

(English version)

**Question for written answer E-002148/25**  
**to the Commission**  
**Margarita de la Pisa Carrión (Pfe)**  
(28 May 2025)

*Subject:* Implementation of EU legislation to protect healthcare workers from exposure to hazardous medicinal products

Healthcare workers in oncology are often exposed to hazardous medicinal products (HMPs), many with carcinogenic, mutagenic or reprotoxic properties (CMR substances), which poses a serious risk to their health. Since April 2024, Directive (EU) 2022/431 has required the implementation of specific measures, such as the use of closed systems where it is impossible to do away with or replace an HMP. However, shortcomings remain: there is an absence of clear risk assessment protocols, a shortage of adequate protective equipment and insufficient training. Although the Commission published an indicative list of HMPs to facilitate risk assessments on 18 February 2025, this measure is limited if not accompanied by real guarantees of protection for workers.

In light of this situation:

1. Does the Commission consider it necessary to have minimum training criteria and adequate protective equipment for people working with such substances?
2. What technical guidance will the Commission provide on the use of closed systems, with a view to ensuring that workers have effective means to reduce their exposure?

Submitted: 28.5.2025

**Answer given by Executive Vice-President Minzatu on behalf of the European Commission**  
(10 July 2025)

The EU *acquis* in the area of health and safety at work protects workers against all risks to their occupational safety and health.

Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens, mutagens or reprotoxic (CMR) substances at work <sup>(1)</sup>, in particular, requires employers to assess all risks from exposure or likely exposure to CMR substances that their workers face, and to take the measures necessary to prevent or minimise these risks, including related to training and personal protective equipment (PPE).

In addition to the Commission Communication with an indicative list of hazardous medicinal products (HMPs) <sup>(2)</sup>, the Commission issued, in 2023, a Guidance for the safe management of HMPs at work <sup>(3)</sup>.

This non-binding guide provides detailed information and guidelines on the safe handling of HMPs during their whole lifecycle, covering different aspects, such as risk assessment, training, personal protective equipment and the use of closed systems.

Both initiatives will help prevent and control risks from occupational exposure to HMPs, especially in the healthcare sector.

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<sup>(1)</sup> 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, mutagens or reprotoxic substances at work (OJ L 158 30.4.2004, p. 50) — <https://eur-lex.europa.eu/eli/dir/2004/37/oj/eng>.  
<sup>(2)</sup> <https://eur-lex.europa.eu/eli/C/2025/1150/oj/eng>  
<sup>(3)</sup> <https://op.europa.eu/en/publication-detail/-/publication/ee1e6d15-4095-11ee-952f-01aa75ed71a1/language-en>.