Opinion of the Committee of the Regions on the 'Pharmaceutical package'

(2010/C 79/10)

THE COMMITTEE OF THE REGIONS

— stresses that patients' need and interests must always come first;

— believes that the pharmaceutical industry's principle task is to develop, on the basis of quality and safety criteria, medicinal products whose effectiveness and safety have been proven in clinical trials, meeting patients' therapeutic needs with a concomitant increase in their quality of life. Companies' investment efforts should therefore focus on investment in research and development;

— believes that it is difficult to establish which information channels can be defined as health-related publications and therefore proposes that such channels be removed from the proposal except from information from patient organisations;

— would like to make sure that the proposal on falsified medicinal products does not delay the entry of generic drugs to the marketplace;

— asks the Commission to monitor price developments with a view to ensuring that the proposed authorisation procedure does not lead to higher medicine prices;

— would emphasise that the tasks of regional pharmacovigilance centres must not be confined to collecting information but should also include information and prevention, advice and evaluation of benefits and risks; regional pharmacovigilance centres are involved in health monitoring and health conferences

Rapporteur: Ms Susanna Haby (SE–EPP), Member of the Executive Committee of the City of Gothenburg

Reference document

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

COM(2008) 662 final - 2008/0255 (COD)

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

COM(2008) 663 final - 2008/0256 (COD

Proposal for a Regulation of the European Parliament and of the Council amending, as regards pharmacovigilance of medicinal products for human use, 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

COM(2008) 664 final - 2008/0257 (COD)

Proposal for a Directive of the European Parliament and of the Council amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use

COM(2008) 665 final - 2008/0260 (COD)

Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions - Safe, Innovative and Accessible Medicines: a Renewed Vision for the Pharmaceutical Sector

COM(2008) 666 final

Proposal for a Directive of the European Parliament and of the Council amending Directive 2001/83/EC as regards the prevention of the entry into the legal supply chain of medicinal products which are falsified in relation to their identity, history or source

COM(2008) 668 final

I. POLICY RECOMMENDATIONS

THE COMMITTEE OF THE REGIONS

General comments

1. broadly welcomes the initiatives set out by the Commission in the pharmaceutical package. In earlier opinions [1], the CoR asked DG Enterprise to present a policy on medicinal products and called for better coordination with the public health policy proposed by DG Health and Consumer Protection. The legislative proposal on pharmacovigilance and the proposal for more effective collection of data on the side-effects of medicines are beneficial from the point of view of public health protection in Europe;

2. stresses that it is important that drug treatments are ethically, medically and economically justified. The goal must be that the right patients receive the right dose of the right medicine at the right time so that resources can be used in the best possible way. Patients' needs and interests must always come first;

3. believes that the proposed directive is of direct relevance to local and regional authorities in that in many Member States they are responsible for health and healthcare services. The Commission proposal does not consider the local and regional role in this regard. The principle of subsidiarity should be preserved;

[1] In its opinion of 9-10 April 2008 on the White Paper *Together for Health: A strategic approach for the EU 2008-2013*, the Committee of the Regions noted that the proposed strategy did not address the issue of pharmaceuticals and therefore called for closer examination of this issue.

4. welcomes the Commission's focus on measures reducing the harmful consequences of medicinal products on the environment, but these measures need to be specified in more detail;

Communication: Safe, Innovative and Accessible Medicines: a Renewed Vision for the Pharmaceutical Sector (COM(2008) 666 final)

5. recognises that the European-based pharmaceutical industry plays role both as a scientific base for the healthcare sector and as an economic player;

6. emphasises the need to strike a balance between competitiveness and public health policy;

7. believes that all the interested parties must ensure that biosimilar medicinal products (biological medicinal products which have been authorised by a procedure similar to that used for generic medicinal products) and generic medicinal products (medicinal products which do not enjoy patent protection) become quickly accessible once they have lost their patent protection, and that they be of impeccable quality from the point of view of the patient and manufactured to high standards;

8. recommends that the Commission take into account the findings of the Commission inquiry in the pharmaceutical sector ([2]);

Information to the general public on medicinal products subject to medical prescription (COM(2008) 663 and COM(2008) 662 final)

9. shares the view that members of the general public are interested in decisions concerning their own health and will become increasingly so in the future;

10. believes that the pharmaceutical industry's principle task is to develop, on the basis of quality and safety criteria, medicinal products whose effectiveness and safety have been proven in clinical trials, meeting patients' therapeutic needs with a concomitant increase in their quality of life. Companies' investment efforts should therefore focus on investment in research and development;

11. calls on pharmaceutical companies to comply with their obligations regarding improving the quality of package labelling and the information it contains and in a format that is accessible and comprehensible patient leaflets in more than one community language, in accordance with current legislation on better use of drugs by patients. These companies should also be encourage to establish a scheme guaranteeing the traceability of medicinal products and substances;

12. also supports the maintenance of the ban on advertising for medicinal products subject to prescription. The 'promotion' of diseases and disorders by pharmaceutical companies in the media to circumvent the ban must also be controlled Pharmaceutical companies must only be allowed to provide information on medicinal products subject to medical prescription in accordance with established quality criteria and via pre-specified information channels. Advertising on TV, radio and other non-prespecified channels of communication must not be permitted;

13. believes that information provided by the pharmaceuticals industry must comply with quality standards and with respect of national legislation be approved in advance, either by the Member State where the medicinal product is authorised or at EU level in the case of centrally-authorised medicinal products. Each Member State would decide itself on a monitoring system for ensuring compliance with the rules applicable to medicinal products authorised under the mutual recognition framework in accordance with Directive 2001/83/EC. Centrally authorised medicinal products would be monitored at EU level in accordance with Regulation (EC) 726/2004;

14. thinks that there is a need to abolish the exception concerning advertising in respect of vaccination campaigns and other campaigns promoting public health. Information on these medicinal products should be subject to the same legislation as other prescription-only medicines. The exemption from the advertising ban should only be maintained with regard to preventive travel vaccines;

15. is in favour of strengthening and promoting the role of local healthcare professionals in providing information and of clarifying the roles of different players. Informing patients and ensuring that their needs are met as fully as possible implies a relationship of trust which is at the very core of the work of healthcare professionals;

16. would point out the importance of providing information on both the risks and benefits of a particular medicinal product and believes that such information is essential to ensure that the purpose of the information provided by pharmaceutical companies is not to promote sales;

17. wants to ensure that it will continue to be possible for the information channels of authorities and healthcare services to contain information on medicines subject to prescription and on comparisons between different treatment options;

18. believes that it is difficult to establish which information channels can be defined as health-related publications and therefore proposes that such channels be removed from the proposal except from information from patient organisations;

19. stresses that it is important that interpretations of the directive do not differ significantly from each other across Member States. Therefore the Commission should draw up a list of practices for monitoring systems and communicate them to Member States;

20. believes that the possibility for retailers to provide information on medicinal products subject to prescription should be subject to more in-depth examination by the Commission;

([2]) Commission inquiry in the pharmaceutical sector, preliminary report (working document of DG Competition), 28 November 2008.

Prevention of the entry into the legal supply chain of medicinal products which are falsified in relation to their identity, history or source (COM(2008) 668 final)

21. supports proposal to set up a coordinated network of all those concerned by the falsification of medicines in order to make it easier to identify falsified medicinal products, prevent them from entering the supply chain, as well as imposing more stringent obligations on sellers and buyers with regard to these products;

22. requests the Commission to also take steps to address to the problem of falsified medicinal products traded outside the legal supply chain. The directive stipulates that the legislation only applies to medicinal products intended to be sold in member States ([3]);

23. believes that public knowledge and awareness of the risks attached to and possible after-effects of medicinal products outside the legal distribution channel should be increased;

24. calls on the Commission to take adequate steps to ensure the total traceability of medicinal products, in particular by recognition for each medicinal product packaging at European level;

25. supports the possibility of continuing parallel trade in safe medicinal products as this helps to keep prices down;

26. would also like to make sure that the directive does not delay the entry of generic drugs to the marketplace;

27. asks the Commission to monitor price developments with a view to ensuring that the proposed authorisation procedure does not lead to higher medicine prices and notes that the measures taken must be devised so as to strike a balance between increased safety and growing costs;

28. calls on the Commission, in cooperation with the Member States, to support the drawing up of an international convention against the counterfeiting of medicinal products, thus strengthening the sanctions applicable to counterfeiting of medicinal products, or to provide for the inclusion of an additional protocol in the Palermo Convention on Organised Crime;

Pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use (COM(2008) 664 final and COM(2008) 665 final)

29. welcomes changes in Community legislation aimed at strengthening legal provisions governing medicinal products;

30. believes that both patients and healthcare services should always be encouraged to report the adverse effects of medicinal products. Healthcare professionals must report any adverse reaction to medicinal products of which they are aware. This is all the more important for medicinal products subject to a conditional authorisation. One way to make this clear for patients is to use a common symbol or an agreed system of symbols on the packaging and for safety information to be provided in more than one community language;

31. thinks that healthcare services must be able to carry out safety checks of medicinal products and have access, via regional or national pharmacovigilance centres, to the European database on adverse effects;

32. calls for regional pharmacovigilance centres to become an integral part of public health and the main contact point for patients on pharmacological issues;

33. believes that the publication of adverse effects must be the subject of serious prior study and approved by the competent authorities before such information is made available to patients;

34. would emphasise that the tasks of regional pharmacovigilance centres must not be confined to collecting information but should also include information and prevention, advice and evaluation of benefits and risks; regional pharmacovigilance centres are involved in health monitoring and health conferences. In addition to this, the aim must be for enhanced cooperation between doctors, pharmacists and patient self-help groups on issues relating to medication;

35. believes that the proposed amendments with respect to package leaflets – in particular those concerning the close monitoring of adverse reactions – will help to speed up changes to the contents of package leaflets. This may lead to a situation where patients receive out-of-date package leaflets, possibly containing misleading or false information. The long-term aim must be that when a medicinal product is dispensed it is always accompanied by an up-to-date package leaflet; Healthcare professionals should inform patients of any adverse effects that have not yet been included in the leaflet should this be deemed necessary, in line with each patient's specific situation;

36. opposes the proposal to introduce a summary of the package leaflet in a square surrounded by a black border as there is a risk that patients would only read the information contained in the square.

([3]) 2001/83/EC, Article 2: 'This Directive shall apply to medicinal products for human use intended to be placed on the market in Member States… .'

II. **RECOMMENDATIONS FOR AMENDMENTS**

Amendment 1

COM(2008) 663 final - Article 1(2)

Text proposed by the Commission	CoR amendment
Directive 2001/83/EC is amended as follows:	Directive 2001/83/EC is amended as follows:
Article 88(4) is replaced by the following:	Article 88(4) is replaced by the following:
'(…) 4. The prohibition set out in paragraph 1 shall not apply to vaccination campaigns and other campaigns in the interest of public health carried out by the industry and approved by the competent authorities of the Member States.'	'(…) 4. The prohibition set out in paragraph 1 shall not apply to preventive travel vaccines ~~vaccination campaigns and other campaigns in the interest of public health carried out by the industry and approved by the competent authorities of the Member States~~.'

Reason

Vaccines should be subject to the same rules as other prescription-only medicinal products. The exception with respect to vaccination campaigns and other campaigns in the interest of public health should be limited to preventive travel vaccines. Under current European legislation only vaccination campaigns are exempt from the general advertising ban. The Commission proposal seeks to make it possible for the pharmaceutical industry to inform the public about campaigns in the interest of public health. It is judged that the present exception has led pharmaceutical companies to provide information on their products in a way which is perceived to be assertive, with a message which is clearly geared to selling the product. The Commission proposal to widen the scope of the exception to include 'other campaigns in the interest of public health' runs the risk of undermining the advertising ban on prescription-only medicinal products. This is because it is difficult to define exactly what is meant by 'other campaigns in the interest of public health'.

Thanks to scientific advances, the number of vaccines will increase in the future, for example with the emergence of therapeutic vaccines, with the result that differences between vaccines and conventional medicinal products are likely to become more blurred. Vaccination of the population is an important part of public health work. At present, Member States apply different routines in their vaccination programmes. In order to carry out an overall risk-benefit assessment and make optimal use of healthcare resources, information related to vaccination campaigns should be evaluated by society at large and not just by pharmaceutical companies.

Amendment 2

COM(2008) 663 final - Article 1(5)

Text proposed by the Commission	CoR amendment
Article 100b	Article 100b
The following types of information on authorised medicinal products subject to medical prescription may be disseminated by the marketing authorisation holder to the general public or members thereof:	The following types of information on authorised medicinal products subject to medical prescription may be disseminated by the marketing authorisation holder to the general public or members thereof:
(…) (c) information on the environmental impact of the medicinal product, prices and factual, informative announcements and reference material relating, for example, to pack changes or adverse-reaction warnings;	(…) (c) information on the environmental impact risk arising from abuse or improper use of the medicinal product. deviating from the specifications contained in the summary of product characteristics, ~~prices and factual, informative announcements and reference material relating, for example, to pack changes or adverse-reaction warnings;~~
(d) medicinal product-related information about non-interventional scientific studies, or accompanying measures to prevention and medical treatment, or information which presents the medicinal product in the context of the condition to be prevented or treated.	~~(d) medicinal product-related information about non-interventional scientific studies, or accompanying measures to prevention and medical treatment, or information which presents the medicinal product in the context of the condition to be prevented or treated.~~

Reason

The term 'environmental impact' is far too vague. In view of the increased attention paid to the potentially adverse effects of medicinal products on the environment, the term 'environmental risk' is to be preferred. Use of the term 'environmental risk' better reflects the type of environmental effect the Commission wants to reduce.

The rules should be devised in such a way that it is made clear that only the contents of the summary of the product characteristics, the label and the package leaflet are considered as information. This information can, however, be complemented with information on the environmental effects of the medicinal product. Article100b (d) is unclear and should therefore be deleted. The Commission itself noted in a report ([4]) that non-interventional safety studies are 'often of poor quality and frequently promotional'.

Amendment 3

COM(2008) 663 final – Article 1(5)

Text proposed by the Commission	CoR amendment
Article 100c	Article 100c
Information on authorised medicinal products subject to medical prescription disseminated by the marketing authorisation holder to the general public or members thereof shall not be made available on television or radio. It shall only be made available through the following channels:	Information on authorised medicinal products subject to medical prescription disseminated by the marketing authorisation holder to the general public or members thereof shall not be made available on television or radio. It shall only be made available through the following channels:
(a) health-related publications as defined by the Member State of publication, to the exclusion of unsolicited material actively distributed to the general public or members thereof;	~~(a)~~ ~~health-related publications from the patient organisation as defined by the Member State of publication, to the exclusion of unsolicited material actively distributed to the general public or members thereof;~~
(b) internet websites on medicinal products, to the exclusion of unsolicited material actively distributed to the general public or members thereof;	~~(b)~~ (a) internet websites on medicinal products where the information should contain solely the data contained in a medicinal product's package leaflet or in its labelling, to the exclusion of unsolicited material actively distributed to the general public or members thereof;

Reason

The term 'health-related publications' is difficult to define and therefore this channel should be omitted. The current proposal requires each Member State itself to define the publications concerned, which creates the risk of different interpretations. The current wording raises the problem of the definition of advertising and information.

([4]) *Strategy to better protect public health by strengthening and rationalising EU pharmacovigilance: public consultation on legislative proposals*, Brussels, 5 December 2007 (point 3.2.5).

Amendment 4

COM(2008) 668 final – Article 1(1)

Text proposed by the Commission	CoR amendment
Directive 2001/83/EC is amended as follows:	Directive 2001/83/EC is amended as follows:
1) In Article 1, the following point 17a is inserted after point 17:	1) In Article 1, the following point 17a is inserted after point 17:
'17a. *Trading of medicinal products:*	'17a. ~~*Trading*~~ *Brokering of medicinal products*:
All activities consisting of negotiating independently on behalf of another person the sale or the purchase of medicinal products, or billing or brokering medicinal products, apart from supplying medicinal products to the public, and not falling under the definition of wholesale distribution.'	All activities consisting of negotiating independently on behalf of another person the sale or the purchase of medicinal products, or billing ~~or brokering~~ of medicinal products, apart from those ~~supplying medicinal products to the public, and not~~ falling under the definition of wholesale and retail distribution.'

Reason

The proposed point 17a is entitled 'Trading of medicinal products'. The definition states, inter alia, that gross and retail distribution do not fall under the concept of 'trading of medicinal products'. In view of the fact that 'trading of medicinal products' already has a well established meaning in many Member States, the transactions referred to in point 17a should be called something else. Failure to do so could result in a confusion of concepts

Amendment 5

COM(2008) 665 final – between points 17 and 18

Text proposed by the Commission	CoR amendment
	Directive 2004/27/EC Article 1 (40) (e) is amended as follows:
	Point (j) shall be replaced by the following:
	'information relating to the fact that unused or outdated medicinal products may not be flushed down the toilet or disposed of via other wastewater or household waste, as well as reference to any appropriate collection system in place;'

Reason

The Committee of the Regions would like to propose an amendment to the current legislation which has not been taken into account in the Commission proposal. The current legislation, Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, states in Article 54(j): 'specific precautions relating to the disposal of unused medicinal products or waste derived from medicinal products, where appropriate, as well as reference to any appropriate collection system in place:'

The current legislation requires all Member States to have collection systems for unused and outdated medicinal products, but patients have not been given enough information about these systems. Lack of clear instructions for patients leads to unwanted medicinal products ending up in wastewater systems and to increased loads on waste treatment facilities and wastewater reservoirs. The provision of clearer information on the packaging would improve the prerequisites for adequate management of unused and outdated medicinal products.

Amendment 6

COM(2008) 665 final - between points 15 and 16

Text proposed by the Commission	CoR amendment
	Directive 2004/27/EC Article 1 (1) (i) is amended as follows: Point (28) shall be replaced by the following points: '28. Risks related to the use of the medicinal product: — any risk pertaining to the quality, safety or efficacy of the medicinal product as regards patients' health, public health — any risk of undesirable effects on the environment; 28a. Risk-benefit balance: An evaluation of the positive therapeutic effects of the medicinal product in relation to the risks defined in point 28.'

Reason

The CoR considers that where medicines are concerned it is much more appropriate to separate the environmental risks from those relating to health, as is the case in Directive 2004/27/EC. This retains the conventional risk-benefit concept for medicines.

Brussels, 7 October 2009.

The President
of the Committee of the Regions
Luc VAN DEN BRANDE