

Working towards a better prevention and protection of those working with hazardous drugs

On 7 March 2019 EPSU participated in a [roundtable](#) of more than 40 participants in the European Parliament on the prevention of exposure to hazardous drugs in the healthcare sector in Europe. The event was organised by the European Biosafety Network ([EBN](#)) and hosted by Siôn Simon MEP (United Kingdom, S&D). His position has led to a prolonged engagement of the EP EMPL Committee with issues surrounding hazardous drugs. Siôn Simon opened the event with a short introduction, in which he emphasised the importance of exposure prevention and of hearing from healthcare workers and their representatives from across Europe about the actual situation and existing problems in relation to the preparation, handling and disposal of dangerous drugs at the workplace. Every year more than 12.7 million health workers, mostly women, are potentially exposed to carcinogenic, mutagenic and hazardous drugs. Siôn Simon said the time has come for some solid protections for workers, against the risks of exposure to carcinogens and mutagens in general and also in the health care sectors when it comes to hazardous drugs.

One of the speakers in the first panel was Laurent Vogel of the European Trade Union Institute (ETUI). He i.a. underlined the role and responsibility of the sectoral social partners to improve the prevention and protection of the workforce in the context of EU-level legislation and highlighted the gender dimension of the issue. He considered that we have to combine legislative initiatives with agreements in the health sector. In the legislative field we should include dangerous drugs in the scope of application of the carcinogens directive but we should also improve the regulations on medicines in order to introduce the concept of pharmacovigilance for the people exposed to medicines during their work. More women than men are endangered by the preparation, handling and disposal of dangerous drugs and they bear additional risks in relation to reproduction and offspring stemming from their exposure to carcinogens, mutagens and reprotoxic substances, e.g. in oncology units. He also underlined that a broad range of workers are concerned, from the health professions administering drugs, doing exams and giving treatments to care assistants and cleaning and waste disposal personnel. EPSU fully supports all these points.

EPSU also shares the view long held and defended by the European Trade Union Confederation (ETUC) and the ETUI that there is a need for a comprehensive EU strategy against work related cancer. In the last two years EPSU has supported the ETUC policy and lobbying activities, including on the protection of health workers exposed to and handling carcinogenic, mutagenic and reprotoxic hazardous drugs. In the run up to a vote in the EP EPSU on 28 August 2018 had sent a [letter](#) calling for revisions of the Carcinogens and Mutagens Directive (2004/37/EC) (CMD) in the [third batch of amendments](#) (CMD3). On 20 December 2017 EPSU had [replied](#) to the second phase social partner consultation on possible revisions of the Carcinogens and Mutagens Directive (2004/37/EC), again in close coordination with the ETUC.

Amongst the case studies presented at the roundtable was a recently agreed Italian consensus document on the management of risk to healthcare staff in relation to the handling of antineoplastic drugs and to effective prevention and safety measures. A representative of the Italian Society of Hospital Pharmacy outlined their work in cooperation with the nursing sector and profession as well as progress made through this, but assured those present that there was still far more to be done.

Discussion was then focused on Spain. Representatives of bodies including the

Spanish General Nursing Council, EPSU member FeSP UGT and the National Institute of Health and Safety at Work emphasised that ongoing work has been making widespread improvements on a localised and regional government basis. A [manifesto](#) (available in Spanish only) calling for a better protection of the health workers has been agreed upon on 20 December 2018. Their ambition was now to bring different regulations and best practice guidelines into one place on a national level with a new national law on hazardous drugs. Strong regional efforts have been made e.g. in the region of Castilla-La Mancha by the Health Service of this autonomous region, whose guidelines have now come to be regarded as a reference document in exposure prevention. EU institutions could use these comprehensive guidelines – available in [Spanish](#) and [English](#) – as a blueprint for EU-level legislation. On 30 November 2017 EPSU affiliate FSS-CC.OO had given a [presentation](#) on its activities and campaigns to better prevent exposure to and/or to reduce risks linked to the manipulation or use of cytotoxic drugs at the Plenary Meeting 2017 of the Sectoral Social Dialogue Committee for the Hospital/Health Care Sector.

The work of the DG EMPL Health and Safety Unit on the third batch of the CMD was broadly welcomed and supported by the participants. It was also recognised that the updated regulatory framework at EU level would accelerate the movement to adequately protect workers and patients, but that it did not alone guarantee progress. In the wide-ranging discussion, the use and impact of hazardous drugs guidelines were analysed and a number of participants made calls for a stringent legislation at EU and national level combined with clear and up to date guidance on the preparation, handling and disposal of hazardous drugs.

EPSU supports the [amendments](#) agreed upon in the EP on 20 November 2018 in relation to cytotoxics included in the version of the third batch of the Carcinogens and Mutagens Directive (CMD) pending final agreement in the trilogue:

- “Hazardous drugs, including cytotoxic drugs that are primarily used for cancer treatment, could have genotoxic, carcinogenic or mutagenic properties. It is therefore important to protect workers exposed to such drugs resulting from the preparation, administration or disposal of hazardous drugs, including cytotoxic drugs, or from work involving services related to cleaning, transport, laundry or waste disposal of (materials contaminated by) hazardous drugs, or personal care for patients treated with hazardous drugs. Hazardous drugs, including cytotoxic drugs, are subject to Union measures providing for minimum requirements of the

protection of health and safety of workers, in particular those provided for in Council Directive 98/24/EC. Those drugs that are also carcinogens or mutagens are subject to Directive 2004/37/EC. The Commission should assess the most appropriate instrument for ensuring occupational safety of workers exposed to such drugs. In doing so, in accordance with Article 168(1) Treaty for the Functioning of the European Union (TFEU), access to the best available treatments for patients should not be jeopardised.”

- "No later than the end of the second quarter of 2020, the Commission shall, taking into account the latest developments in scientific knowledge, and after appropriate consultation, assess whether to amend this Directive to include hazardous drugs, including cytotoxic drugs, or to propose a more appropriate instrument for the purpose of ensuring occupational safety of workers from exposure to such drugs. On that basis, the Commission shall present, if appropriate, and after consulting management and labour, as well as health practitioners and health professionals, a legislative proposal." (Article 18a)

Ian Lindsley, Secretary of the EBN, emphasised that the US had already done much of the necessary work on legislation, definitions and guidance, particularly their health and safety agency (NIOSH). This work now would need to be “Europeanised”. Further, he emphasised that a list of hazardous drugs would need to be formalised as part of the Carcinogens and Mutagens Directive during the research and consultation work by the Commission in 2019 for a clear and uniform approach to exposure prevention.

Following these examples, Claude Rolin MEP (Belgium, EPP), EP rapporteur on the second batch of the Carcinogens and Mutagens Directive (CMD) and former Secretary General of EPSU member CSC reiterated that any legislation on hazardous drugs, both a national and at European level, needed to go hand in hand with firm guidance, and that either one on its own would fail to provide adequate protection. EPSU shares and fully supports Claude Rolin’s position and approach.

The roundtable ended with an agreement from those engaged in the work on the better prevention and protection of the healthcare workers involved in the preparation, handling and disposal of dangerous drugs that, whilst great strides had been made, particularly in the securing of the amendments to the CMD, the problems causing exposure to hazardous drugs were far from solved. Sustained and ongoing work was required to ensure that practice across the EU was providing healthcare workers and patients with adequate protection via a sufficiently

stringent legislative framework and clear guidance from the European Commission and other EU institutions.

You can read the [press release](#) of the Romanian Presidency of the European Council on the compromise reached on 29 January 2019 on third batch of the Carcinogens and Mutagens Directive.

The other group of workers organised by EPSU members which strongly concerned by occupational risks and hazards from carcinogens and mutagens are the firefighters. They also [demand](#) a greater protection from exposure to carcinogens, mutagens and reprotoxics.

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