EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Health systems, medical products and innovation
Medicines: policy, authorisation and monitoring

PHARM 750

PHARMACEUTICAL COMMITTEE
08 March 2018

Subject: **Questionnaire – health and safety preventive and protective measures for the workers in a healthcare area while handling cytotoxic pharmaceuticals**

Agenda item AOB 4 iii

This document and relevant questionnaire is a follow up to the discussions of the 79th Pharmaceutical Committee meeting. The background for this questionnaire is linked to the European Society of Oncology (ESOP) request for a "Yellow Hand" symbol on the packaging and package leaflets of pharmaceuticals for human use to raise awareness about the issues of handling cytotoxic pharmaceuticals along supply chain by workers/employees in a healthcare area at their working place (e.g. pharmacies and hospitals) in all EU Member States.

In regard to the protection of the health and safety of workers/employees at their work place, there are specific EU Directives, in particular as regards this specific issue the Framework Directive 89/391/EEC[1] and the following relevant individual Directives: the Chemical Agents Directive (CAD, 98/24/EC)[2] , the Carcinogens and Mutagens Directive

[1] Council Directive of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (89/391/EEC) http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1520436806054&uri=CELEX:01989L0391-20081211

[2] Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1520436931116&uri=CELEX:01998L0024-20140325

(CMD, 2004/37/EC)[3] and the Biological Agents Directive (2000/54/EC)[4], that put an obligation on the employers (e.g. hospitals and pharmacies) to determine and assess the risks posed by the chemical and biological compounds and to take appropriate preventive and proactive measures.

The EU pharmaceutical legislation (Directive 2001/83/EC as amended)[5] regulates the particulars that appear on the outer and/or immediate packaging (labelling) and on the leaflet of the medicinal products. According to the current legislation the packaging and labelling may include symbols or pictograms designed to clarify certain information which is useful to the patients and where requested by the marketing authorisation holder. These requirements for pharmaceuticals labelling focus on the safety of patients and healthcare professionals. The EU pharmaceutical legislation (under Art 11 of Directive 2001/83/EC as amended) already requires that a leaflet for healthcare professional, summarizing the products characteristics, should include special precautions for the handling the cytotoxic pharmaceuticals. The EU pharmaceutical legislation for the labelling is not covering other actors along supply chain of the distribution of pharmaceuticals.

With this document we would like to acquire information on measures put in place by the Member States on safety of employees/workers while handling cytotoxic medicinal products at their working environment.

[3] Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (codified version) (Text with EEA relevance) http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1520437044908&uri=CELEX:02004L0037-20140325

[4] Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (seventh individual directive within the meaning of Article 16(1) of Directive 89/391/EEC)http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1520437126535&uri=CELEX:32000L0054

[5] Directive 2001/83/EC on the Community code relating to medicinal products for human use, OJ L 311, 28.11.2001, as amended http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1520437200864&uri=CELEX:02001L0083-20121116

Questionnaire:

1. Does your country have any specific measures in place to address the safety of and health of employees/workers in regard to handling cytotoxic pharmaceuticals? *(max. 4000 characters)*

2. Does your country have any specific legal measures in place, please explain? *(max. 4000 characters)*

3. Does your country have any specific administrative measures in place, please explain? *(max. 4000 characters)*

4. Does your country have any mandatory measures (e.g. list of specific pharmaceuticals, symbols, pictograms, text, other visualisations, additional leaflets, labels etc.), please explain? *(max. 4000 characters)*

5. Does your country have any voluntary measures (e.g. list of specific pharmaceuticals, symbols, pictograms, text, other visualisations, additional leaflets, labels etc.), please explain? *(max. 4000 characters)*

6. Please provide examples of these measures (e.g. list of specific pharmaceuticals; full text of additional information, leaflets or other labels; mock of symbols, pictograms or other visualisations, etc.) *(max. 4000 characters)*

We would appreciate your reply by 19 April 2018. Please submit your replies to SANTE-PHARMACEUTICALS-B5@ec.europa.eu