Joint Statement of the European Association of Hospital Pharmacists (EAHP) and the European Society of Oncology Pharmacy (ESOP) on the report for the 'Study supporting the assessment of different options concerning the protection of workers from exposure to hazardous medicinal products, including cytotoxic medicinal products'

The European Association of Hospital Pharmacists (EAHP) and the European Society of Oncology Pharmacy (ESOP) have a great interest in a protective framework for health workers in all parts of the supply chain. Work safety conditions throughout Europe differ significantly. To protect all health workers and patients in Europe equally, more comprehensive steps against exposure to hazardous medicinal products must be taken.

The handling of hazardous medicinal products is a complex process that requires sufficient human resources and proper training that is tailored to the conditions of the working environment and offered to all staff involved. Occupational health, patient safety and environmental protection should be the main goal of all health systems compounding and/or working with hazardous substances to support a multi-professional therapeutic decision making that also invokes the expertise of pharmacists. Safe handling procedures as referred to within the QuapoS (Quality Standard for Oncology Pharmacy Service), a set of guidelines published by ESOP to ensure that similar standards for the handling of cytotoxics and other hazardous medicinal products, are in place across Europe. Centralised preparation under controlled conditions is essential for protecting both employees and patients but it is not yet the norm in all countries. The recommendations put forward in the report for the 'Study supporting the assessment of different options concerning the protection of workers from exposure to hazardous medicinal products, including cytotoxic medicinal products' partially factored in the suggestions proposed by EAHP and ESOP, however, more could be done to increase the protection of health workers and patients.

Standards vary across Europe. Thus, to achieve the ultimate goal of sufficiently protecting all involved actors in the handling of hazardous medicinal products, like health workers, patients and carers, European level support is needed. Regulations in the field of hazardous medicinal products should focus on the identification and minimisation of risks and at the same time account for the different settings in which these products are handled. There is no "one size fits all solution" since different health systems have different means at their disposal. The same quality standards should however be applied throughout Europe. Health workers should be provided with a range of approved handling options out of which they can select the best method that fits their needs to protect themselves and others. Additional support mechanisms, like the use of uniform warning labels (e.g. the "yellow hand") should be further expanded, including but not limited to medicinal products with carcinogenic, mutagenic and/or reproductive toxicity.

Proper training of the healthcare workforce is an important key factor. Healthcare professionals working with hazardous medicinal products need to be familiarised with the associated risks and the necessary precautions since only well prepared and well-trained staff can help lower exposure. Continuous education of health workers, along with the use of appropriate personal protective and drug handling equipment, is

recommended to effectively prevent exposure to hazardous medicinal products. The training that is provided should be standardised. It should also guarantee that every health worker, in particular the pharmacist, is trained adequately to inform and educate patients and their families and carers about the risks associated with and the necessary precautions that should be taken at home while undergoing treatment with hazardous medicinal products.

In addition to setting up a clear regulation frame for the protection of workers from exposure to hazardous medicinal products, modification to the legislative framework should also foster a cultural change within the healthcare system. Emphasis should be put on key elements such as the training of workers, the education on hazardous medicinal products and the awareness of safety risks in a wider sense and how these are managed. The actions on training, education and awareness-raising should be linked to a common EU standard for the management of hazardous medicinal products taking into account the different means that each health system has at its disposal. Central EU guidelines and standards of practice could help bring about a cultural change within all member states towards a common European safety culture.

To further supplement the findings of the 'Study supporting the assessment of different options concerning the protection of workers from exposure to hazardous medicinal products, including cytotoxic medicinal products', independent experts should be engaged together with representatives of EAHP and ESOP to carry out an integrated investigation that focuses on the following four components in relation to the exposure of health workers to hazardous medicinal products:

1) determination of aerosols,
2) measurement of surface contamination,
3) identification of potentially abnormal clinical laboratory findings (bloodwork) and changes occurring within the individuals' genome
4) presence of hazardous medicinal products in the urine and other bodily fluids.

This assessment should look at different types of safe-handling procedures, including but not limited to closed system transfer devices, since independent studies have shown that the assumption that CSTDs always offer additional protection in practice, is not correct.

Based on the shortcomings contained in the report for the 'Study supporting the assessment of different options concerning the protection of workers from exposure to hazardous medicinal products, including cytotoxic medicinal products', EAHP and ESOP call on the European Commission to further analyse the reality of exposure to hazardous medicinal products in a comprehensive manner for all parties involved with a fundamental independent investigation.