CONSEJO GENERAL DE ENFERMERÍA DE ESPAÑA

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Webinar on preventing sharps injuries and the standard on safety mechanisms in medical devices, 22 June 2022



SURVEY ON SHARPS INJURIES IN SPAIN AND THE SHARPS DIRECTIVE

CONSEJO GENERAL DE ENFERMERÍA DE ESPAÑA

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.

REGULATIONS ON MEDICAL DEVICES INCORPORATING SAFETY-ENGINEERED MECHANISMS

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Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC (MDR), Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

- The Regulation (EU) 2017/745 on Medical Devices is a European Regulation aimed at ensuring proper operation of the internal market as regards medical devices, taking as its basis a high level of protection of the health of healthcare workers and patients, users and lay persons, and taking into account the interests of small- and medium-size enterprises in the healthcare industry.

- One key element is the development by the manufacturer of the required technical documentation which shall contain information for the demonstration of conformity with the general safety and performance requirements set out in Annex I of the MDR that are applicable to the device taking into account its intended purpose.

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- It is very important that there are no gaps in the interpretation of the MDR and in particular of the general safety and performance requirements, to avoid anomalous scenarios which might affect free market competition in Europe, and to avoid situations that might unequally affect the safety of healthcare workers, patients and lay persons who could administer medication using invasive medical devices.

- The new MDR includes many Articles that require, as far as possible, that medical devices be designed and manufactured in such a way as to ensure the safety of patients, healthcare professionals and lay persons.

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As regards the safety of healthcare workers, patients and lay persons, the MDR includes two critical points in ***Annex I***, given below:

- ***Annex I, Point 11.1: "Devices and their manufacturing processes shall be designed in such a way as to*** *eliminate or to reduce as far as possible the risk of infection to patients, users and, where applicable, other persons. The design shall: reduce as far as possible and appropriate the risks from unintended cuts and pricks, such as needle stick injuries; allow easy and safe handling; reduce as far as possible any microbial leakage from the device and/or microbial exposure during use; and prevent microbial contamination of the device or its content such as specimens or fluids."*

- ***Annex I, Point 22.2: "Devices for use by lay persons shall be designed and manufactured in such a way as to:*** *ensure that the device can be used safely and accurately by the intended user at all stages of the procedure, if necessary after appropriate training and/or information; reduce, as far as possible and appropriate, the risk from unintended cuts and pricks such as needle stick injuries; and reduce as far as possible the risk of error by the intended user in the handling of the device."*

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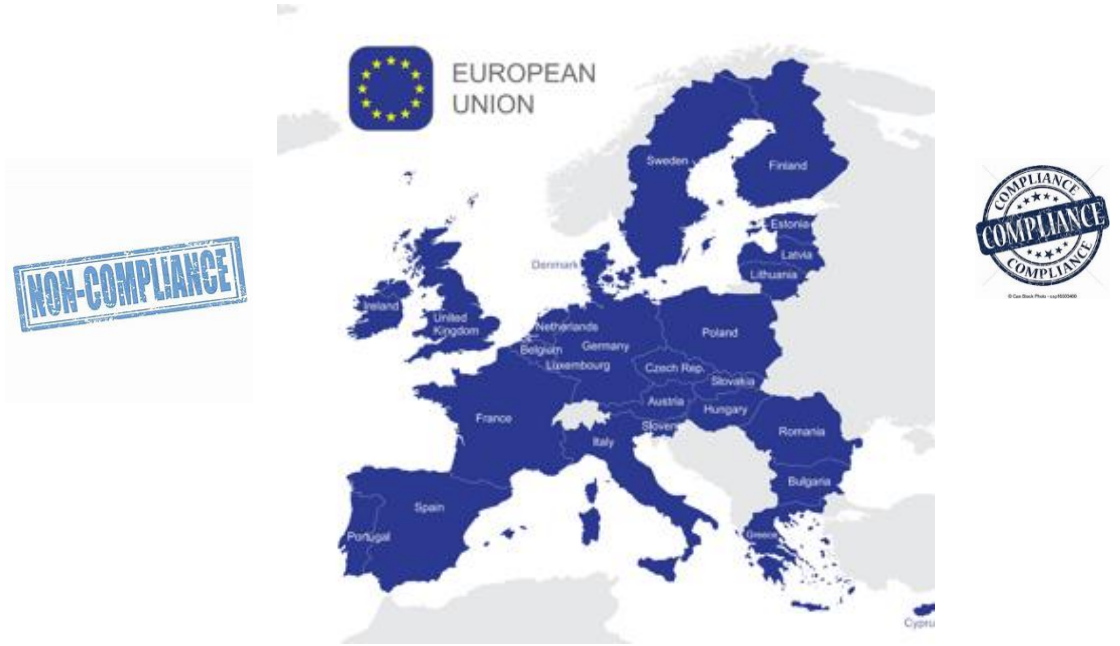
Lack of homogenity in the interpretation

- Both Articles (points 11.1 and 22.2 of Annex I to the MDR) are not sufficiently specific to ensure a consistent interpretation by all the European medical devices stakeholders.
    - What is the correct interpretation of the requirement ***"as far as possible and appropriate"***?
    - How and when should it be determined that a medical device was designed to reduce the risk from unintended cuts and pricks as far as possible and appropriate?

With the current text of points ***11.1 and 22.2 of Annex I***, **the same medical device** could be regarded as **non-compliant** with the MDR by one notified body, while another notified body could regard it as **compliant** with the Regulation.



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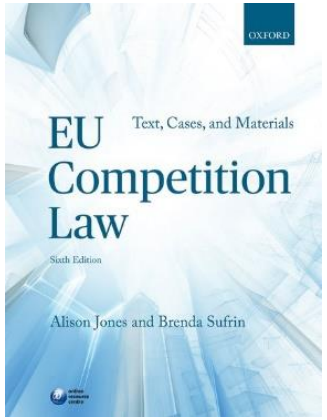
Consequences of lack of homogenity in the interpretation

- **No guarantee of safety** for healthcare workers, patients and lay persons :
  - Medical devices with CE mark that are not safe
  - Co-existence of safe and unsafe devices in the European market for the same intended use.

- **No free competition in Europe** of medical devices manufacturers in the European market.

As the Certification of the CE mark would depend on the subjective view of the involved notified body, not on objective criteria, a medical device manufacturer could be denied a CE Certification for a medical device by a notified body in one country while another manufacturer of the same device could obtain the CE Certification through a different notified body in another country.



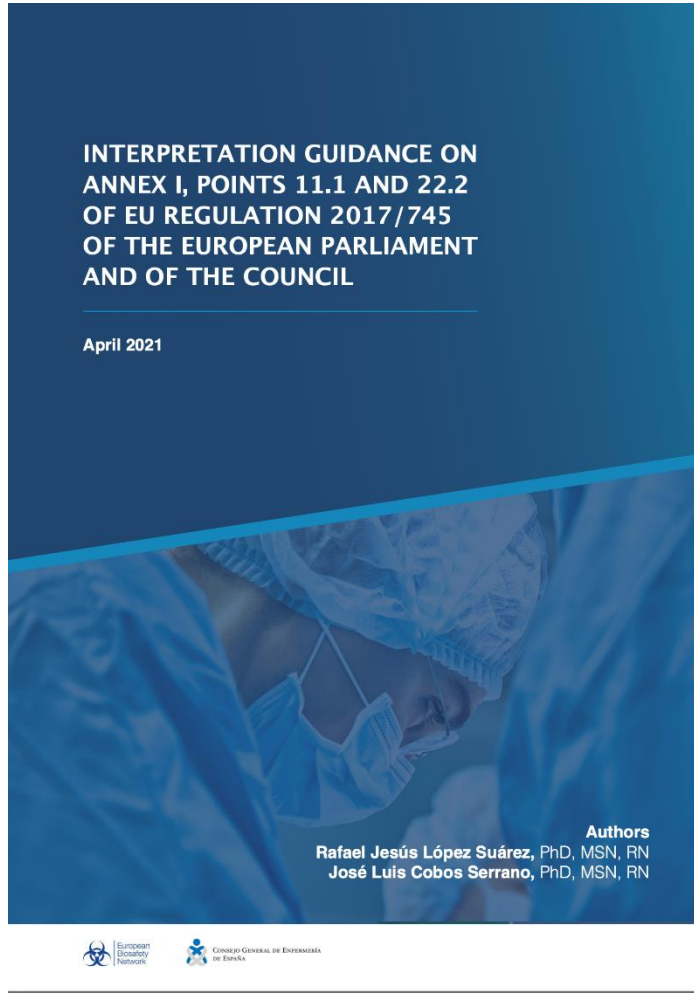
To solve this significant issue, one standard to ensure consistency in the implementation and the interpretation of the MDR across Notified Bodies, Member States and manufacturers regarding the requirements defined in Annex 1, points 11.1 and 22.2. is required.

INTERPRETATION GUIDANCE ON ANNEX I, POINTS 11.1 AND 22.2 OF EU REGULATION 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

The Spanish General Council of Nursing drafted interpretation guidance which, following consultation with a number of 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



REGULATIONS ON MEDICAL DEVICES INCORPORATING SAFETY-ENGINEERED MECHANISMS

Objective criteria

- The only way to ensure a homogeneous interpretation of points 11.1 and 22.2 of Annex I to the MDR is the inclusion of one objective criteria:

> ***"medical devices incorporating safety-engineered protection mechanisms"***

Objective criteria:
Safety –engineered mechanism

- The European regulations in force in the form of Directives clearly establish that medical devices with a built-in safety mechanism are the most suitable solution to guarantee the protection of healthcare workers, patients and lay persons against biological risk due to unintended pricks or cuts, such as needle stick injuries.

Safety mechanism

REGULATIONS ON MEDICAL DEVICES INCORPORATING SAFETY-ENGINEERED MECHANISMS

Commission standardisation request in support of Regulation (EU) 2017/745 and 746 of the European Parliament and of the Council

The standardisation request in Table 1 of Annex I among the “existing harmonised standards to be revised” and in Annex III, Part B, among the “Requirements for certain specific standards listed in Annexes I and II”, includes:

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

2.3. Sharps injury protection - Requirements and test methods - Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling (EN ISO 23908:2013)
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.

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The deadline for the updated ISO 23908 standard commissioned by the European Commission is 27 May 2024 for the drafting, technical work and editing to be completed to produce a final standard.

- Working Group 8 of ISO/TC 84 is now undertaking the work and making good progress on updating ISO 23908 “Sharps injury protection – Requirements and test methods – Sharps protection mechanisms for single-use needles, introducers for catheters and needles used for blood testing, monitoring, sampling and medical substance administration.”

- The MDCG sub group on standards should also help with providing greater clarity and guidance to Notified Bodies, Member States and manufacturers to ensure consistency in the implementation and the interpretation of the MDR regarding the requirements defined in Annex 1 , points 11.1 and 22.2.

- The MDCG should adopt guidance based on the interpretation guidance drafted by the Spanish General Council of Nursing

PREVENTING SHARPS INJURIES

Conclusions

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 and the updated ISO standard 23908;
- 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 the publication and implementation of the new standard and MDCG guidelines on safety mechanisms in medical devices.