Survey on Medical Device Regulation & post market surveillance

Initial responses
Please respond by 19 June

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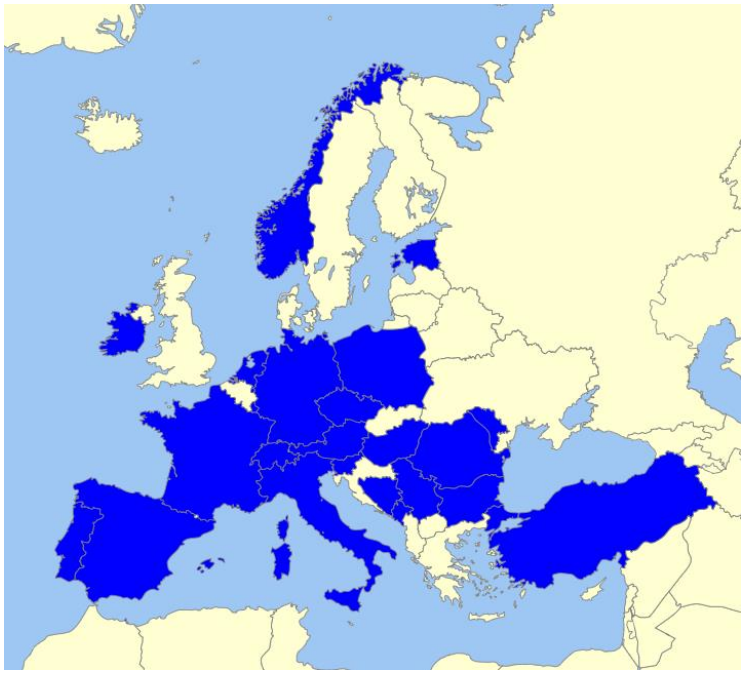
Background

- The Medical Devices Regulation (MDR) (EU) 2017/745 will apply fully from **26th May 2020**
- The Medical Devices Directive (MDD) will then be withdrawn.



Answers from:

Estonia, Netherlands, Montenegro, Czech Republic, Luxemburg, Portugal, Italy, Turkey, Germany, Moldova, Bulgaria, Norway , Austria, Slovenia, Hungary, Ireland, Serbia, Poland, Bosnia and Herzegovina, Romania, France, Spain (23 of 38)

Initial survey responses

Q: Does your country currently require (in national regulation) post market surveillance of Medical Devices with a measuring function?

A: Nearly all countries answered, that they have a post market surveillance. For the majority of them it is required by national regulations.

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*some of the answers need clarification, they have might not realised post market survaillance rather than pre market testing and some of post market surveillances are only for NAWI

Q: If there is no national regulation, is there an equivalent system imposed by health insurers or national health providers on their suppliers?

A: Four countries have additional regulation systems parallel to national regulations

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First conclusion:
There is an significant number of members that could have interest on an EMN about the Medical Device Regulation