



Medical Device Coordination Group

Agenda point 2 - Update from the Commission

14 October 2024
Agenda point 2

Q&A on Art10a – Development process

- **Objective:** produce COM Q&A on practical aspects of implementation of the obligations to inform about interruption or discontinuation of supply of certain devices
- **Art10a :** introduced OJEU 9 July 24, applicable from 10 Jan 25
- **Development:**
 - 2 CA only meetings in May and June
 - 3 workshop of MDCG CAs + Stakeholders 22 Aug, 5 Sept, 27 Sept 24
 - Written consultations
- **Next Steps:**
 - Publication – aim for end October 2024
 - Potential updates - decision tree diagram on risk assessment, practical experience

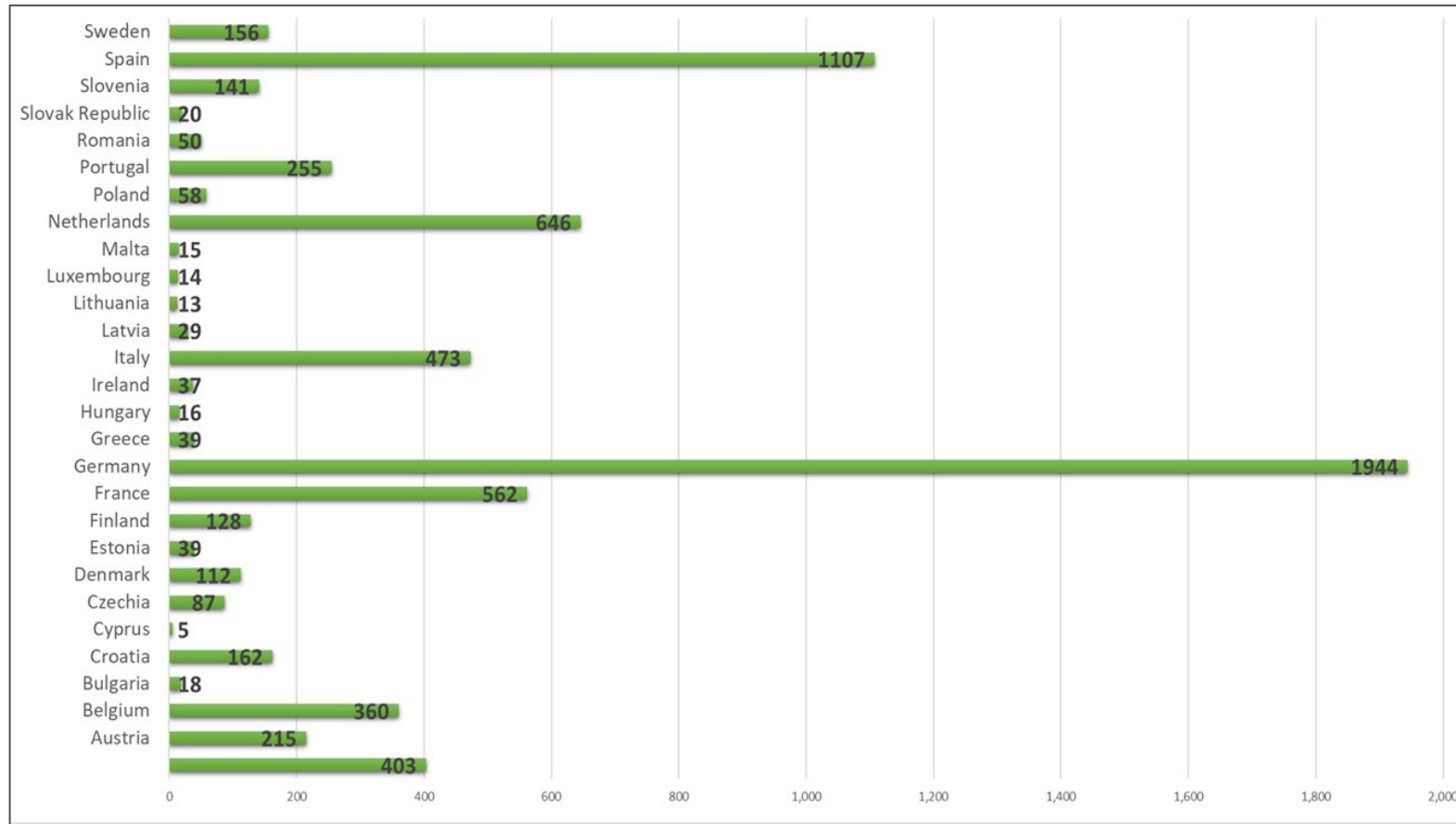
2.e - Supporting measures for MDR/IVDR implementation

Electronic instructions for use (e-IFUs)

- **Survey:** launched by the European Commission on August 1 2024 for healthcare professionals and other professionals working in healthcare institutions on the topic of e-IFUs. The survey ended on 11 October 2024.
- **Scope:** collecting feedback on the ongoing consideration to expand the scope of the e-IFU implementing regulation to all professional use devices.
- **Statistics** (as of 10 October 2024):
 - 7000+ responses received
 - 6701/7104 responses from healthcare professionals
(Physician/Surgeon, Nursing staff, Technician/Operator, Emergency Room medical staff, Central service sterile department processor, Pharmacist, Midwives)
 - 403 responses from procurement and administrative staff

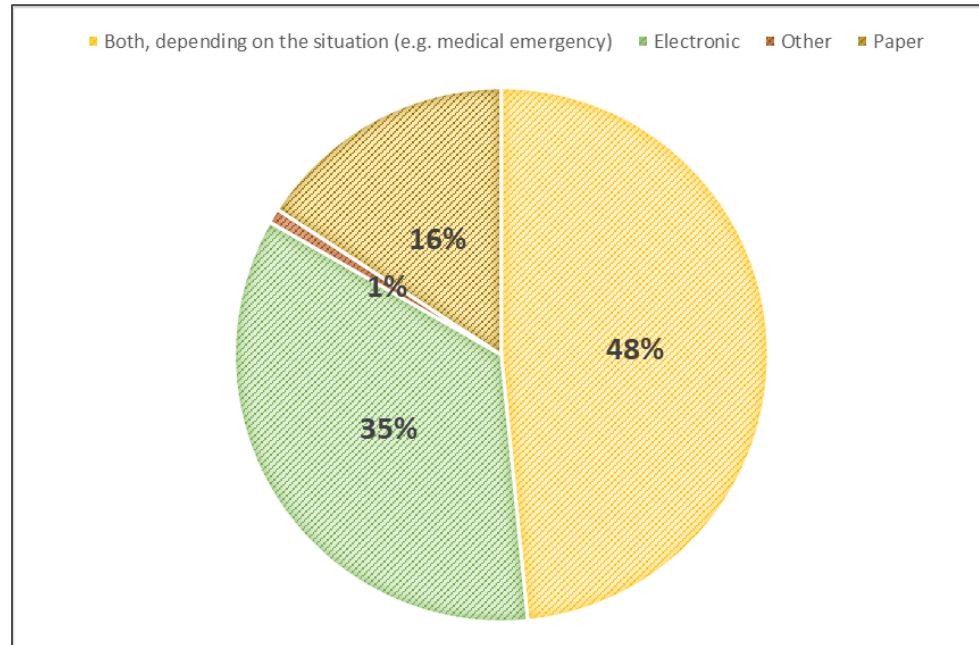
2.e - Supporting measures for MDR/IVDR implementation

Preliminary results received distributed by MS

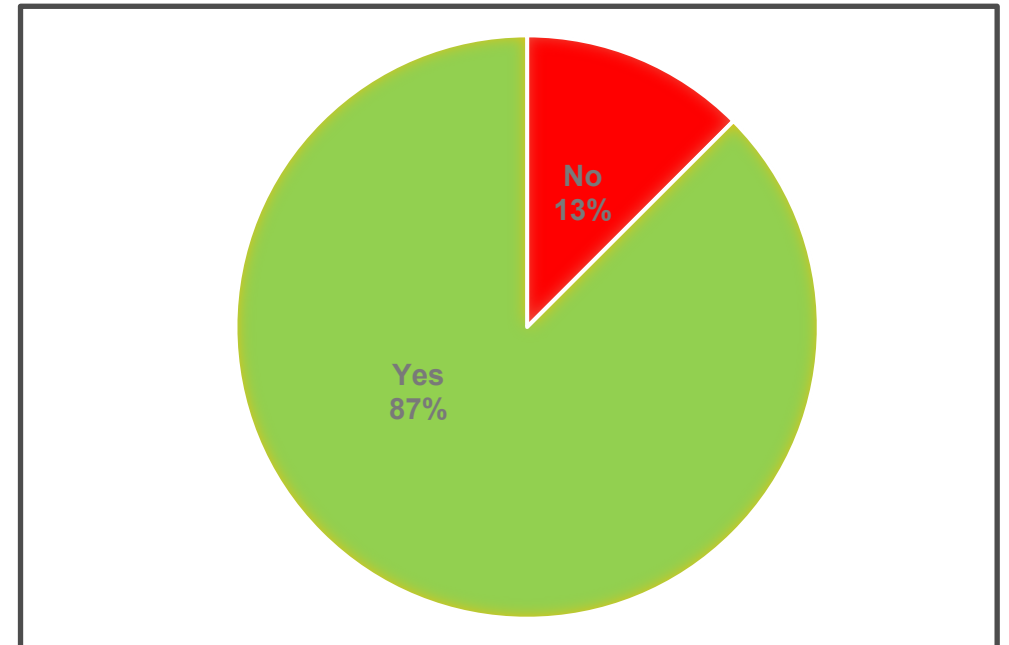


2.e - Supporting measures for MDR/IVDR implementation

When you **currently consult instructions for use (IFU)** do you consult a paper version or an electronic version?



Would you **prefer** using electronic instructions for use (eIFU) if available to you?



2.e - Supporting measures for MDR/IVDR implementation

For the respondents that indicated they **prefer PAPER** instructions for use, they underlined the following reasons:



Thank you

