EBN webinar on preventing sharps injuries, MDR and safety mechanism in medical devices

15 June 2021, 10.30 CET

1. **Welcome and introduction**

Philip Bickford Smith, Retired Consultant Anaesthetist and former Chair of the Safer Needles Network, Technical Expert on Standards for Medical Devices

Speakers

2. **Follow-up on and implementation of the Directive 2010/32/EU on the prevention from sharps injuries in the hospital and healthcare sector**

Simone Mohrs, Policy Officer, Hospital European Hospital and Healthcare Employers' Association (HOSPEEM)

Adam Rogalewski, Policy Officer- Health and Social Services, European Federation of Public Services Unions (EPSU)

- HOSPEEM represents national employers' organisations operating in the hospital and healthcare sector at the European level and its members consist of state, regions and private health sector with the powers to negotiate on pay and on terms and conditions of service with their respective Trade Union partners
- EPSU represents national trade unions' from across Europe in the hospital and healthcare sector and influences the policies and decisions of employers, governments and European institutions that affect public service workers, their families and communities
- HOSPEEM and EPSU have continuously been working on this issue since 2009 starting with the Framework Agreement, which was transposed into a Council Directive in May 2010. Following this, EPSU and HOSPEEM initiated a project on the implementation of sharps. On 11 May 2013, the MSs had to transpose the Directive into national law. As a follow up to the work done, the SPs agreed to include it in their work programme and launched the survey in 2017
- The purpose of the directive is:
  - to achieve the safest possible working environment
  - to prevent workers' injuries caused by all medical sharps
  - to set up an integrated approach establishing policies in risk assessment, risk prevention, training, information, awareness raising and monitoring
  - to put in place response and follow-up procedures
- **Who:** Any persons employed by an employer including trainees and apprentices in the hospital and healthcare sector-directly related services and activities. Workers employed by temporary employment agencies
- **Where:** Healthcare organisations/services in public and private sectors, and every other place where health services/activities are undertaken and delivered
- **What:** Objects or instruments necessary for the exercise of specific healthcare activities, which can cut, prick, cause injury and/or infection

- **Responses to survey:** The ESP received 29 responses of which 8 HOSPEEM, 16 EPSU and 3 joint responses and 1 not affiliated to either of the ESP. Therefore, in total 12 HOSPEEM Members, 18 EPSU Affiliates and 1 organisation not affiliated to either of the ESP replied
- Out of the 27 national Social Partners who replied to the online survey 19 indicated impacts they attributed to the practical transposition of stipulations of the Directive. Most of the issues reported indicated still existing problems. Most of the problems reported are linked to deficits regarding the elimination, prevention and protection of risks from injuries and/or infections from medical sharps. The second most important category and potential field of action for the future is linked to deficits when it comes to the reporting of injuries and/or the systems for reporting in place
- **Main takeaways:**
  - Compliance of Directive more effective when NSP are involved from beginning, creating ownership
  - Grassroots level implementation as major justification for success in formulation and support of implementation
  - conduct assessment of the Directive, elaborate on implementation report: indicate improvements and existing challenges, how they to be addressed by European Commission, Social Partners and/or by other relevant stakeholders

3. How sharps injuries are managed in the Netherlands and how governmental institutions are dealing with them

Paul van Wijk, Former Senior Inspector at the Dutch Healthcare Inspectorate and Infection Control Practioner and Epidemologist at the Amsterdam University Medical Center

- An estimated 13000-16000 blood exposure accidents in NL per year
- An estimated 15 incidents per 100 hospital beds
- One organisation in NL which deals with Blood exposure accidents outside hospitals: PrikPunt
- Currently there is a low prevalence of HBV, HCV and HIV in NL – Healthcare workers must be vaccinated
- Following the directive 2010/32/EU implemented in Occupational Law NL still experiences some accidents
- There are still no safe alternatives for all current sharp devices (e.g. those used by dentists)
- Smaller organisations keep struggling with the implementation
- Home health care providers do not always use safety devices
- The process of implementation is ongoing in the Netherlands

4. The impact of COVID-19 on sharps injuries – Ipsos MORI survey

Ian Lindsley, Secretary, European Biosafety Network

- Healthcare workers are exposed to sharps injuries leading to a high risk of infection. The main risk from a sharps injury is the potential exposure to infections such as blood-borne viruses (BBV), such as HIV, Hep B or C. This can occur where the injury involves a sharp that is contaminated with blood or a body fluid

- The number of sharps injuries each year is high, estimated at 1.2m each year in Europe before the pandemic, although underreporting continues to be a major problem
- The EBN commissioned the survey to understand whether, why and how there has been a change in the number, type and location of sharps injuries because of the COVID pandemic
- The survey conducted by Ipsos MORI in March/April 2021 included 80 of the largest hospitals in Europe, in Spain, France, Germany, Poland and Italy, covering more than 300,000 healthcare workers
- The number of sharps injuries has increased as a result of the COVID-19 pandemic with an average reported increase of 23% over the last year, an estimated increase of 276,000 sharps injuries
- The increased pressure of work and stress due to COVID is the overwhelming reason cited by almost all respondents (98%), followed by the lack of safety devices (47%) and PPE (45%)
- As a result of COVID, over 2 in 5 respondents said the location in which sharps injuries occur has shifted, being mainly in the emergency department and intensive care
- In most countries, nurses (82%) and doctors (54%) are the workers who have experienced the highest increase in sharps injuries
- Covid vaccination rollout more recently has also increased the number of sharps injuries by almost half
- Over 2 in 5 OH respondents consider that the location in which sharps injuries occur has changed, with the highest proportion in Spain and lowest in Poland
- Overall, the emergency department and intensive care are where sharps injuries are most stated to have increased because of COVID
- As a result of COVID, over half of respondents in France, Germany and Spain said that the job category of workers injured by sharps has changed
- In general, nurses are the workers who experienced the highest increase in the number of sharps injuries
- Approximately half of respondents said there had been an increase in the number of sharps injuries resulting from the COVID vaccination programme in early 2021

5. Sharps injury prevention and compliance in Spain and Interpretation guidance on preventing sharps injuries in the Medical Devices Regulation (MDR)

Jose Luis Cobos Serrano, Vice Secretary General, Spanish General Council of Nursing (SGCN) Consejo General de Enfermeria de Espana

- The Spanish General Nursing Council undertook a study to look at compliance with the Sharps Directive 2010/32/EU and implementation of safety measures in Spanish healthcare facilities
- The study examined the situation in 144 healthcare facilities (71 hospitals and 73 healthcare centres), with the cooperation of 120 surveillance nurses
- 95% of Spanish healthcare facilities had experienced sharps injuries and risk assessments were not carried out in 9.7% of facilities examined
- More needle free devices and safety devices were provided in hospitals than healthcare centres
- 18.8% of staff were not trained to use a medical device with a safety mechanism
- Safety devices were most often available for blood collection and in catheters but least frequently in pre-loaded syringes, scalpels and insulin pens

- The study concluded that safety devices were the main preventive measure put in place to protect nurses in Spain, that the Sharps Directive was not being implemented in all Spanish facilities and that a European Biosafety Observatory should be established to collect data and information on workplace injuries
- The Spanish General Council of Nursing drafted interpretation guidance which, following consultation with several bodies, was published, together with the European Biosafety Network, on 28 April 2021
- The scope of this guidance is to ensure consistency in the implementation and the interpretation of the MDR across Notified Bodies, Member States and manufacturers regarding the requirements defined in Annex 1, points 11.1 and 22.2
- The guidance is designed to be adopted and/or adapted for publication by the Medical Devices Coordination Group (MDCG) following the full applicability of the MDR on 26 May 2021, but also to inform the development of a new standard and a possible technical report for updating the standard on safety mechanisms in medical devices
- The deadline for the draft standard commissioned by the European Commission is 27 May 2024 and it should take 2-3 years for the drafting, technical work and editing to produce a final standard.
- Working Group 8 of ISO/TC 84 (alongside CEN/TC 205) has agreed in principle to undertake the new standard over the next year in parallel with, and in anticipation of, the development of the new standard.
- A proposal for a new work item will be submitted in due course to the secretariat of ISO/TC 84/WG8 and CEN/TC 205.
- The MDCG should adopt guidance based on the interpretation guidance drafted by the Spanish General Council of Nursing
- Sharps injuries will be eliminated and health workers and patients will be protected from deadly diseases by:
  - Consistent interpretation and universal implementation of the existing Sharps Directive and Medical Devices Regulation
  - Introducing EU wide surveillance and the development of a permanent Observatory to deliver detailed and updated information and data on sharps injuries and other accidents
  - Comprehensive use of safety devices and a new standard on safety mechanisms in medical devices

6. Implementation of the Medical Device Regulation post May 2021, sharps injuries and new standard on safety mechanisms in medical devices

Francoise Schlemmer, Director, The European Association Medical devices - Notified Bodies (Team-NB)

The aims:

- Represent Notified Bodies
- Communication with
  - European Commission
  - Competent Authorities
  - Industry
  - Other stakeholders

- Promote technical and ethical standards
- Participate in improving the legal framework
- Contribute to harmonization (e.g. training 'for notified bodies by notified bodies')
  The tasks:
- Involved in the conformity assessment of medical devices (risk class LLA and higher)
- Involved in assessment of technical documentation (including clinical data)
- Surveillance and review
- Issue a certificate: gives a manufacturer the right to attach CE-marking to the device
- The code of conduct for Notified Bodies has harmonisation of members as a key priority
- From 2019 training has been provided across a range of topics to help NB's to deal with the new MDR
  New requirements of regulations:
  - EUDAMED & UDI
  - Person responsible for regulatory compliance
  - Control of distributors by manufacturers and vice versa
  - 6 new general requirements for performance and safety (13 to 23)
  - Structure and content of the specified technical file
  - Post-Market Surveillance Report
- MDR DoA postponed for one year due to the Covid19 pandemic
- "Commission Notice on remote MDR initial audits" published Jan 2021:
  - COM exempts Member States from their obligation to 'punish' NBs if they do not go onsite, and stipulates very strict conditions
  - Implementation differs across Member States; limited number of MDR initial audits can be finalized
- An alternative way of getting new notified bodies approved is through NANDO, the New Approach Notified and Designated Organisations Information System

7. Standardisation Request for MDR/IVDR and new harmonised European standards, including sharps injury protection, and interpretation of points 11.1 and 22.2 of Annex I of the MDR

Mario GABRIELLI-COSSELLU, Policy and Legal Officer, European Commission

- Positive opinion on the draft act for the MDR/IVDR standardisation request, delivered by the Committee on Standards (Member States) on 12 March 2021
- Commission Implementing Decision on a standardisation request to CEN and Cenelec as regards medical devices in support of Regulation (EU) 2017/745 and in vitro diagnostic medical devices in support of Regulation (EU) 2017/746, adopted on 14 April 2021 and published on the Commission's database "Standardisation - Mandates" as M/575 and on the Commission's webpage "Medical Devices - New Regulations - Topics of Interest", section "Harmonised European standards", including:
  - 201 existing harmonised standards to be revised and 27 new harmonised standards to be drafted in support of Regulation (EU) 2017/745, by 27 May 2024
  - 46 existing harmonised standards to be revised and 3 new harmonised standards to be drafted in support of Regulation (EU) 2017/746, by 27 May 2024
- Notified to CEN and Cenelec on 15 April 2021 and accepted on 12 May 2021 to make the standardisation request fully applicable

- CEN and Cenelec submitted the joint work programme to the Commission on 28 May 2021
- Standardisation request to be periodically revised in the lists of standards and possibly other contents when deemed necessary
- Two Commission Implementing Decisions for harmonised standards in support of Regulations (EU) 2017/745 and (EU) 2017/746, under preparation, to be adopted and published in the OJEU likely by June 2021
- First publications of lists of references of harmonised standards to confer presumption of conformity under the Regulations, including:
  - 5 references for Regulation (EU) 2017/745
  - 4 references for Regulation (EU) 2017/746
- A new cycle starting: publications to be periodically updated with subsequent amendments, each three/four months, to enlarge the lists according to the development of the standardisation work at European and international level and the correspondent state-of-the-art technical solutions for the highest degree of health, safety and performance of medical devices in the EU
- Concerning standardisation on sharps injury protection, the standard EN ISO 23908:2013 Sharps injury protection - Requirements and test methods - Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling, it was harmonised for Directive 93/42/EEC under mandate M/295, but not cited in OJEU (thus not conferring presumption of conformity)
- The standard is now included in the MDR/IVDR standardisation request in its Annex I, Table 1 among the existing harmonised standard to be revised, with 27 May 2024 as deadline for the adoption
- Requirements specified in its Annex III, point 2.3: “The existing standard EN ISO 23908:2013 shall be modified by describing technical solutions for safety-engineered mechanisms to be applied in design and manufacture of devices to ensure compliance with points 11.1 and 22.2 of Chapter II of Annex I to Regulation (EU) 2017/745. The standard shall apply to devices which are intended to be used for administration and/or extraction of body/blood fluids and/or medicinal substances”
- To be developed by the Technical Committee CEN/TC 205 - Non-active medical devices by 27 May 2024, as per the CEN-Cenelec Joint Work Programme
- Legal interpretation, possible only by the Court of Justice of the European Union
- Possible guidance on the sound implementation of the requirements, by the sectorial working parties:
  - the Medical Device Coordination Group (MDCG) and its Subgroups (on Standards – WG 2 – and on Notified Bodies Oversight (NBO) – WG 1)
  - the group of Competent Authorities for Medical Devices (CAMD)
  - others? (notified bodies, sectorial entities, etc.)
- Practical steps to be followed:
  - collection of information from different sources (associations, experts, etc.)
  - drafting of a text (Commission, working groups, task forces…)
  - procedures for discussion, revision, endorsement and publication

- Concerning the revision on the existing standard EN ISO 23908:2013, standardisation process usually takes at least a couple of years; the relevant CEN/TC 205 should start the

work soon to prepare for this new work item with the cooperation of a number of players and experts, including industry, also in parallel with the relevant ISO TCs

- A small taskforce could be set up in the coming months to take forward the proposed guidance on requirements 11.1 and 22.2 of Annex I MDR in the MDCG Subgroups on Standards and Notified Bodies, using the draft published by the Spanish General Nursing Council and other reference documents as a basis, to undertake the drafting and then for further consultations. Such a guidance would be developed in parallel with the standardisation work and could be in place by 2022

- DG SANTE of the European Commission to liaise with DG Employment in Luxembourg about the possibility of setting up an Observatory to collect information from Member States and EPSU/HOSPEEM to feed into that process alongside the EBN. EPSU/HOSPEEM would need the support of the European Commission to ensure effective and universal implementation of the Sharps Injuries Directive 2010/32/EU, along with the Member States.

8. New standard on sharp injury protection on sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling (EN ISO 23908:2013)

Laurence Bouret, CEO of DASTRI, French Producer Responsibility Organisation for sharps and member of CEN/ISO TC 84 / WG8

- DASTRI is a coalition of healthcare companies focussed on sharps regulations (French)
- Scope of ISO/TC 84 Devices for administration of medicinal products and catheters:
- Standardization of the performance of metered devices and supplies intended for administration of medicinal products, and standardization of syringes, needles and catheters
- Currently excluded from scope:
  - non catheter devices intended for diagnostic use
  - anaesthetic and respiratory equipment, including lung ventilators and oxygen therapy devices, covered by ISO/TC 12
  - cartridge systems for dental use, covered by ISO/TC 106
  - specific requirements for components and devices, including prefilled syringes, covered by ISO/TC 76
- DASTRI would like to include all devices capable of causing sharps injuries and consider the whole life cycle of the sharp
- May 2024 is the final deadline

9. Q&As and conclusions

- Paul van Wijk highlighted that the discussions of the day raised concerns about the number of injuries which continue to occur from both safe and unsafe devices and called for more data on the subject to aid understanding and allow for better prevention of injury. In the past a number of countries had signed up to the EPINET software reporting system for sharps injuries, developed by the University of Virginia but this has fallen into disuse, partly as the reporting is too detailed for most healthcare professionals to complete on a regular basis. The Sharps Directive requires reporting at local, national and European levels but no

system has been put in place to deliver EU wide reporting which is why the Observatory is so important and the European Commission should be helping to facilitate this.

- Philip Bickford Smith thanked all the participants and particularly the excellent speakers for a high quality event and looked forward to putting the discussion into action.