SENATE OF THE REPUBLIC

XVIth PARLIAMENTARY TERM

Doc. XVIII

No 149

RESOLUTION OF THE 12TH STANDING COMMITTEE

(**Hygiene and Health**)

(Rapporteurs: GRANAIOLA and DE LILLO)

adopted at the sitting of 28 March 2012

CONCERNING THE

AMENDED PROPOSAL FOR A DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL AMENDING DIRECTIVE 2001/83/EC AS REGARDS INFORMATION TO THE GENERAL PUBLIC ON MEDICINAL PRODUCTS FOR HUMAN USE SUBJECT TO MEDICAL PRESCRIPTION (COM (2012) 48 FINAL)

CONCERNING THE

AMENDED PROPOSAL FOR A DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL AMENDING REGULATION (EC) NO 726/2004 AS REGARDS INFORMATION TO THE GENERAL PUBLIC ON MEDICINAL PRODUCTS FOR HUMAN USE SUBJECT TO MEDICAL PRESCRIPTION (COM (2012) 49 FINAL)

CONCERNING THE

PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL AMENDING REGULATION (EC) NO 726/2004 AS REGARDS PHARMACOVIGILANCE (COM (2012) 51 FINAL)

AND CONCERNING THE

PROPOSAL FOR A DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL AMENDING DIRECTIVE 2001/83/EC AS REGARDS PHARMACOVIGILANCE (COM (2012) 52 FINAL)

pursuant to Article 144(1) and (6) of the Rules of Procedure

Communicated to the Office of the Prime Minister on 30 March 2012

CONTENTS

The Committee,

having examined:

– the amended proposal for a Directive of the European Parliament and of the Council amending Directive 2001/83/EC as regards information to the general public on medicinal products for human use subject to medical prescription (COM(2012) 48 final);

– the amended proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 726/2004 as regards information to the general public on medicinal products for human use subject to medical prescription (COM(2012) 49 final);

– the proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 726/2004 as regards pharmacovigilance (COM(2012) 51 final);

– the proposal for a Directive of the European Parliament and of the Council amending Directive 2001/83/EC as regards pharmacovigilance (COM(2012) 52 final);

whereas the objective of the package of Commission proposals, as shown by the reports, is to introduce amendments to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 and to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 to ensure the proper functioning of the internal market for medicinal products for human use and to better protect the health of EU citizens;

noting that the proposed COM(2012) 48 final and COM(2012) 49 final aim to provide for a clear framework for provision of information by marketing authorisation holders about their prescription-only medicines to the general public with a view to enhancing the rational use of these medicines, while ensuring that the legislative framework continues to prohibit direct-to-consumer advertising of prescription-only medicines;

whereas the aim is therefore to:

– ensure the high quality of information provided by coherent application of clearly defined standards across the EU;

– allow information to be provided through channels addressing the needs and capabilities of different types of patients;

– allow marketing authorisation holders to provide in an understandable way objective and non-promotional information about the benefits and the risks of their medicines;

– ensure that monitoring and enforcement measures are in place to ensure that information providers comply with the quality criteria, while avoiding unnecessary bureaucracy;

whereas the proposals aim in particular to optimise the availability of information, promoting the interoperability and promotion of various data banks and portals concerning medicines and health operating within the Union; as regards the provision of information to the general public about prescription-only medicines for human use, the intention is to:

1) establish a single, automatic procedure in the event of serious safety issues concerning products authorised at national level to ensure that the problem is assessed and tackled in all Member States in which the medicine is authorised;

2) reformulate the information obligations on the holder, so that any voluntary withdrawal of a marketing authorisation does not entail the possibility of circumventing existing safety issues in the Union;

3) submit for vetting by the European Medicines Agency any information contained in websites registered with the national competent authorities of the Member States concerning medicines for human use authorised in accordance with the Regulation, and information concerning medicines authorised within the meaning of that Regulation, by means of a series of derogations from the Directive;

whereas the first proposals to amend Regulation (EC) No 726/2004 and Directive 2001/83/EC were drawn up by the European Commission in documents COM(2008) 662 final and COM(2008) 663 final respectively; the European Parliament has adopted a series of amendments to the package which have largely been accepted by the European Commission; COM(2008) 662 final and COM(2008) 663 final have therefore been amended following the adoption by the European Parliament of legislative resolution P7_TA(2010)0429;

whereas the resolution affirms, among other things, the central nature of patients' rights; the usefulness of eliminating differing interpretations of 'advertising' [and] 'information' in the Member States; the need to provide as much information as possible to individuals and the general public, and in forms appropriate for blind and visually-impaired people; the use of national competent authorities and health professionals to ensure the provision of information to the general public, with an obligation for the latter to publicly declare any interests linking them to marketing authorisation holders; the usefulness of using specific channels to provide information on medicines; the need for the Member States to establish specific monitoring and enforcement mechanisms in the event of failure to comply with the regulations; these mechanisms should be harmonised at Union level to ensure their coherence; the recognition of a consultative role for associations of health professionals, patients, consumers and health operators;

whereas European patients are more determined to play an active role as consumers in the health sector, calling for more information concerning medicines and medical treatment;

whereas, with regard to pharmacovigilance, the amendments in COM(2012) 51 final and COM(2012) 52 final are intended to ensure transparency in the surveillance of authorised medicines, strengthening the European system and harmonising pharmacovigilance regulations throughout the Union, which cannot be accomplished sufficiently by the Member States and is therefore better accomplished at Union level;

whereas, in particular:

– the list of medicinal products subject to additional monitoring established by Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 should systematically include medicinal products that are subject to post-authorisation safety conditions;

– voluntary action by the marketing authorisation holder should not lead to a situation where concerns related to the risks or benefits of a medicinal product authorised in the Union are not properly addressed in all Member States;

– provisions should be made for the marketing authorisation holder to inform the Agency of the reasons for the withdrawal of a medicinal product, for interrupting the placing on the market of a medicinal product, for requests for revoking a marketing authorisation, or for not renewing a marketing authorisation;

whereas European consumers have the right to obtain further information on matters relating to pharmacovigilance and the risk-benefit ratio for the medicines they are taking;

whereas certain alarming data have driven the European Union to pay greater attention to adverse drug reactions; it is estimated that five per cent of hospital admissions are due to adverse drug reactions, that five per cent of hospital patients suffer adverse drug reactions, and that they are the fifth-ranking cause of death in hospitals, with approximately 197 000 deaths per year in the EU and an annual social cost of approximately EUR 79 billion within the EU;

whereas it is also necessary to tackle the growing problem of fake or counterfeit drugs, which constitute a major threat to public health;

with regard to Protocol No 2 on the application of the principles of subsidiarity and proportionality, attached to the Treaty of Lisbon, the Committee considers that the proposals are in line with the principle of subsidiarity both in terms of the need for the Union institutions to act and with reference to the value added by the Union, and that, as regards the principle of proportionality, they are in line with the intended objectives;

with regard to the substantive elements, the Committee expresses a favourable opinion, within its area of competence, with the following comments:

a) in terms of ensuring the right of patients to receive complete and targeted information on authorised prescription-only medicinal products, overcoming the current disparities in access, the information obligations on the marketing authorisation holders, referred to in particular in Article 100b of Directive 2001/83/EC as amended by COM(2012) 48 final, should be sufficient to promote appropriate use of pharmaceutical products for pediatric use and for the treatment of elderly people and women, permitting the current limit concerning gender profiles in information on the use of pharmaceutical products, with particular regard to their effectiveness and related risks, to be exceeded. This objective appears consistent with the condition laid down in Article 100d(1)(b) of Directive 2001/83/EC as amended by COM(2012) 48 final, whereby the information made available to the public 'shall be patient-oriented to adequately meet the needs and expectations of patients';

b) the objectives referred to in a) should also refer to information concerning medicinal products which marketing authorisation holders publish on websites registered within the meaning of Article 100h of Directive 2001/83/EC as amended by COM(2012) 48 final;

c) the condition referred to in Article 100d(1)(f) of Directive 2001/83/EC as amended by COM(2012) 48 final, whereby the information made available to the public 'shall be understandable and legible for the general public or members thereof', should also be aimed at

overcoming the issues encountered by elderly people regarding the form of communication and the writing on information documents contained in medicinal products;

d) with reference to the objectives of COM(2012) 51 final and COM(2012) 52 final regarding transparency in the surveillance of authorised medicines, measures should be adopted to promote more widespread and focused research into and testing of pharmaceutical products for pediatric use, to overcome the current shortage thereof; it is essential that specific lines of action be identified at EU level concerning information on the risks and benefits of pharmaceutical products for pediatric use;

e) with reference to the objectives of COM(2012) 51 final and COM(2012) 52 final regarding transparency in the surveillance of authorised medicines, measures should be adopted to overcome the current limits concerning gender profiles, determined by the insufficient level of research into and testing of pharmaceutical treatments for women.

RESOLUTIONS OF THE FOURTEENTH STANDING COMMITTEE

(EUROPEAN UNION POLICIES)

(Rapporteur: SIRCANA)

Rome, 15 March 2012

The Committee, having examined COM (2012) 48 final and COM (2012) 49 final,

having regard to the examination, at the European institutions, of the original proposals COM(2008) 662 final ("Proposal for a Regulation of the European Parliament and of the Council amending, as regards information to the general public on medicinal products for human use subject to medical prescription, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency") and COM(2008) 663 final ("Proposal for a Directive of the European Parliament and of the Council amending, as regards information to the general public on medicinal products subject to medical prescription, Directive 2001/83/EC on the Community code relating to medicinal products for human use");

Having examined, in particular, the discussions within the Council of the European Union, which highlight views among the national delegations which are not always favourable, and the proposed amendments drafted by the European Parliament on 24 November 2010 contained in legislative resolution P7_TA(2010)0429;

noting:

– the replacement of the original proposals quoted above by COM(2011) 632 final ("Amended proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 726/2004, as regards information to the general public on medical products for human use subject to medical prescription and as regards pharmacovigilance") and COM(2011) 633 final ("Amended proposal for a Directive of the European Parliament and of the Council amending Directive 2001/83/EC, as regards information to the general public on medical products for human use subject to medical prescription and as regards pharmacovigilance");

– the withdrawal and entire replacement of the documents indicated above by the documents COM(2012) 48 and COM(2012) 49;

– the extract of the rules on pharmacovigilance, incorporated into COM(2012) 51 and COM(2012) 52,

fully sharing, in principle, the view that a clear and homogenous legal framework must be established for the communication of information on medical products subject to medical prescription which assures the fundamental rights of patients and eliminates any possible ambiguity between "information" and "advertising";

also considering the specific nature of information on medical products, which must be seen in the context of a wider framework concerning, among other things, the available

pharmacological treatments, and the specific pathology and full medical history of individual patients;

comments favourably on the proposals, for matters within its remit, highlighting the following points:

The legal basis chosen appears to have been correctly identified as Articles 114 ("the European Parliament and the Council shall, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee, adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market") and 168(4) ("the European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, shall contribute to the achievement of the objectives referred to in this Article through adopting in order to meet common safety concerns … measures setting high standards of quality and safety for medicinal products and devices for medical use") of the Treaty on the Functioning of the European Union;

the proposals appear to be in line with the principle of subsidiarity:

1) in terms of the need for the European institutions to intervene, *inter alia* because:

a) only they can fill the gaps identified in the previous Community legislation on pharmaceuticals;

b) inconsistent national standards and practices can lead to obstacles to the free movement of goods, with an adverse impact on the completion of the single market for pharmaceuticals;

2) as regards added value for the Union, in terms of the elimination of disparities between national pharmaceutical standards, safeguarding the smooth functioning of the internal market for pharmaceuticals and guaranteeing a high level of public health protection;

as regards the principle of proportionality, the proposal appears to be in line with the intended objectives.

With particular reference to the acts mentioned in the title, we would like to make the following observations:

– we welcome both the exhaustive definition of the concept of 'advertising of medicinal products' in Article 86 (amended) of Directive 2001/83/EC (Article 1(1) of proposal COM(2012) 48) and the definition of the concept of 'information', established, *inter alia*, with a list of information that marketing authorisation holders must provide for the public (new Article 100c, introduced by proposal COM(2012) 48). In this regard, we would ask you to consider whether it would be better to have a more detailed definition;

– the new Article 100c, introduced by proposal COM(2012) 48, obliges 'marketing authorisation holders' (i.e. the pharmaceutical industry) to make certain information available to the public. Given that the manufacturers are not independent third parties, we would ask for all the necessary measures to be taken so that such information is subject to the most scrupulous checking by the competent authorities, taking maximum account of budgetary requirements;

– calls, finally, for an analysis of the possible consequences of information which, while exact and precise, may still be interpreted wrongly by patients lacking suitable medical preparation.

From a purely semantic perspective, we would like to note that the proposal repeatedly uses the phrase "*il pubblico ed i suoi membri*" ("the general public and its members") in the Italian version. This is not correct Italian. We suggest that the phrase "*il pubblico o i singoli individui*" ("the general public or individuals") be used instead.

(Rapporteur: ADERENTI)

Rome, 15 March 2012

The Committee, having examined COM (2012) 51 final and COM (2012) 52 final,

having regard to the examination, at the European institutions, of the original proposals COM(2008) 662 final ("Proposal for a Regulation of the European Parliament and of the Council amending, as regards information to the general public on medicinal products for human use subject to medical prescription, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency") and COM(2008) 663 final ("Proposal for a Directive of the European Parliament and of the Council amending, as regards information to the general public on medicinal products subject to medical prescription, Directive 2001/83/EC on the Community code relating to medicinal products for human use");

having examined, in particular, the discussions within the Council of the European Union, which highlight views among the national delegations which are not always favourable, and the proposed amendments drafted by the European Parliament on 24 November 2010 contained in legislative resolution P7_TA(2010)0429;

noting:

– the replacement of the original proposals quoted above by COM(2011) 632 final ("Amended proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 726/2004, as regards information to the general public on medical products for human use subject to medical prescription and as regards pharmacovigilance") and COM(2011) 633 final ("Amended proposal for a Directive of the European Parliament and of the Council amending Directive 2001/83/EC, as regards information to the general public on medical products for human use subject to medical prescription and as regards pharmacovigilance");

– the withdrawal and entire replacement of the documents indicated above by the documents COM(2012) 48 and COM(2012) 49;

– the extract of the rules on phamarcovigilance, incorporated into COM(2012) 51 and COM(2012) 52,

comments favourably on the proposals, for matters within its remit, highlighting the following points:

The legal basis chosen appears to have been correctly identified as Articles 114 ("the European Parliament and the Council shall, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee, adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market.") and 168(4) ("the European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, shall contribute to the achievement of the objectives referred to in this Article through adopting in order to meet common safety concerns … measures setting high standards of quality and safety for medicinal products and devices for medical use") of the Treaty on the Functioning of the European Union;

the proposals appear to be in line with the principle of subsidiarity:

1) in terms of the need for the European institutions to intervene, *inter alia* because:

a) only they can fill the gaps identified in the previous Community legislation on pharmaceuticals;

b) inconsistent national standards and practices can lead to obstacles to the free movement of goods, with an adverse impact on the completion of the single market for pharmaceuticals;

2) as regards added value for the Union, in terms of the elimination of disparities between national pharmaceutical standards, safeguarding the smooth functioning of the internal market for pharmaceuticals and guaranteeing a high level of public health protection;

as regards the principle of proportionality, the proposal appears to be in line with the intended objectives;

with particular reference to the above-mentioned acts, agrees with the decision to include the rules on pharmacovigilance in individual proposals;

welcomes, in particular:

– the establishment of a list of medicinal products subject to additional monitoring (Article 23 of Regulation (EC) No 726/2004, as amended by Article 1(4) of proposal COM(2012) 51);

– the stepping up of the automatic procedure for notification and assessment of the safety of medicinal products which a State or a marketing authorisation holder intends to withdraw from sale (Article 107(i)(1) of Directive 2001/83/EC, as amended by Article 1(4) of proposal COM(2012) 52).