PARLAMENT EWROPEW

2004 *2009*

Kumitat għall-Agrikoltura u l-Iżvilupp Rurali

2008/0045(COD)

24.6.2008

ABBOZZ TA' OPINJONI

tal-Kumitat għall-Agrikoltura u l-Iżvilupp Rurali

għall-Kumitat għall-Ambjent, is-Saħħa Pubblika u s-Sikurezza ta' l-Ikel

dwar il-proposta għal direttiva tal-Parlament Ewropew u tal-Kunsill li temenda d-Direttiva 2001/82/KE u d-Direttiva 2001/83/KE fir-rigward tal-varjazzjonijiet għat-termini ta' l-awtorizzazzjonijiet għat-tqegħid fis-suq ta' prodotti mediċinali
(COM(2008)0123 – C6-0137/2008 – 2008/0045(COD))

Rapporteur għal opinjoni: Petya Stavreva

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ĠUSTIFIKAZZJONI QASIRA

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.

EMENDI

Il-Kumitat għall-Biedja u l-Iżvilupp Rurali jistieden lill-Kumitat għall-Ambjent, is-Saħħa Pubblika u s-Sikurezza ta' l-Ikel, bħala l-Kumitat responsabbli, sabiex jinkorpora l-emendi li ġejjin fir-rapport tiegħu:

Emenda 1

Proposta għal Direttiva- att li jemenda
Premessa 6

Test propost mill-Kummissjoni	*Emenda*
(6) Għal raġunijiet ta' saħħa pubblika, konsistenza legali u previdibbiltà għall-operaturi ekonomiċi, varjazzjonijiet għat-tipi kollha ta' l-awtorizzazzjonijiet għat-tqegħid fis-suq għandhom ikunu soġġetti għal regoli armonizzati.	(6) Għal raġunijiet ta' saħħa pubblika, konsistenza legali, ***tnaqqis tal-piż amministrattiv u t-tisħiħ tal***-previdibbiltà għall-operaturi ekonomiċi, varjazzjonijiet għat-tipi kollha ta' l-awtorizzazzjonijiet għat-tqegħid fis-suq għandhom ikunu soġġetti għal regoli armonizzati.

Or. en

Emenda 2

Proposta għal Direttiva- att li jemenda
Premessa 6 a (ġdida)

Test propost mill-Kummissjoni	*Emenda*
	(6a) Jeħtieġ li l-proċeduri amministrattivi attwali jiġu riveduti kif stipulat fir-Regolamenti dwar il-Varjazzjonijiet (Regolamenti KE 1084/2003 u 1085/2003), billi, b'mod partikulari, ikun hemm iffukar fuq is-simplifikazzjoni tal-proċeduri amministrattivi.

Or. en

Emenda 3

Proposta għal Direttiva- att li jemenda
Artikolu 3 – paragrafu 1 – subparagrafu 1

Test propost mill-Kummissjoni	*Emenda*
1. L-Istati Membri għandhom idaħħlu fis-seħħ il-liġijiet, ir-regolamenti u d-dispożizzjonijiet amministrattivi meħtieġa sabiex jiġu konformi ma' din id-Direttiva sa mhux aktar tard minn [12-il xahar wara d-dħul fis-seħħ]. Immedjatament għandhom jikkomunikaw lill-Kummissjoni t-test ta' dawn id-dispożizzjonijiet u tabella ta' korrelazzjoni bejn dawn id-dispożizzjonijiet u din id-Direttiva.	1. L-Istati Membri għandhom idaħħlu fis-seħħ il-liġijiet, ir-regolamenti u d-dispożizzjonijiet amministrattivi meħtieġa sabiex jiġu konformi ma' din id-Direttiva sa mhux aktar tard minn [***24***-il xahar wara d-dħul fis-seħħ]. Immedjatament għandhom jikkomunikaw lill-Kummissjoni t-test ta' dawn id-dispożizzjonijiet u tabella ta' korrelazzjoni bejn dawn id-dispożizzjonijiet u din id-Direttiva.

Or. en