UKHealthTech CONFERENCE 2016

MediWales

Medical Device Regulations – An Industry Perspective.

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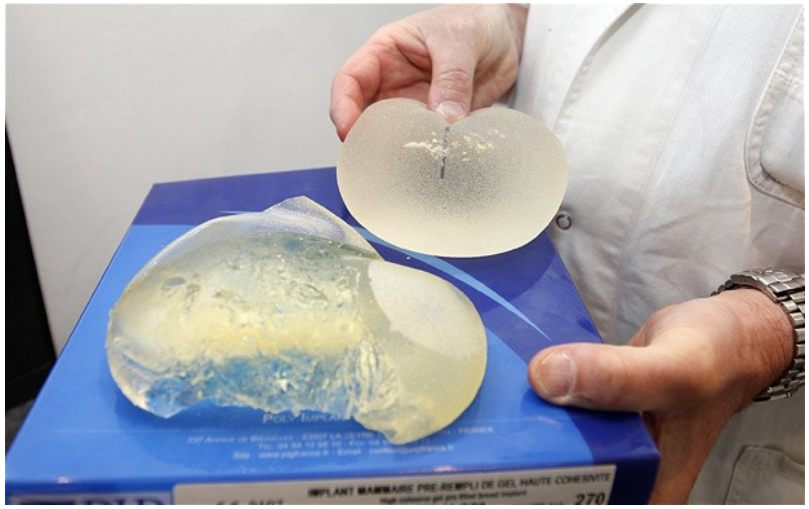
Agenda

1. Why the Need for Change?
2. The IVDr and MDr.
3. Overall Regulatory Process.
4. The Detail.
5. The Timelines.

Why the need for change?

Breasts have a lot to answer for!!

PIP (Poly Implant Prothèses) breast implants affair



Why the need for change?

Notified Bodies

- Some poor performing NBs
- Lack of consistency (e.g. designation) and competence

List Based Classification

- Annex II was politically driven decision
- Does no accommodate potential new high risk devices

Post-Market Monitoring

- Member States not sharing information on product issues
- Lack of visibility of pan EU issues

The IVDr and MDr

Draft Regulation 2012/067 (IVDs) & 2012/266 (MDs)

- Regulation not Directive
- No Transposition
- Transition Period
  - IVDs - 5 years
  - MDs – 3 years

Who are the players?

- The EU Commission
- The European Parliament
- The Council Members (Member States)

What is Changing?

What is changing?

- Classification (based on IMDRF)
- Pre-Market Clinical Evidence & PM Surveillance (state-of-the -art)
- UDI/EUDAMED
- Notified Body designation and monitoring
- Person responsible for regulatory compliance
- Definitions
- Economic operators
- Reference Laboratories

Current vs Future

IVD Directive - 98/79/EC

Require a Notified Body

Do not Require a Notified Body (80-90%)

IVD Regulation

Require a Notified Body (80-90%)

Do not Require a Notified Body

Overall Regulatory Process

Draft IVD Regulations (2012/067)

Notified Bodies

- More scrutiny
- Consistent designation process across EU
- Consistent approach by Notified Bodies

Risk Based Classification

- Adoption of IMDRF (GHTF) Classification (A, B, C and D)
- Allows for new tests
  - Need for guidance to ensure consistent application

In-House Assays (Health Institutions)

- More Controls e.g. QMS /Accredited to EN ISO 15189
- Exempted use need to be justified if CE mark device available.
- Provide details of compliance to Competent Authority

Draft IVD Regulations (2012/067)

Transition Period

- The transition period for IVDs will be 5 years
  - Classification changes
  - More products will require a Notified Body review
- No grandfathering

Reference Laboratories

- Designation and governance (currently 6 months prior to application)
- Involved both pre and post market (CS testing & batch testing)

Companion Diagnostics (CoDx)

- Involve Notified Body – all Class C
- Prior authorisation by a Members States
- Will involve the EMA

Draft IVD Regulations (2012/067)

Self Testing & Near Patient Tests

- Specific requirements for ST and NPT
- Most ST devices are Class C except pregnancy, cholesterol tests and urine dipsticks (glucose, RBC, WBC etc.)

Clinical Evidence & Post Market Performance Follow-up

- Analytical & clinical performance / scientific validity
- Post-Market Surveillance – Plans & Reports
- Vigilance – reporting time 15 days

Scrutiny Mechanisms

- Medical Device Coordination Group (MDCG)
  - Novel Class D devices
  - Not covered by an existing Common Specification (CS)

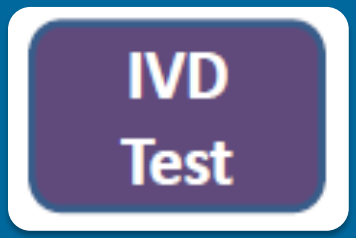
Draft IVD Regulations (2012/067)

Supply Chain (Economic Operators)

- Manufacturers, Authorised Representatives (ARs), Importers and distributors
  - Increased responsibilities for importer and distributors
  - Manufacturers, ARs & Importers – register on EUDAMED

Notified Body Resource Constraints

- More products under NB review (expertise/competence)
- More companies requiring NB assessments and ISO 13485 certification
- More companies / critical suppliers subject to unannounced audits



Scope of Regulations for IVDs

- Genetic tests, Near Patient Tests, CDx, Software
- Distance Sales
- Predisposition to a medical condition or a disease
  - Indirect medical purpose e.g. Lifestyle tests

Draft IVD Regulations (2012/067)

Increased Cost for Manufacturers

- Initial costs for compliance – no grandfathering
- Notified Body costs – more products/classification changes
- Labelling updates
- On-going costs – Post-Market Surveillances

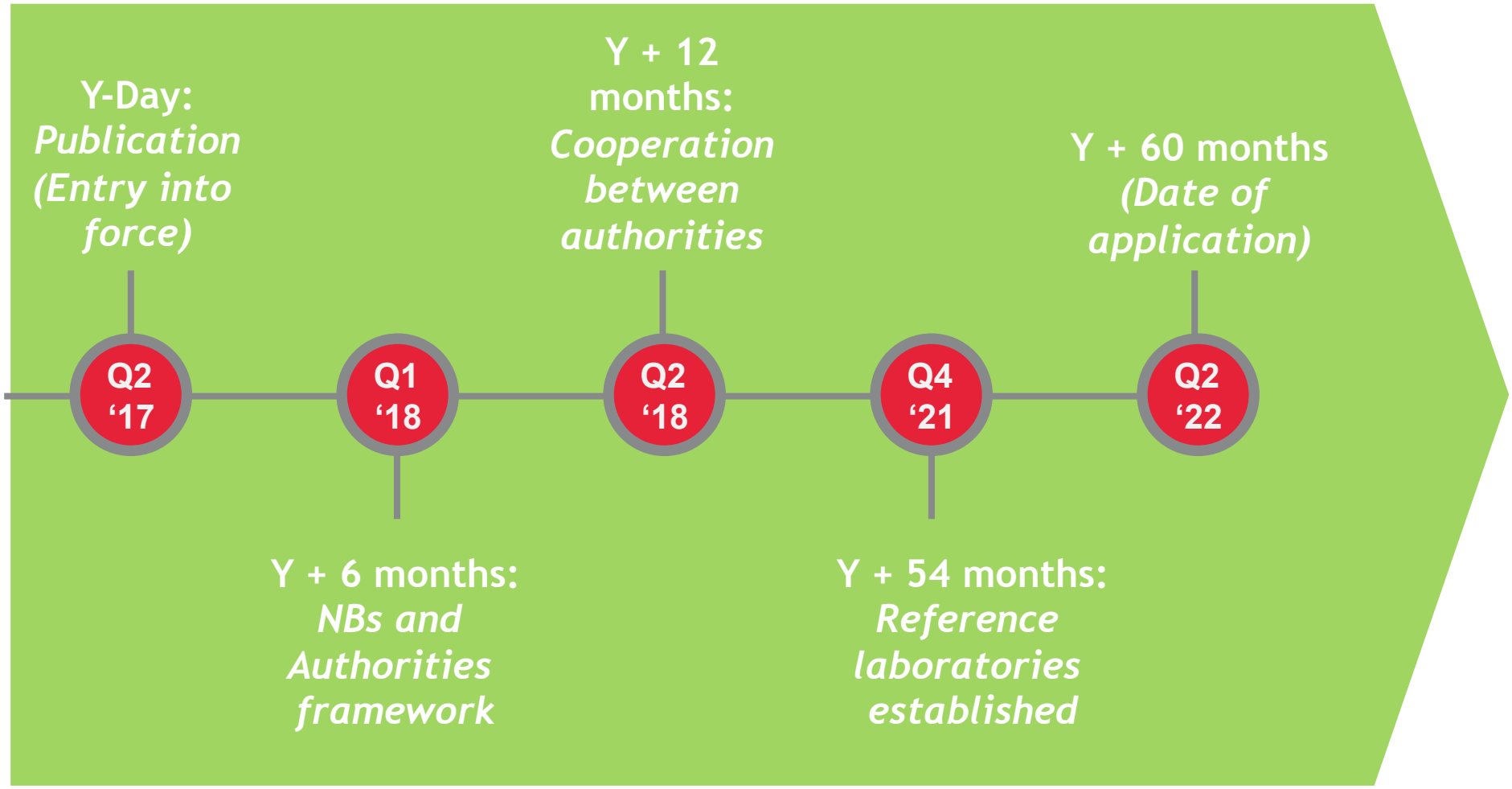
Time to Market

- Scrutiny mechanism and Ref Lab involvement will extend timelines for getting approvals
- Potentially more clinical performance studies required

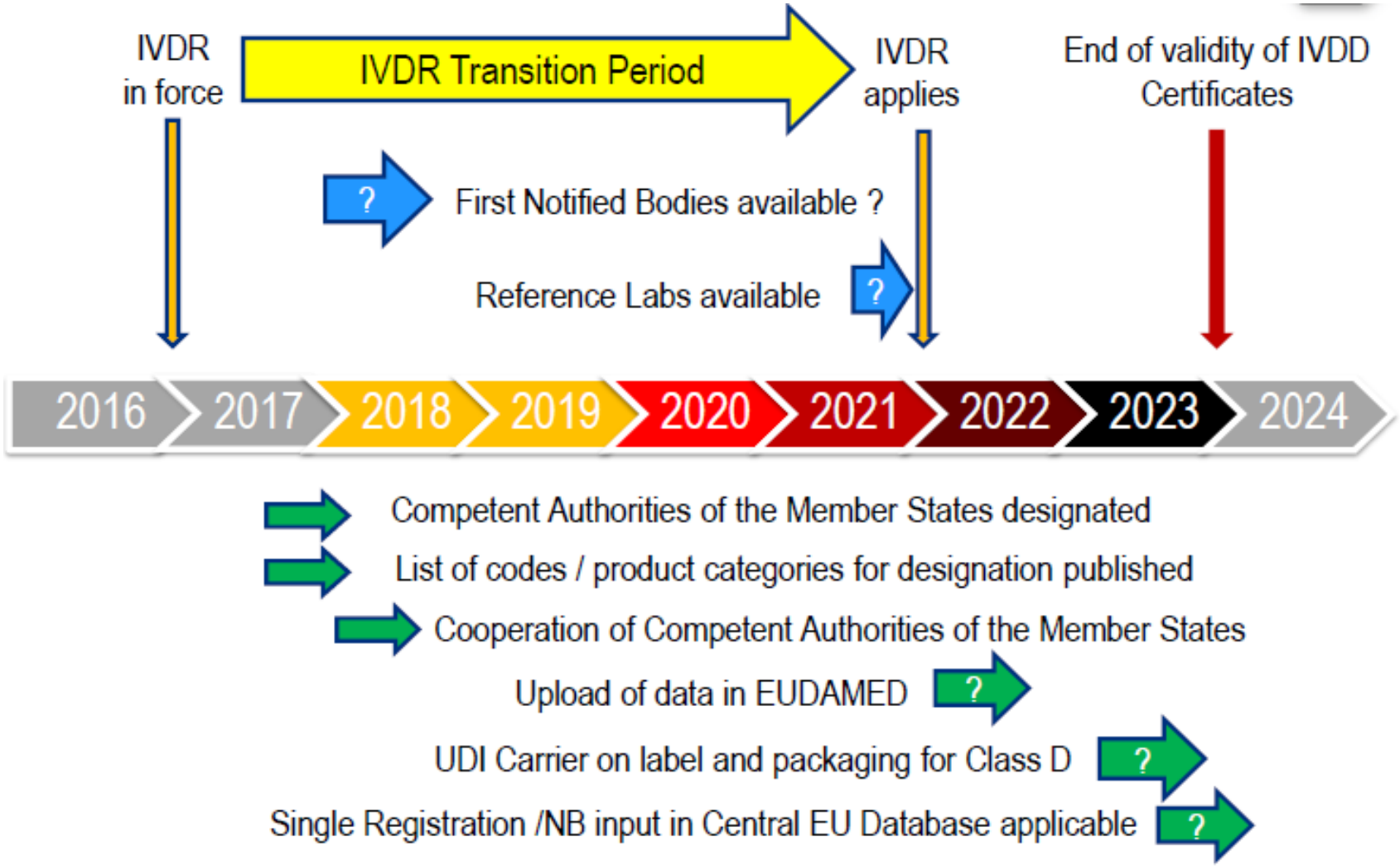
Stifle Innovation / Novel Tests in EU

- Due to costs / time - smaller manufacturers may not develop/market novel/ innovative tests
- Some novel test will be classified as "high risk" – longer scrutiny/approval.

Timelines



Timelines



Summary

1. The requirements will be a regulation not a directive – no transposition but a transition period.
2. New Classification scheme.
3. More Notified Body involvement for – class B, C and D devices.
4. More emphasis on clinical evidence and post-market surveillance.
5. Increased initial costs and ongoing costs for manufacturers.
6. Key to success is a cooperative working relationship between manufacturers, Notified Bodies & Competent Authorities.

Thank You!

Any Questions ?

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