IVDR & Rare Diseases – update on steps taken so far

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**IVDR 2017/746** (May, 26th 2022) – *Harmonization*

- **European regulation**
  - CE-IVD & In-house (IH)-IVD
  - Industry & Health Institution

- **EU guidelines / interpretation documents – MDCG**
  - MDCG 2022-15, MDCG 2022-22 rev1, MDCG 2022-9, ...

**MDCG Guidelines**
Initiatives ESHG took to help genetic diagnostic laboratories

Initiatives taken by ESHG
1. Member of Biomed Alliance
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1. Member of Biomed Alliance
2. Task Force IVDR – ESHG

June 2022:
Online webinar - “IVDR – beneficial or just an expensive straitjacket?”

June 2023:
Get2gether - IVDR is a challenge for all of us, the greatest challenge is keeping "orphan" diagnostics available
"IVDR – Beneficial or just an expensive straight-jacket?"

June 22, 2022, 10:00 – 16:30 hrs

The new IVD EU regulation (IDVR 2017/746) has major implications on the use, availability and associated costs of in vitro diagnostic tests. But on the other hand, it also builds in many ways new assurance points to improve and monitor the quality of our diagnostic services.

To help laboratories prepare for the IVDR, including compliance with IVDR requirements for in-house devices, the ESHG is hosting a free of charge full-day webinar on IVDR, providing the basics and latest updates on implementation, as well as tips and tricks for working towards compliance.

During these webinar presentations we invite speakers from the EU Commission, Notified Bodies, Competent authorities, national IVDR working groups, lab people working on the implementation of the IVDR will share their knowledge and experience.

Program – 8 speakers & discussion sessions

- Introduction on IVDR
- Role of different organisation: EC, CA, NB, Reference labs, observers
- IH-IVD’s and hospital exemption
- MDCG guidelines and the guideline of in-house devices

Participation is free of charge, registration is necessary!

High attendance > 300 persons
Get2gether: IVDR is a challenge for all of us, the greatest challenge is keeping "orphan" diagnostics available

Monday June 12, 2023 - Room Boisdale – 15:00-16:30

Speakers

- Insight into the main elements of IVDR and initiatives ESHG took to help genetic diagnostic laboratories
  Els Dequeker, University of Leuven, Liaison for the ESHG in the Task Force of IVDR Biomed Alliance
- Process for CE-marking of a genetic test
  Alex Laan, Head of the IVD Notified Body BSI The Netherlands
- Where can genetic diagnostic laboratories help industry and vice versa
  Maurizio Suppo, Co-owner/VP QARAD

Panel discussion

With persons a laboratory, clinician, a diagnostic company, a Notified Body and a consultant
Initiatives ESHG took to help genetic diagnostic laboratories

Initiatives taken by ESHG
1. Member of Biomed Alliance
2. Task Force IVDR – ESHG
3. Conference on Rare Diseases – CZ Presidency Council of Europe
Message:

*a realistic incubation period for ‘orphan’ diagnostics* to encourage continued to innovate and truly help families and patients with rare disease
IVD’s under the IVDR

Main goal:
Regulating medical devices’ quality, safety and reliability

Impact:
• More demanding requirements for manufacturers and health institutions
• Use of IH-IVDs will be restricted
• Discouraging innovation for diagnostics
Conformity assessment is needed before use of the device

**Justification of use of IH-IVD**
- Quality Management System
- General Safety Performance Requirements
  - Risk management
  - Performance evaluation studies
    - Scientific validity
    - Analytical validity
    - Clinical validity
  - Post market surveillance studies

**Competent authority**
- IH-IVD article 5.5

**CE-IVD**
- Notified Body
  - 175 pages
  - 10 chapters, 123 articles
  - XVII Annexes

*‘Orphan’ diagnostics*

Flexibility will be the key
“Orphan” IVD devices - before and after implementation of IVDR

Before IVDR  | RUO  | Under validation according ISO 15189
After IVDR   | CE-IVD | IH-IVD

- Discourage investment in technological and medical innovations
- Jeopardize patient health
- Reverse all the initiatives of Europe to reduce the diagnosis time

Development process of a diagnostic device

G Rosati et al, ACS Nano 2021, 15, 11, 17137–17149
EPSCO Council Meeting - December 9, 2022

- ESHG member of Biomed Alliance = stakeholder EU
- Call for action > 80% EU population
Biomedical Alliance in Europe

Today we are presenting at the European Commission’s MDCG on issues around the availability of orphan #medicaldevices & #IVDs under #MDR and #IVDR.

Urgent action is needed to improve the availability of these essential devices, read more in our recent press release: https://lnkd.in/ehzddrQ4

Elisabeth Dequeker, Marc Gewillig
‘Orphan’ IVD’s – possible solutions

And keep focus on IVDs’ quality, safety and reliability

Importance: Keep harmonization in EU and protecting the aim of the IVDR

Article 54:
Derogation from the conformity assessment procedures
54.1: …level of member state to bring a product on the market or putting into service
54.2-4: …possibility to make derogation European wide for the device

Article 54 of the IVDR provides that the national authorities may authorise the use of a specific device even though the conformity assessment procedures have not been carried out if the use of the device in question is in the interest of public health or patient safety or health. The European Commission has the possibility of extending national derogations to the entire territory of the Union.

Article 5.5
Annex I: General safety and performance requirements