EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

21.12.2011

Submission of comments on 'Commission Guidelines on Good Distribution Practice of Medicinal Products for Human Use'

Comments from:

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1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment (if any)	Outcome (if applicable) *(To be completed by the Agency)*

DG SANCO launched a public consultation on the revised guidelines for Good Distribution Practice which have been published in 1994 and are no longer adequate. It needs to be reviewed to take into account the new requirements for wholesale distributors and brokers and other distributors which were established by the new Directive 2011/62/EU of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products.

The new directive also implies regulations on mail order pharmacies, which are already beneficial for patients in some European member states and will be even more in the future. The directive says:

(24) Therefore, and in the light of the case-law of the Court of Justice, Member States should be able to impose conditions justified by the protection of public health upon the retail supply of medicinal products offered for sale at a distance by means of information society services. Such conditions should not unduly restrict the functioning of the internal market.

(25) The public should be assisted in identifying websites which are legally offering medicinal products for sale at a distance to the public. A common logo should be established, which is recognisable throughout the Union, while allowing for the identification of the Member State where the person offering medicinal products for sale at a distance is established. The Commission should develop the design for such a logo. Websites offering medicinal products for sale at a distance to the public should be linked to the website of the competent authority concerned. The websites of the competent authorities of Member States, as well as that of the European Medicines Agency ('the Agency'), should give an explanation of the use of the logo. All those websites should be linked in order to provide comprehensive information to the public

Therefore the European Association of Mail Service Pharmacies (EAMSP) wants to underline the importance of mail order services and their contribution to an efficient distribution of medical products for human use.

The Association of European Mail Order Pharmacies promotes and protects the interests of mail order pharmacies in the European Union, EEA States and Switzerland. It is committed to free movement of goods and to greater trade competition in Europe. The association promotes knowledge and information transfer between members. It ensures information on current developments in politics, business and the pharmaceutical market.

Mail order pharmacies store medicinal products under the relevant pharmacy ordinances and drug laws of the member state of their origin. They deliver drugs under the rules of the cross border directive into other member states. Therefore it`s relevant to harmonize prescriptions for cross border health care (see our statement to the open consultation on measures for improving the recognition of medicinal prescriptions issued in another Member State, which ends Jan. 8th). Further on it makes sense to harmonize the rules for the transport of medicinal products across Europe, so that our partners (logistic companies for B2C business) have clear rules and the safety of the drug delivery is given in whole Europe. That`s also important for cool chain delivery from the manufacturer, via the wholesaler and the pharmacy, including mail order pharmacies to the customer. Even today mail order pharmacies can guarantee the cool chain until the customer and that`s an important factor for drug and patient safety.

2. Specific comments on text

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*	Outcome *(To be completed by the Agency)*
		Comment: Proposed change (if any):	
		Comment: Proposed change (if any):	
		Comment: Proposed change (if any):	

Please add more rows if needed.