmental Organisations (NGOs) cannot be ruled out.
 - The Committee is of the opinion that no disadvantage to the patient community will occur by withdrawing the MDV pack size of diclofenac injection as a precautionary approach.
 - One crucial aspect of the matter to be noted is that the petitioners were given adequate opportunity by the Expert Committee, but the writ petitioners replied to just one of the many questions.
 - The study was not conducted just by the NGOs, but also by the Indian Veterinary Research Institute, which conducted a state-wise study of the presence of Diclofenac-positive ungulate samples, which shows the rampant use of diclofenac.
 - We cannot wait till we get complete evidences and researches; it will be too late to act. The precautionary principle and the polluter pays principle have been accepted as part of the law of the land.
 - The state shall endeavour to protect and improve the environment and to safeguard the forest and wildlife of the country, to protect and improve the natural environment including forests, lakes, rivers and wildlife and to have compassion for living creatures.
 - There is a need for an exclusive parliamentary legislation for the preservation and protection of endangered species, so as to carry out the recovery programs before many of the species become extinct.
- a) Article 21 of the Constitution of India guarantees protection of life and personal liberty.
 - b) Articles 47 of the Constitution talks on duty of the State to raise the level of nutrition, the standard of living and to improve public health;
 - c) Articles 48A of the Constitution guarantees Protection and improvement of environment and safeguarding of forests and wild life;
 - d) Articles 51 A (g) of the Constitution guarantees to protect and improve the natural environment including forests, lakes, rivers and wild life, and to have compassion for living creatures.

As we are accepting the precautionary principle theory advanced as an argument by the learned Solicitor, lack of decline in vulture population post 2012 argument of writ petitioners also pales into insignificance.

Moreover, referred to what the Supreme Court had to say in a judgment; National Wildlife Acton Plan- NWAP (2002-2016) has already identified species like the Great Indian Bustard, Bengal Florican, Dugong, the Manipur Brow Antlered Deer, over and above Asiatic Lion and Wild Buffalo as endangered species and we are therefore inclined to give a direction to the Government of India and the MoEF to take urgent steps for the preservation of those endangered species as well as to initiate recovery programmes.

Petition dismissed

Finally, the Court dismissed the writ petition of Laborate Pharmaceutical India Ltd. and Alpa Laboratories Ltd and upheld the ban on MDV of diclofenac and the drug will be available only in single dose vials of 3ml.

Appreciation by the court

In the judgment, Honorable Judge appreciated our role and mentioned as two public spirited individuals *Seshan* and *S.Bharathithasan* for submitting various documents. Thanks to *Mr.A. Yogeshwaran*, advocate for drawing the Court attention to the judgments of the Honourable Supreme Court of India.

Hallmark Judgement

This judgement is an important one in protecting not only vulture species but also other endangered species.

We can hope that Vultures will soar high again in the sky in the near future.

Acknowledgments:

My contribution in this court case is limited; however I should mention many individuals who helped voluntarily.

All hearings will be notified only on the previous day late evening and Mr. Sundar, assistant to government counsel informed the same to me each time through text messages by midnight. I record my sincere thanks to him.

Lenin and Nagaraj, Volunteers of Arulagam made arrangement for travel tickets and stay etc for every visit to Chennai for attending the court hearings. Mac Mohan needs a mention here for giving advices in various aspects including the precautionary principle.

Jack Tordoff (CEPF), Sashikmar (MNHS), Chris Bowden (SAVE), Vibhu prakash (BNHS), Toby (OBC), Homi RSK (BNHS), Kiran (RRCF), Dr. C. Maheswaran and Ramesh venkatraman of Junglescapes, Gagan Pathik of Ashirvadam Foundation were eagerly asking the status of the case and encouraging me.

Thanks to Mr. S. Chandrasekar, bird enthusiast for gave the book "Aftermath of diclofenac & Vulture conservation in NBR".

I would like to mention the following persons in this case. Advocates Lajapathirai, Thilageswaran, Radhakrishnan, Yogeswaran, Junior Advocates – Vetriselvan Surya, Nila, Logeswari and Santhanaraman of the Green Tribunal.

I also would like to mention my appreciation for the timely hep of Britto, Vasanthi Rubert, Kalaivani Anand, and Rammohan for their support. I also want to convey my regards to Seshan, wildlife enthusiast for voluntarily impleading in this case. Thanks to the media especially The Indian Express, Deccan chronicle and The Hindu for publishing the article.

That I could spend the better part of the last 2 years with peace of mind was entirely due to the limitless love and patience of my family. Their support ensured that I remained strong and willing to take up any challenge that came my way.

I extend my sincere thanks to P.Kalyanasundaram and Raghunath Krishna for translating this article from Tamil to English.

I also would like to mention the support of Ministry of Environment and Forest and Climate Change, Indian Veterinary Research Institute (IVRI), Ministry of Health and Family Welfare, Bombay Natural History Society (BNHS), Salim ali Center for Ornithology and Natural History

(SACON), Oriental Bird Club (OBC), Mohamad Bin Zayed Species Conservation Fund (MBZ), Rufford Foundation, Saving Asia's Vulture from Extinctions (SAVE), Royal Society for the Protection of Birds (RSPB) and Ashirvadam Foundation.

The Chronology of Events

Chronology of events		
S No	Hearing Date	Event
1	27.11.15	Gazette Notification dated 17.7.15 on Ban of MDV of diclofenac was challenged by laborate pharma
3	29.12.15	Stay order issued by the court
4	17.2.16	Impleading petition filed by me
5	07.4.16	Judge questioned why did the expert committee was not formed
6	17.6.16	Judge ordered to form the Committee
7	23.8.16	Court itself formed the committee
8	01.2.17	Expert Committee Report submitted
9	02.02.17	Counter affidavit filed by the Deputy Drug Controller, CDSO, Gol
10	03 to 09	Argument from March,2017 to September 2017
10	24.10.17	Judgment announced and stay removed

Supported documents

1. Collapse of Asian Vulture Population -- Rhys E.Green et all. - Journal of applied ecology
2. Diclofenac residues as the cause of Vulture population decline - Pakistan - Lindsay oaks et all - Letters to Nature
3. Diclofenac poisoning is widespread in declining vulture populations across the Indian Subcontinent - Susanne Schultz et all - Proceedings of The Royal Society
4. Toxicity of diclofenac to Gyps vultures - Gerry E swan et all Biology letter
5. Rate of decline of oriental WBV - Rhys E.Green et all. - PLOS one
6. Recent Changes of population - V.Prakash et all - JBNHS
7. Assessing the on-going threat - Richard J.Cuthbert et all - Oryx
8. The population decline of Gyps vultures in India and Nepal - Vipu prakash et all - PLOS one
9. Post-mortem report- SACON, India - Dr. Muralidharan, SACON
10. Continuing mortality of vultures in India - Richard J.Cuthbert et all - Oryx
11. Diclofenac monitoring in cattle and buffalo carcasses surveyed in 2009-10 & investigating other causes of mortality in vultures in India - IVRI & BNHS
12. Action plan for Vulture Conservation in India, MoEF- GOI
13. Supreme Court of India- TN Godavarman Thirumalpad Vs Union of India - Judgement by Justice KS Radhakrishnan
14. The urgent need and justification for ban of all multi dose human diclofenac vials larger than 3ml - Chris Bowden
15. Regional Declaration on the conservation of South Asia's Critically Endangered Vulture Species - Governments of Bangladesh, Nepal, India & Pakistan