New advisory structures

timescales, needs of the regulators and opportunities

European Society of Cardiology

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Paul Piscoi
Health Technology and Cosmetics
DG Internal Market, Industry, Entrepreneurship and SMEs
Scientific advisory bodies

(1) Expert panels

(2) Expert laboratories and

(3) EU reference laboratories
Expert panels - functions

- provision of scientific, technical and clinical opinion and advice necessary for the assessment of the clinical evaluation in relevant medical fields;
- covering specific categories or groups of devices or specific hazards linked to these;
- provide scientific, technical, clinical assistance to the Commission and MDCG;
- contribute to the development and maintenance of guidance and common specifications;
- contribute to the development of international standards;
- provide opinions in response to consultation by manufacturers;
- contribute to the identification of concerns and emerging issues linked to devices;
- provide views on the performance evaluation of certain *in vitro* diagnostic medical devices.
Expert panels - timelines

Mandatory by 26 of May 2020 but *de facto* they should to be in operation after the first notified body that may certify certain class III and IIb and class D *in vitro* diagnostic medical devices is designated, which is estimated to occur towards mid-2019 – smooth transition.
Expert laboratories - functions

Same as for the panels with the exception of:

- Article 54(1) MDR – clinical evaluation consultation procedure
- Article 61(2) MDR – consultation by the manufacturer
- Article 48(4) IVDR – views on the performance evaluation of class D in vitro diagnostic medical devices
Designation of expert laboratories is not mandatory, as Commission may designate such scientific advisory bodies and this only when a Member State submits an application for designation.
**EU reference laboratories - functions**

- verify the performance claimed by the manufacturer and the compliance of class D devices with the common specifications;
- test batches of class D devices;
- provide scientific, technical, clinical assistance to the Commission and MDCG, Member States and notified bodies;
- provide scientific advice regarding state of the art in relation to specific devices;
- set up and manage a network of national reference laboratories;
- contribute to the development of appropriate testing and analysis methods;
- provide recommendation on suitable reference materials and reference measurement procedures;
- contribute to the development of common specifications and international standards.
EU reference laboratories - timelines

The designation of EU reference laboratories should be done before 25 November 2020 and they need to perform their functions as from 26 November 2020.
Needs and opportunities – next steps

- IAs to designate expert panels
- IAs for fees for expert panels and laboratories
- Calls for selection and the selection of the experts to be appointed for each panel and on the central list of experts
- Guidance on the consistent interpretation of the criteria used to provide a scientific opinion on the CEAR for medical devices
Thank you for your attention