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Committee on Agriculture and Rural Development

2008/0045(COD)

24.6.2008

DRAFT OPINION

of the Committee on Agriculture and Rural Development

for the Committee on the Environment, Public Health and Food Safety

on the proposal for a directive of the European Parliament and of the Council amending Directive 2001/82/EC and Directive 2001/83/EC as regards variations to the terms of marketing authorisations for medicinal products (COM(2008)0123 – C6-0137/2008 – 2008/0045(COD))

Rapporteur: Petya Stavreva

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SHORT JUSTIFICATION

The draftswoman is in favour of the Commission proposal and wishes to see harmonisation of medicinal products take effect also as regards the marketing of medicinal products for human and veterinary use.

So far, only a small proportion of the medicinal products are subject to harmonized European legislation (around 20 %, i.e. those products that had received their authorisation in accordance with two accepted procedures, "centralised" and "mutual recognition"). Those products that have a purely national authorisation are not regulated by the current European legislation on variations and subsequently are dealt with through specific and varying national rules. This is both inefficient and lead to significant economic costs, in addition to affecting the proper functioning of the internal market. The present directive would grant legal basis for harmonisation and would permit for the adoption of implementing measures through comitology with regards to all types of variations.

The rapporteur is in favour of harmonisation, which will bring great benefits to both consumers and industry and would speed up the access to the latest medicines across the Member States. So far, the lack of harmonisation with regards to variations has caused great delays and inefficiency, from both an economic point of view and also as regards the needs of the veterinary medicinal sector. It is also illogical to have harmonisation for every stage in the lifecycle of a product except when it comes to changes brought to it.

Nevertheless, there is a need to be careful about the implied costs for the Member States and a proper schedule for achieving harmonisation in practice. Member States cannot be called on to change their internal regulations in order to comply with the present directive and further changes adopted through comitology in a period of time that is too short and that implies too high costs.

In accordance with the Impact Assessment conducted, the public consultation and the position papers submitted by regulatory agencies of the Member States, proposals by the draftswoman focus on several points.

Firstly, we need to achieve a schedule for harmonisation that corresponds to variations in preparedness between Member States. In the papers submitted, there have been different calls for different schedules and it is apparent that a 2-year period for transposition is preferred by a significant number of Member States. We need to take these into account as it is essential to the real implementation of harmonisation into practice.

Secondly, we need to further stress the need for Parliament supervision of legislation adopted under comitology. We need to be able to supervise the legislative process through the regulatory procedure with scrutiny.

Thirdly, the draftswoman believes Parliament should call for the simplification of the Variations Regulations. This issue was raised by several participants in the public consultation and we need to ensure that the Variations Regulations we have in place at the moment do not create unnecessary bureaucracy for the Member States, companies and the citizens.

AMENDMENTS

The Committee on Agriculture and Rural Development calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to incorporate the following amendments in its report:

Amendment 1

Proposal for a directive – amending act
Recital 6

Text proposed by the Commission	*Amendment*
(6) For reasons of public health, legal consistency ***and*** predictability for economic operators, variations to all types of marketing authorisations should be subject to harmonised rules.	(6) For reasons of public health, legal consistency***, reducing the administrative burden and strengthening*** predictability for economic operators, variations to all types of marketing authorisations should be subject to harmonised rules.

Or. en

Amendment 2

Proposal for a directive – amending act
Recital 6 a (new)

Text proposed by the Commission	*Amendment*
	(6a) It is necessary to revisit current administrative procedures as laid down in the Variations Regulations (EC Regulations 1084/2003 and 1085/2003), with a focus, in particular, on simplifying administrative procedures.

Or. en

Amendment 3

Proposal for a directive – amending act
Article 3 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by [***12*** months after entry into force] at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.	1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by [***24*** months after entry into force] at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

Or. en