


Procedure file

Basic information	
COS - Procedure on a strategy paper (historic)	2001/2054(COS)
Veterinary medicinal products: availability	Procedure completed
Subject	3.10.08 Animal health requirements, veterinary legislation and pharmacy

Key players			
European Parliament	Committee responsible	Rapporteur	Appointed
	ENVI Environment, Public Health, Consumer Policy	PPE-DE DOYLE Avril	09/01/2001
Council of the European Union	Committee for opinion	Rapporteur for opinion	Appointed
	AGRI Agriculture and Rural Development	The committee decided not to give an opinion.	
European Commission	Commission DG	Commissioner	
	Internal Market, Industry, Entrepreneurship and SMEs		

Key events			
05/12/2000	Non-legislative basic document published	COM(2000)0806	Summary
15/03/2001	Committee referral announced in Parliament		
10/04/2001	Vote in committee		Summary
10/04/2001	Committee report tabled for plenary	A5-0119/2001	
02/05/2001	Debate in Parliament		
03/05/2001	Decision by Parliament	T5-0230/2001	Summary
03/05/2001	End of procedure in Parliament		
31/01/2002	Final act published in Official Journal		

Technical information	
Procedure reference	2001/2054(COS)
Procedure type	COS - Procedure on a strategy paper (historic)
Procedure subtype	Commission strategy paper
Legal basis	Rules of Procedure EP 142

Stage reached in procedure	Procedure completed
Committee dossier	ENVI/5/14131

Documentation gateway

Non-legislative basic document		COM(2000)0806	05/12/2000	EC	Summary
Committee report tabled for plenary, single reading		A5-0119/2001	10/04/2001	EP	
Text adopted by Parliament, single reading		T5-0230/2001 OJ C 027 31.01.2002, p. 0022-0080 E	03/05/2001	EP	Summary

Veterinary medicinal products: availability

PURPOSE : the present communication aims to find possible answers to the health-care and welfare needs of food-producing animals on a basis guaranteeing a high level of consumer protection, in a context which presents a satisfactory economic interest for the medical veterinary industry. **CONTENT** : The Commission proposes as part of the general process for revision of the marketing authorisation system, to take account of the special features of the veterinary sector and the question of the availability of veterinary medicinal products. The Commission intends to finalise its proposals along these lines in 2001. The process, however, will take several years to complete. The heart of the problem, and its urgency, reside in the absence of Community MRLs for a large number of "old" active substances used to treat certain species.

Thought must also be given to measures aimed at a sustainable broadening of the range of new veterinary medicinal products on offer in the "minor" segments of the market. The Commission trusts that the prospects opened by the measures for the short term (MRL extrapolation) and the medium term (revision of existing legal instrument) will reverse the current trend and also facilitate the sustainable development of new therapies for the species and indications which are currently ignored by the veterinary pharmaceutical industry. The Commission is nevertheless continuing its reflections on the possibility of developing in parallel a policy analogous to the "orphan drugs for human use" scheme for veterinary medicinal products, by means of a specific legal instrument. The paths to be explored should seek in particular to define indirect incentives to promote the development of the new veterinary medicinal products specific to these abandoned market segments (reduced registration fees, technical assistance from the Agency, longer exclusive market rights, and others). Direct incentives could be considered (financial contributions to R&D, reimbursement of certain investments on granting of marketing authorisation, voluntary co-financing by associations of breeders of the species concerned). But the Commission considers that if such a proposal should see the light of day, the scope and the ways and means of its application will need to be precisely identified.?

Veterinary medicinal products: availability

The committee adopted the report by Avril DOYLE (EPP-ED, IRL) on the Commission communication. The committee called for urgent measures to tackle the shortage of veterinary medicines, saying that the situation had reached crisis level with serious consequences for animal health and welfare. The shortage of local anaesthetics, in particular, was creating "unacceptable situations". The committee backed the short-term measures announced by the Commission to make more drugs available and called, in the longer term, for a pan-European licensing system to enable veterinary medicines to move more freely between Member States. It also wanted the use of substances without MRLs to be allowed for horses.?

Veterinary medicinal products: availability

The European Parliament adopted the report by Mrs Avril DOYLE (EPP/ED, Ire) on the availability of veterinary medicinal products. (Please refer to the previous document).?