Reactie Europese Commissie
Lucia Caudet Lucía Caudet, EU spokesperson for the Internal Market, Industry, Entrepreneurship and SMEs

Vraag en antwoord (Engles)

1– EUDAMED

Although we understand many points are still under discussion, could you please confirm on the record

1)which elements will be made publicly available in EUDAMED

- Actors (manufacturers, authorised representatives, importers, sponsors, notified bodies, competent authorities),

- UDI/Devices,

- Certificates,

- Field Safety Notices (vigilance),

- Some information about Clinical investigation but always including the final report and its summary,

- results summaries of the reviews and assessment of market surveillance activities of the Member States.

2) which elements will NOT be made publicly available

All data considered as confidential data or personal data and related exchange of information between Member States as well as between Member States and the Commission.

3) which points are still being discussed

Discussions are still taking place on the extent of public access for i) data on clinical investigation beyond the final report and its summary; ii) vigilance data beyond the Field Safety Notice and iii) stage for disclosing vigilance data on incident reports.

The more exhaustive the list, the better, of course.

Could you also please state the reasons for 2) and 3)? Or refer to a MDCG document stating the reasons?

MDR Art 73(3), Art 92(3), Art 100(3)

2– Concerning INCIDENTS

Could you confirm that, at this point, it is still not known whether incidents will be made available to the public and/or to health care professionals (like in MAUDE)? Please feel free to add any further reason you think is necessary to mention.

Please use the following quote:

"In the context of the ongoing preparation of the future EUDAMED data base there are still discussions on the type and level of information to be disclosed. The aim of these discussions is to weigh and find the right balance between different objectives including the need for transparent public information and ensuring the effective protection of public health, while avoiding damage to patients or manufacturers resulting from the disclosure of preliminary, possibly inaccurate or unverified information. ”

3–« The public »

It wasn’t clear to us whether the definition of « the public » was under discussion too. Does the « public » include health care professionals ? Or is it only citizens ? Both ?

When talking about the accessibility to data in Eudamed, the notion of public covers both health care professionals and the public in general (I.e. health care professionals are thus included in public for Eudamed purposes).

4–Sanctions

COM quote: « The Commission does not have the authority to sanction manufacturers or other operators in the field of medical devices. The enforcement of the rules related to medical devices is the responsibility of national authorities and other national bodies. The Commission can only initiate action in the form of infringement proceedings if it finds that Member States are in breach of EU legislation. »

[quote ok correct, please see small slight stylistic change only]

5–MDR

COM quote : There was no lobby to block the reform. There was a willingness to reform."

"The Commission always acts in the public interest, not in the interest of any one group."