



26 May 2021

Stop Cancer at Work Campaign briefing note on the inclusion of hazardous drugs (or hazardous medicinal products - HMPs) and reprotoxins in the Carcinogens and Mutagens Directive (CMD)

Every year more than **12.7 million healthcare workers** in Europe are potentially exposed to carcinogenic, mutagenic and reprotoxic hazardous drugs (also known as hazardous medicinal products or HMPs). Studies show that hospital workers who handle cytotoxic (antineoplastic) drugs, used to treat cancer, are **three times more likely** to develop malignancy and that nurses exposed to cytotoxic drugs are twice as likely to miscarry.

The trilogue process with the European Council, Parliament and Commission has now started to finalise the legislative changes to the fourth batch of amendments to the Carcinogens and Mutagens Directive (CMD4), with the first full meeting due to take place on 27 May.

The Stop Cancer at Work Campaign believes that the European Commission, Council and Parliament should now, without further delay, **include hazardous drugs (HMPs) and reprotoxins in the CMD**. The European Parliament has already voted by 98% for immediate legislative action – not just guidance – to protect workers from cancer and miscarriages at work, by including hazardous drugs and reprotoxins in the CMD.

Legislation to protect workers is not only supported by the **European Parliament** but also - according to an independent year-long study on HMPs published in March by the European Commission - by the **majority of the Member States** that make up the European Council, along with **nurses, doctors, workers, trades unions and employers in healthcare, scientific experts and cancer patients**.

The Commission's report narrowed down to accept **only 3 possible options**, one legislative and two non-legislative, to protect workers from occupational exposure to HMPs:

"2C Add relevant pharmacotherapeutic groups of HMPs in Annex I of CMD

4A Introduce central EU guidelines and standards of practice

4B Prepare a definition of HMP and prepare a list of HMPs and active agents that meet a certain definition"

The independent report goes on to conclude that **stakeholders and the majority of Member States (16 out of 21) believe that all three sub-options in combination is the best solution**.

The report itself clearly defines and lists the HMPs that would be included if the co-legislators agree to include HMPs in the CMD. Also, across Europe **HMPs are already**

defined, listed and used in practice in healthcare, according to definitions and classifications developed internationally, principally by NIOSH and IARC.

The accredited European social partners representing **employers and workers in healthcare**, the European Hospital and Healthcare Employers' Association (HOSPEEM) and the European Public Service Union (EPSU), also support the legislative option of inclusion of HMPs in Annex I of the CMD, together with non-legislative guidance.

Legislation is the only way to deliver the necessary **certainty, legal clarity and compliance** with the CMD to prevent workers contracting cancer or suffering reproductive problems. Non-legislative guidance, and a definition and European list of HMPs, alone will not deliver protection for workers and patients from the consequences of exposure to hazardous drugs or reprotoxins. Legislation has been proven to work in delivering changes in prevention, practice and behaviour in the European healthcare system, for example with the Sharps Directive 2010/32/EU.

The Commission has already undertaken the necessary **consultation, impact assessment and scientific justification** so that the EU can proceed immediately to legislate on both HMPs and reprotoxins. There is no need to wait for non-legislative guidelines before legislating to include HMPs or reprotoxins in the CMD. Legislation in CMD4 to include HMPs and reprotoxins should not be delayed pending the development of non-legislative European guidelines.

The independent study team's consultation and impact assessment on HMPs has delivered a **consensus for legislative change** amongst the Member States as well as the healthcare sector and its employers and workers. The **cost benefit analysis** in the independent study for the legislative inclusion of HMPs in Annex I of the CMD is not significantly greater than if the Commission were just to introduce non-legislative guidance.

The independent study supporting the assessment of different options concerning the protection of workers from exposure to hazardous medicinal products, including cytotoxic medicinal products – March 2021 published by the European Commission can be found here:

<https://ec.europa.eu/social/main.jsp?catId=148&langId=en>

The Stop Cancer at Work Campaign:

The Standing Committee of European Doctors (CPME),
European Association of Pharmacy Technicians (EAPT)
European Biosafety Network (EBN)
European Cancer Patient Coalition (ECPC)
European Federation of Nursing Associations (EFN)
European Public Service Union (EPSU)
European Specialist Nurses Organisation (ESNO),
The European Trade Union Confederation (ETUC)
The European Trade Union Institute (ETUI)

Inclusion of hazardous drugs in Annex I and reprotoxins in the title of the CMD will prevent the occupational exposure of workers and patients in healthcare to carcinogenic, mutagenic and reprotoxic drugs, which cause workplace cancer and reproductive problems and result in unnecessary deaths and harm to those exposed.

As a coalition of essential workers, professionals and cancer patients, the Campaign is demanding action from policymakers and political leaders to stop further preventable deaths. The European Commission's own research shows that at least 40% of cancer cases are avoidable - but we have yet to see meaningful change and very little on preventing workplace cancer in Europe's Beating Cancer Plan.

The scale of the problem is vast: it is estimated that 100,000 new deaths each year of work related cancer from occupational exposure to hazardous substances, the biggest killer in the EU. The European Commission's own research shows that at least 40% of cancer cases are avoidable. The protective equipment, safer technology and proper practices are available and not costly but employers are unlikely to universally introduce them unless they are required to do so.

The Campaign is calling for:

- Legislative action - not just guidance – now, not next year or the year after.
- Specifically, the European Commission should include hazardous drugs (hazardous medicinal products or HMPs) in Annex I, and reprotoxins, in CMD4.
- This legislative action should be supported (but not replaced) by new guidance to ensure that effective prevention measures are put in place and implemented across Europe.

Many have no idea that they are putting themselves at risk when doing their job. Sadly, this means if they develop cancer years later they may be unaware that it was caused by long-term occupational exposure to hazardous substances. Others are aware they are putting themselves at risk, yet have little protection and no choice to do otherwise. Either way, no-one should be put at risk of developing cancer from their work.