Protecting health workers from hazardous products

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There is more clarity about hazardous medicinal products but awareness still needs to be raised to protect workers.

Every year more than 12.7 million healthcare and veterinary workers in the European Union are potentially exposed to hazardous medicinal products (HMPs) which are carcinogenic, mutagenic and reprotoxic (CMR). HMPs are used mainly in cancer treatment, but also as antivirals, vaccines and immuno-suppressants, for treating such diseases as multiple sclerosis, psoriasis and systemic *lupus erythematosus* (an auto-immune disease) and in organ transplant.

Studies show that hospital workers who handle these HMPs are three times more likely to develop malignancy and that nurses exposed are twice as likely to miscarry. Increased genetic damage has been demonstrated particularly among day-hospital nurses, who handle HMPs most during their administration.

As cancer often takes decades to emerge, a case of leukaemia diagnosed in a nurse, pharmacist or cleaner today might be the product of workplace exposures starting in the 1980s. The scientific evidence of the serious risk of harm to healthcare workers, including leukaemia and breast cancer, is however conclusiveand has been available for more than 30 year**s.**

Revised directive

The European Public Service Union and the European Hospital and Healthcare Employers' Association (HOSPEEM), social partners in healthcare, demanded, along with other trade unions and professional organisations, dedicated articles in the CMR-substances directive to protect health workers from HMPs. These efforts came to fruition during the last revision of the directive (2022/431), approved by the Council of the EU in March last year.

To prevent occupational exposure, the directive requires risk assessments and urges the replacement of HMPs—not usually an option as patients still need these drugs for cancer and other life-threatening diseases. HMPs must then be manufactured, transferred and used in a closed system, such as a biological safety cabinet or an aseptic isolator. The new element in the revised directive is that workers exposed to HMPs must be given specific training by their employers to prevent the risk of adverse health effects.

As a follow-up to the revision of the directive and in light of the 2021-27 EU Strategic Framework on Health and Safety at Work, the European Commission commissioned new guidelines for the safe management of HMPs at work. These will be published by the European Agency for Safety and Health at Work (EU-OSHA).

Comprehensive guidance

The guidelines set out that workers need to be protected throughout the life-cycle of HMPs—manufacture, transport, preparation, administration, laundry and waste disposal—and that information needs to flow between its different phases. They aim to reduce disparities between member states and sectors by ensuring comprehensive guidance is available to all stakeholders. They also provide a useful reference point and support for training as required by the directive.

Last October the European Trade Union Institute (ETUI) published a list of HMPs to identify which fall under the legislative scope of the directive, so users of the new guidelines know to which specific HMPs they should apply. (The commission is itself to produce an indicative list no later than April 2025.)

The ETUI list is based on the working definition of HMPs used in the development of the guidelines. These meet the criteria—in Annex VI to the EU regulation ((EC) no. 1272/2008) on the classification, labelling and packaging of substances and mixtures—for categorisation as 1A or 1B CMRs. That is to say they contain one or more substances with a harmonised classification or self-classification as CMR, available in the Classification and Labelling Inventory of the European Chemical Agency (ECHA).

Raising awareness

There is a still work to be done to raise awareness of the risks of HMPs among workers and their employers. The guidelines set a baseline for good practice by workers handling HMPs but employers needs to use them. They will also need to be revised regularly, responding and adjusting to improvements in best practice and technology.

Although implementation of the guidelines on the safe management of HMPs and the drugs identified in the ETUI list will help prevent future occupational exposure for millions of workers across the EU, further changes are needed in the European legislation to provide legal security for workers and employers and complementarity of roles. The next revision of the CMR-substances directive should include the list of HMPs proposed by the ETUI, along with their legal definition.

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