

Challenge 3.4 on Empowering workers on the prevention of occupational exposure to Hazardous Medicinal Products (HMPs)

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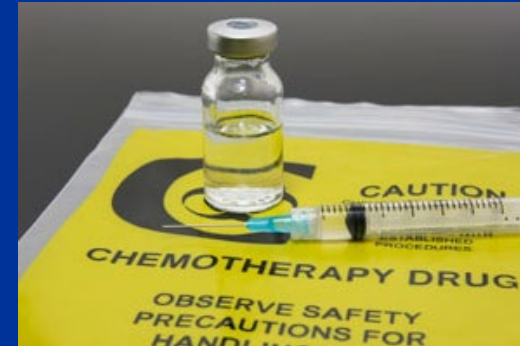
Roadmap on Carcinogens closing event

Brussels, 13 June 2024



Uses of Hazardous Medicinal Products (HMPs)

- cancer treatment
 - - cytotoxic / cytostatic
 - - antineoplastic
- antivirals
- vaccines
- immunosuppressants
- multiple sclerosis
- psoriasis
- lupus erythematosus
- organ transplantation
- ...



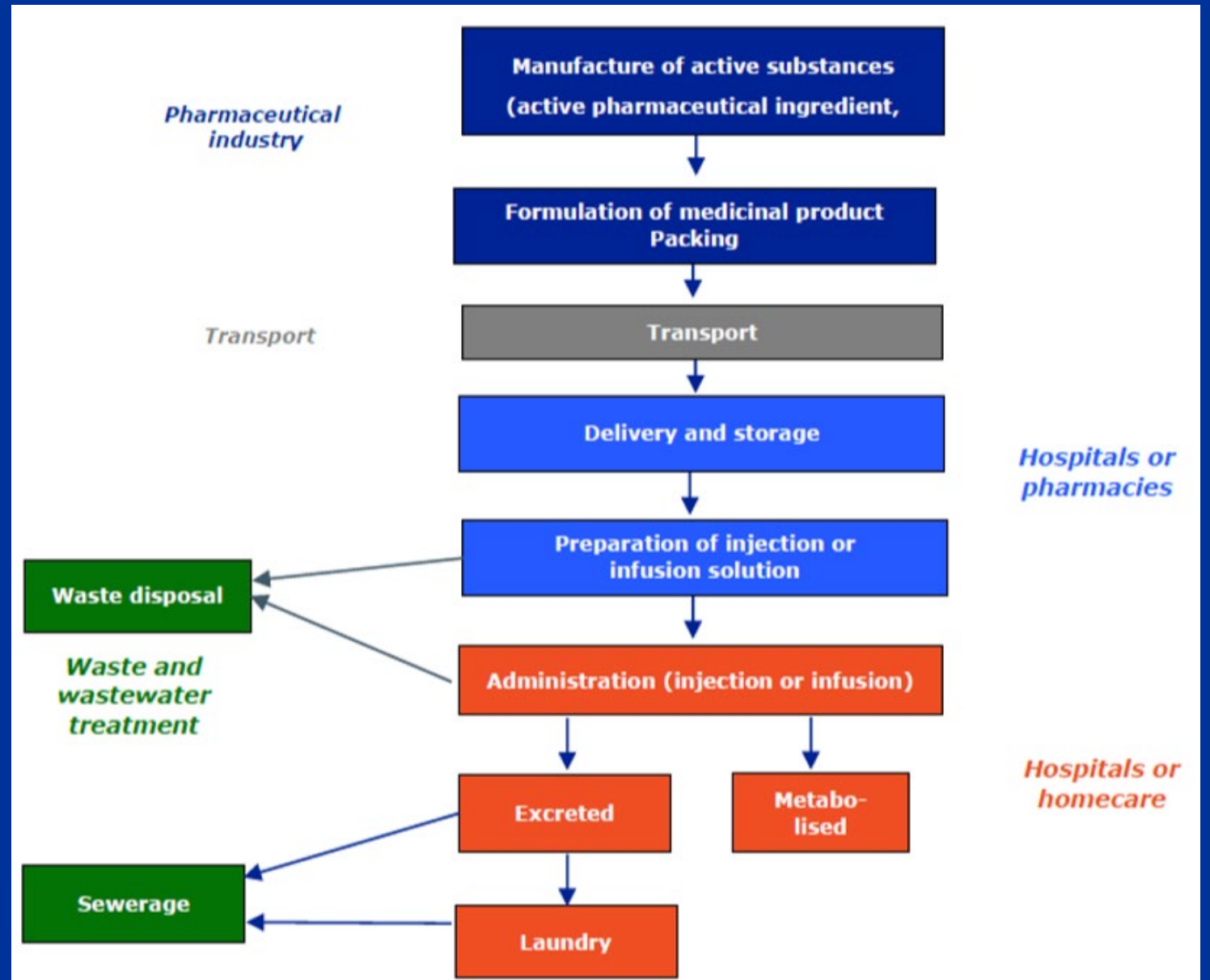
What are the risks for healthcare professionals?

- ✓ hair loss
- ✓ taste disturbance
- ✓ headaches
- ✓ infections
- ✓ respiratory diseases
- ✓ cancers
- ✓ reproductive disorders for male & female workers



What are the risks for healthcare professionals?

12,7 million workers potentially exposed to HMPS in the EU of which 7,3 million are nurses



What does the new EU OSH legislation say on HMPs ? 1/2

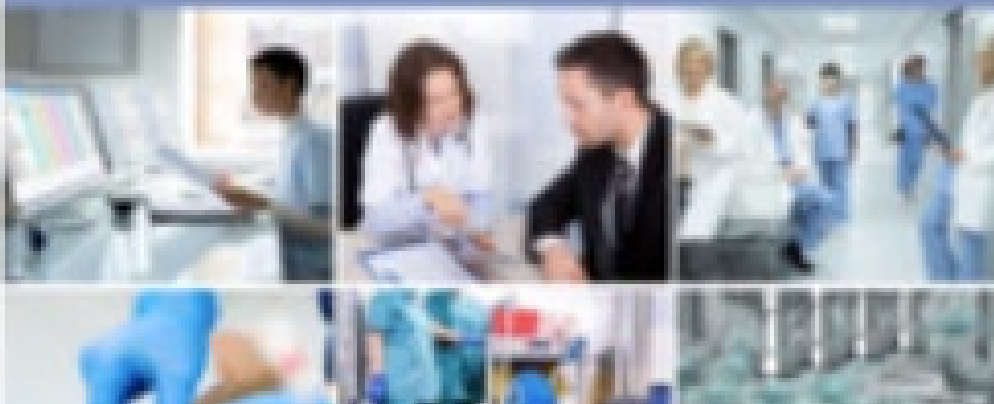
Directive 2004/37/EC on the protection of workers from the health and safety risks related to exposure to carcinogens, mutagens or substances toxic to reproduction (CMR) at work (revised in Dir 2022/431 to include HMPs, March 2022)

- ✓ in Article 11: **mandatory training** for workers exposed to CMRs contained in HMPs
- ✓ recital + joint statement acknowledging that **HMPs** that are CMRs (cat 1A/1B) **are in the scope** of CMR Directive

*“The European Parliament and the Council share the common understanding that **hazardous medicinal products which contain substances which meet the criteria for classification as carcinogenic (categories 1A or 1B), mutagenic (categories 1A or 1B) or reprotoxin (categories 1A or 1B)** in accordance with Regulation (EC) No 1272/2008 fall under the scope of Directive 2004/37/EC. All requirements of Directive 2004/37/EC apply to hazardous medicinal products accordingly.” – 16 March 2022*

What does the new EU OSH legislation say on HMPs ? 2/2

Guidance
for the safe
management
of hazardous
medicinal
products at work



- In Article 18a, obligations put on the Commission:
- to prepare updated EU guidelines for the preparation, administration and disposal of HMPs at the workplace no later than 31 Dec 2022 (published on EU-OSHA website in April 2023).
- to develop a definition for HMPs and establish an indicative a list of HMPs that are CMRs cat 1A/1B no later than 5 April 2025 (ongoing work).

The ETUI's list of HMPs ?

1. Identify which HMPs fall under the scope of new EU legislation
2. Help users of the EU 2023 guidelines know which specific HMPs the guidelines apply to, well ahead of 2025
3. Empower healthcare workers on the prevention of risks related to exposure to HMPs

The ETUI's list of hazardous medicinal products (HMPs)

including cytotoxics and based on the EU CLP classification system of Carcinogenic, Mutagenic and Reprotoxic (CMR) substances

Ian Lindsley and Tony Musu

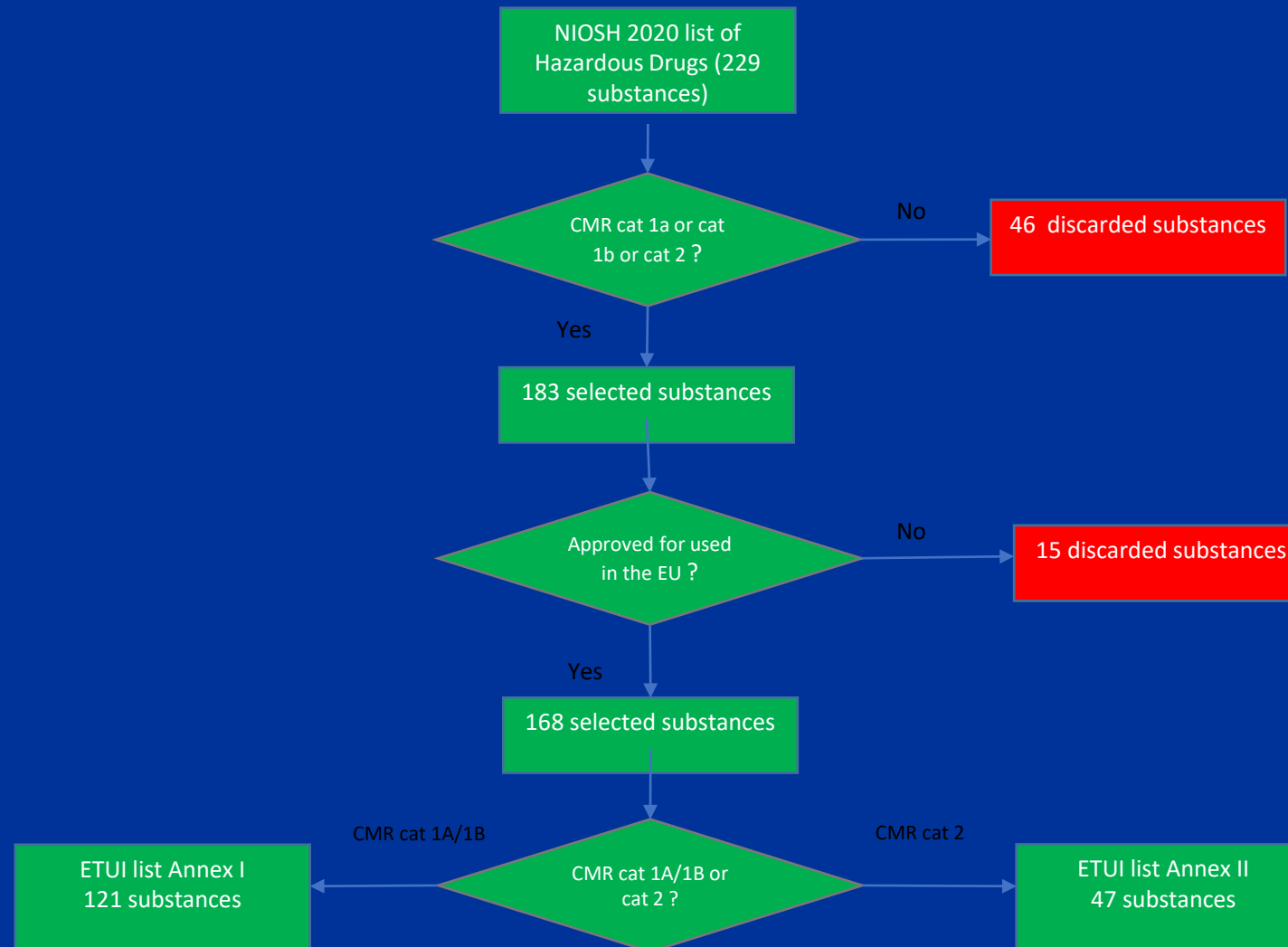
Working definition of HMPs used in the EU guidelines

Hazardous Medicinal Products (HMPs) are 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 of the European Parliament and of the Council and therefore fall within the scope of Directive 2004/37/EC.

Methodology used



Annex I = 121 HMPs strictly falling under CMRD scope

Annex I Drugs which contain one or more substances which 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 of the European Parliament and of the Council

Bold denotes medicinal products that moved from Table 1 to Table 2 in NIOSH 2020 list

Drug	CLP Carc. Group	CLP Muta Group	CLP Repro Group	CAS Number	EC / List Number	Therapeutic Group	IARC Group	NTP Category	MSHI	NIOSH 2020 Table	Supplemental Information
abacavir	1B*	-	2	188062-50-2	620-488-4	antiviral	-	-	no	2	*3 of 45 consider carc 1B, Malignant tumors observed in male and female mice and rats; Genotoxic in vivo micronucleus test.*
acitretin	-	-	1A*	55079-83-9	259-474-4	antipsoriatics	-	-	no	2	*9 of 47 consider repro 1A (otherwise 1B), Only met the NIOSH criteria as a developmental and/or reproductive hazard*
alitretinoin	-	-	1B	5300-03-8	610-929-9	antineoplastic agent	-	-	no	2	Only met the NIOSH criteria as a developmental and/or reproductive hazard
arsenic trioxide (diarsenic trioxide)	1A	-	-	1327-53-3	215-481-4	antineoplastic agent	1	Known to be human carcinogen	yes	1	*Harmonised CLP classification NTP Classification for 7440-38-2 (arsenic)*
azacitidine	1B	-	-	320-67-2	206-280-2	antineoplastic agent	2A	Reasonably anticipated to be a human carcinogen	yes	1	
azathioprine	1A	1A	1A	446-86-6	207-175-4	immunosuppressant	1	Known to be human carcinogen	yes	1	
bendamustine	2	-	1B	3543-75-7	631-540-0	antineoplastic agent	-	-	yes	1	Cytotoxic; Developmental toxicity
bicalutamide	2*	-	1B*	90357-06-5	618-534-3	antineoplastic agent	-	-	no	2	12 of 196 consider carc 2, repro 1A/B
bleomycin	2	1B	2	9041-93-4	232-925-2	antineoplastic agent	2B	-	yes	1	
bosentan	-	-	1B*	147536-97-8	643-099-1	antihypertensives	-	-	no	2	*1 of 4 consider repro 1B (otherwise 2), Only met the NIOSH criteria as a developmental and/or reproductive hazard*

Annex II = 47 HMPs to be treated as Annex I (precautionary approach)

Annex II Drugs that contain one or more substances which meet the criteria for classification as carcinogenic (category 2), mutagenic (category 2), or toxic for reproduction (category 2) in accordance with Regulation (EC) No 1272/2008 of the European Parliament and the Council and/or which contain drugs that contain Manufacturer's Special Handling Information (MSHI) in the package insert

Bold denotes medicinal products that moved from Table 1 to Table 2 in NIOSH 2020 list

Drug	CLP Carc. Group	CLP Muta Group	CLP Repro Group	CAS Number	EC / List Number	Therapeutic Group	IARC Group	NTP Category	MSHI	NIOSH 2020 Table	Supplemental Information
abiraterone	-	-	2	154229-18-2	620-314-7	antineoplastic agent	-	-	no	2	"Only met the NIOSH criteria as a developmental and/or reproductive hazard; Women who are pregnant or women who may be pregnant should not handle without protection (e.g., gloves)"
alretamine (hexastat)	-	-	-	645-05-6	211-428-4	antineoplastic agent	-	-	yes	1	
ambrisentan	-	-	2	177036-94-1	658-059-9	antihypertensives	-	-	no	2	"Only met the NIOSH criteria as a developmental and/or reproductive hazard"
amsacrine	-	-	-	54301-15-4	637-255-8	antineoplastic agent	2B	-	yes	1	
axitinib	-	2*	2*	319460-85-0	638-771-6	antineoplastic agent	-	-	no	2	"32 of 71 consider repro 2, 31 of 72 consider muta 2 Teratogenic, embryotoxic and fetotoxic in mice at exposures lower than human exposures"
bexarotene (targretin)	-	-	2	153559-49-0	681-650-8	antineoplastic agent	-	-	no	2	Only met the NIOSH criteria as a developmental and/or reproductive hazard
bortezomib	-	-	2	179324-69-7	605-854-3	antineoplastic agent	-	-	yes	1	
brentuximab vedotin	-	-	-	914088-09-8	-	antineoplastic agent	-	-	yes	1	Monoclonal antibody conjugated to vedotin
carfilzomib	-	-	2	868540-17-4	692-054-2	antineoplastic agent	-	-	no	2	"Only met the NIOSH criteria as a developmental and/or reproductive hazard; Special warnings on contraception while taking and two weeks post-treatment"
chloramphenicol	2	-	2	56-75-7	200-287-4	antibacterial agent	2A	Known to be human carcinogen		1	
cidofovir	2	2	2	113852-37-2	638-807-0	antiviral	-	-	yes	1	
cladribine	-	-	-	4291-63-8	636-978-6	antineoplastic agent	-	-	yes	1	

What are the limitations of the list of HMPs?

HMPs are identified principally by their CAS number rather than by their brand names

Some HMPs approved for use in the EU but not yet in the US may not be identified

HMPs erroneously discarded from the list (even if this is unlikely)

The list of HMPs will need to be updated on a regular basis

Specific Situation of Firefighters



Specific Situation of Firefighters

Recognition of Professional Exposure for Firefighters as Carcinogenic

More firefighters and more equipment

Compulsory decontamination and mandatory health screening

be

EU



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