Basic information

2023/2796(DEA) DEA - Delegated acts procedure	Procedure completed - delegated act enters into force
Assignment of Unique Device Identifiers for contact lenses Supplementing 2012/0266(COD) **Subject** 2.10.03 Standardisation, EC/EU standards and trade mark, certification, compliance 3.40.11 Precision engineering, optics, photography, medical 4.20.05 Health legislation and policy 4.60.08 Safety of products and services, product liability	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
ENVI Environment, Climate and Food Safety		

Key events

Date	Event	Reference	Summary
10/07/2023	Non-legislative basic document published	C(2023)04568	
10/07/2023	Initial period for examining delegated act 3.0 month(s)		
12/07/2023	Committee referral announced in Parliament		
18/10/2023	Delegated act not objected by Parliament		

Technical information

Procedure reference	2023/2796(DEA)
Procedure type	DEA - Delegated acts procedure
Procedure subtype	Examination of delegated act
	Supplementing 2012/0266(COD)
Stage reached in procedure	Procedure completed - delegated act enters into force
Committee dossier	ENVI/9/12630

Documentation gateway

European Commission

Document type	Reference	Date	Summary
Non-legislative basic document	C(2023)04568	10/07/2023	

Assignment of Unique Device Identifiers for contact lenses

2023/2796(DEA) - 19/06/2014

The Council took note of a presidency progress report on two draft regulations on medical devices and on in vitro diagnostic medical devices.

Ministers provided **guidance for future work** on these files as regards the three following elements:

(1) The designation of conformity assessment bodies as notified bodies and the monitoring of these bodies: most Member States supported the idea of further clarifying the procedures for designating notified bodies and strengthening cooperation between Member States to ensure that notified bodies meet similar standards throughout the EU. But they also warned against increasing the administrative burden unnecessarily.

(2) The reporting of incidents, market surveillance and corrective measures: all Member States supported strengthened requirements on post-market surveillance and responsibility for follow-up by manufacturers, e.g. by collecting and analysing data on the performance of medical devices, in particular on adverse reactions in which they are involved.

However, as regards the balance between controls before and after placing devices on the market there were diverging views.

(3) The role and tasks of the medical device coordination group (MDCG): all delegations support the establishment of the MDCG. Most delegations support the idea to unify co-operation between Member States regarding medical devices and in vitro diagnostic medical devices by appointing one representative per Member State in the Medical Device Coordination Group (MDCG) rather than separate representatives for medical devices and in vitro diagnostic medical devices. There is broad agreement that the establishment of a network of reference laboratories is important for the proper evaluation of in vitro diagnostic medical devices.

As regards the evaluation of medical devices, however, many delegations have expressed an interest in either complementing the reference laboratories with device panels or replacing them entirely with device panels in order to provide relevant expertise input for regulatory measures.

Overall, many Member States stressed the need to develop a **consistent legislative package** that guarantees patient safety and facilitates innovation in order to improve treatments, decrease costs for patients and taxpayers, and preserve the competitiveness of the EU industry.

The Council instructed its preparatory bodies to continue examining the two files with a view to **agreeing a Council position in the autumn**.

Assignment of Unique Device Identifiers for contact lenses

2023/2796(DEA) - 01/12/2014

The Council took note of a **presidency progress report** on two draft regulations on **medical devices** and in vitro diagnostic medical devices.

The report noted that considerable progress has been achieved on these files under the Italian presidency. However, further discussions are needed for the Council to agree its position.

Outstanding issues include:

- **aesthetics devices**: the report noted that 15 delegations favoured inclusion of aesthetic devices under the scope of the Medical device Regulation. Five delegations opposed this, mainly on the grounds that this would increased the financial and administrative burden on competent authorities;
- **ingested products**: the proposal on medical devices provides for inclusion of certain substances or combinations of substances intended to be ingested, inhaled or administered rectally or vaginally ("Ingested products") into the scope of the Regulation. It further provides that all these devices be classified as high risk devices ("Class III"). A compromise has been made in this area given that several delegations expressed concerns on the suitability of the proposal, especially in relation to the delimitation between medical devices and medicinal products. It was however generally recognised that such products could not fall outside the scope of both medicinal products and medical device legislation;
- **reprocessing of single-use devices**: the Commission proposal provides rules for reprocessing of single-use devices to make them suitable for further use within the Union. The Presidency believes that a compromise proposal that allows Member States to prohibit re-processing under national law but provides that if not prohibited re-processing should follow minimum harmonised rules could find support from a broad majority;
- **the unique device identification system**: the Commission proposal contains a requirement that manufacturers fit their devices with a Unique Device Identification (UDI) which allows for traceability. Important issues include the functionality of the system, and the nature and scope of requirements;
- **mechanisms for surveillance and appointment of the Notified Bodies responsible for conformity assessment of medical devices and In vitro diagnostic medical devices**: the main subject of controversy is the level of detail laid down in the legislative provisions and, consequently, what had better be left for guidelines;
- **scrutiny mechanism for certain high-risk devices**: almost all delegations state that the scrutiny procedure as proposed by the Commission is not possible to apply. Many delegations argue that a scrutiny mechanism before devices are placed on the market is not necessary. On the other hand, some delegations would wish to include a "pre-market scrutiny mechanism" for implantable devices in the highest risk class "Class III devices". There is scope for a possible compromise on this issue;
- **clinical investigation**: the discussion of the Working Party is currently going in the direction of further aligning the provisions on ethical and methodological principles to those for clinical trials of medicinal products;
- **tasks of the proposed medical device coordination group (MDCG)**: the progress report noted the discussions of the tasks of the MDCG is closely related to many of the other issues still subject to discussion. A central question is the legal status of the opinions from MDCG, where most delegations hold that this cannot be of a binding nature, as this would make it a decision-making body;
- **role of expert panels and reference laboratories**: while most delegations agree that there is a need for such laboratories for in vitro diagnostic medical devices in order to compare predicting powers of tests, few delegations see the same need as regards other medical devices. Instead, they favour the establishment of expert panels with competence for certain groups of devices.

The Presidency is satisfied to have contributed to the progress of the work and intends to **compile complete texts for both proposals** by the end of its tenancy.