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HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health systems and products
Medicinal products – authorisations, European Medicines Agency

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PHASING-IN REQUIREMENTS ON A BLACK SYMBOL IDENTIFYING MEDICINAL PRODUCTS SUBJECT TO ADDITIONAL MONITORING

REPLIES TO THE PUBLIC CONSULTATION

This document summaries the contributions made by stakeholders to DG Health and Consumer's public consultation on phasing-in requirements concerning the Commission Decision on a "Black Symbol" identifying medicinal products for human use that are subject to additional monitoring.

1. BACKGROUND OF THE CONSULTATION

Under the new pharmacovigilance provisions some medicinal products for human use are authorised subject to additional monitoring for reasons of their specific safety profile.

In accordance with Article 23(5) of Regulation (EC) No 726/2004 all those products shall contain in the summary of product characteristics and the package leaflet the statement 'This medicinal product is subject to additional monitoring'. That statement shall be preceded by a black symbol.

The black symbol shall be selected by the Commission following a recommendation of the Pharmacovigilance Risk Assessment Committee.

In the context of selecting the symbol the Commission considered the arrangements for the inclusion of the symbol in the summary of product characteristics and the package leaflet of all products concerned. The public consultation has been conducted with a view of receiving feedback from stakeholders on this issue.

2. CONTRIBUTORS

The Commission received 14 contributions. The majority of responses were received from stakeholder organisations representing pharmaceutical undertakings or individual companies. Additionally, patient organisations and pharmacists' associations contributed. A list detailing all contributors is provided in the Annex to this document.

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All contributions and comments received provided valuable information for the Commission services. However, in some cases, the contributions submitted went beyond the scope of the public consultation and could not therefore be taken into account.

3. SUMMARY OF CONTRIBUTIONS

As regards consultation item No. 1, i.e. the time needed for the preparation and printing of the updated product information, contributors referred to time periods between 6 weeks and two years. The average time varied between 6 to 9 months.

As regards consultation item No. 2, i.e. on how long stocks of medicinal products packaged with the product information are held by the marketing authorisation holder (or the responsible manufacturer) before being released for sale and supply, contributors referred to time periods between four weeks and 12 months, sometimes extending to periods between 18 months and two years depending on whether the turnover of the product is high or low.

All contributions received have been made available on the Pharmaceuticals website.

ANNEX: LIST OF CONTRIBUTORS TO THE PUBLIC CONSULTATION:

- **Industry Associations**

(1) AESGP – Association of the European Self-Medication Industry

(2) BPI – German Pharmaceutical Industry Association

(3) EFPIA – European Federation of Pharmaceutical Industries and Associations; EBE – European biopharmaceutical enterprises; Vaccines Europe

(4) EGA – European Generic Medicines Association

(5) EUCOPE – European Confederation of Pharmaceutical Entrepreneurs

(6) EUROPABIO – European Association for Bioindustries

(7) PHARMIG – Austrian Association of the Pharmaceutical Industry

(8) PPTA – Plasma Protein Therapeutics Association

- **Individual Companies**

(9) Bausch+Lomb

(10) Pharmaxis Pharmaceuticals Limited

(11) Spirig Pharma AG

- **Other stakeholders**

(12) AEFI – Spanish Association of Pharmacists in Industry

(13) EIPG – European Industrial Pharmacists' Group

(14) Thalassaemia International Federation