Guide on the safe use of hazardous medicinal products (HMPs)

What is the project about?

The European Commission's DG Employment, Social Affairs and Inclusion has contracted a consortium[1] led by RPA Prague to develop a non-binding EU guide on the safe management of hazardous medicinal products[2] (HMPs) at work, including cytotoxics. The objectives of the guide include increasing awareness about the risks of HMPs, improving the uptake of good practice, providing a useful reference point for training activities, improving the flow of information and reducing the inequalities between Member States and sectors by ensuring that a comprehensive guide is available to all stakeholders.

Stakeholder consultation activities for this project include a series of workshops (held in June 2022), consultation on the first draft (August-September 2022, currently ongoing) and pilots of the second draft (October 2022).

What is the role of the pilots?

The purpose of the pilots is to collect additional feedback on the draft guide (Version 2), including individual stakeholders' views on the appropriateness, feasibility, and clarity of the draft advice. We are particularly interested in feedback from the perspective of individual organisations that have practical experience of controlling workers' exposure to HMPs. In addition, the pilots are expected to provide useful input for the development of the graphical presentation of the guide.

Who can take part in a pilot?

Any organisation with practical experience of controlling workers' exposure to HMPs is invited to express interest in participating in a pilot. This includes organisations in all lifecycle stages of HMPs including manufacturing, transport & storage, preparation (pharmacies), hospitals and other healthcare and care facilities, laundrettes, veterinary clinics, etc.

Why should I take part in a pilot?

The pilots are a unique opportunity to contribute to the development of an EU guide and help make it relevant to your and similar organisations. The guide will still be in a draft form when the pilots take place and your participation will contribute to ensuring that the final version is useful for your organisation and/or also other stakeholders across Europe – this is particularly important given the identified need for such a guide in many European countries.

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1 Our consortium comprises of RPA Prague, Risk & Policy Analysts UK (RPA), Institute of Occupational Medicine (IOM), PreventPartner, Exposure Control, NOVA National School of Public Health, and other organisations/technical experts.

2 For the purposes of this guide, HMPs are defined as medicinal products that contain one or more substances that meet the criteria for classification as carcinogenic (category 1A or 1B), mutagenic (category 1A or 1B) or toxic for reproduction (category 1A or 1B) in accordance with Regulation (EC) No 1272/2008 (the CLP Regulation). This includes medicinal products for both human and veterinary use. HMPs belong to the following key therapeutic groups: antineoplastics, antivirals, hormones and hormonal antagonists, and immunosuppressants. There are also some HMPs among antibiotics and other therapeutic groups. The most common areas of HMP use thus include oncology, transplantation, HIV and Hep B&C and rheumatology; however, many other medical fields are also relevant.

The project team is interested in piloting the guide with both organisations that believe that their procedures and processes provide an example of good practice as well as organisations that feel that they would benefit from improvements to their existing practices.

What would a pilot involve?

Before the pilot

The project team will share the most recent version of the guide and indicate which sections are most relevant to your organisation. It would be useful for the key participants in your organisation to read through these sections in advance but, if this is not possible, the project team may be able to present the key points in the guide during the pilot.

During the pilot

For some pilots, the project team will be on the site (attend in person). For others, an online meeting (or meetings) will be conducted (instead of a site visit).

It is expected that the discussion will focus on the appropriateness, feasibility and clarity of the advice in the draft guide, including the following questions:

1. What is good and should stay in the guide?
2. What should be changed/improved or removed from the guide (and reasons why)?
3. What has been missed and why is it important to be into the guide?

We would particularly appreciate a discussion from the perspective of your own organisation but also welcome views on how representative your facility is of the wider situation across your Member State.

If possible, the study team would welcome a walkaround of your facility, with commentary of the current practices and feasibility of implementing the advice in the draft guide. The participating organisations are not expected to change their practices by conforming to the advice in the guide during the pilot, merely to comment on the feasibility and usefulness of the draft advice.

It is estimated that each pilot will take 2-4 hours, depending on the size of the organisation. We would prefer for the discussions to take place in English, but if this is not possible, please let us know – we are able to organize pilots in the national language in a number of Member States.

After the pilot

A draft summary of the main takeaways from the pilot will be sent to your organisation for comments to ensure that you are satisfied with the information recorded. This will also provide a further opportunity for your organisation to add more detail and information to the project.

Unless explicit consent is given, the information provided by your organisation during the pilot will not be included in the published guide. It will only be used (together with the information from the other pilots) to inform the revision of the draft and finalise the guidance. Any information included in the guide will not be attributable to the site or organisation.

I am interested or need further information

Please email HMPguidance@rpaltd.co.uk.