DIAGNED
preventie diagnose prognose therapie

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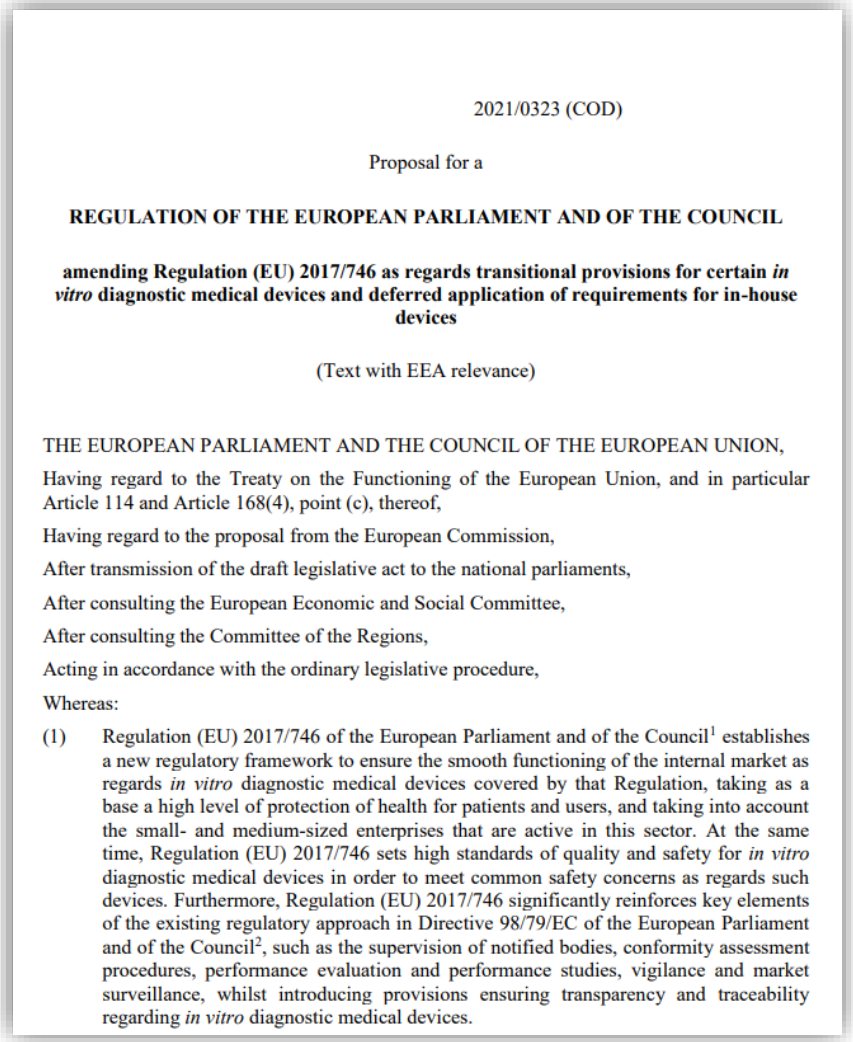
IVDR & Performance

Introduction

- “performance” mentioned 673 times
- “diagnostic” 82 times

- Performance claims of IVDs are evaluated by Notified Body
  - >80% of all IVDs
  - Pre- & post-market assessments



2021/0323 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Regulation (EU) 2017/746 as regards transitional provisions for certain *in vitro* diagnostic medical devices and deferred application of requirements for in-house devices

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 and Article 168(4), point (c), thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

After consulting the European Economic and Social Committee,

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) Regulation (EU) 2017/746 of the European Parliament and of the Council[1] establishes a new regulatory framework to ensure the smooth functioning of the internal market as regards *in vitro* diagnostic medical devices covered by that Regulation, taking as a base a high level of protection of health for patients and users, and taking into account the small- and medium-sized enterprises that are active in this sector. At the same time, Regulation (EU) 2017/746 sets high standards of quality and safety for *in vitro* diagnostic medical devices in order to meet common safety concerns as regards such devices. Furthermore, Regulation (EU) 2017/746 significantly reinforces key elements of the existing regulatory approach in Directive 98/79/EC of the European Parliament and of the Council[2], such as the supervision of notified bodies, conformity assessment procedures, performance evaluation and performance studies, vigilance and market surveillance, whilst introducing provisions ensuring transparency and traceability regarding *in vitro* diagnostic medical devices.

Introduction

- intended purpose
- benefit-risk determination

- the device's intended purpose:
- (i) what is detected and/or measured;
- (ii) its function (e.g. screening, monitoring, diagnosis or aid to diagnosis, prognosis, prediction, companion diagnostic);
- (iii) the specific information that is intended to be provided in the context of:
  - a physiological or pathological state;
  - congenital physical or mental impairments;
  - the predisposition to a medical condition or a disease;
  - the determination of the safety and compatibility with potential recipients;
  - the prediction of treatment response or reactions;
  - the definition or monitoring of therapeutic measures;
- (iv) whether it is automated or not;
- (v) whether it is qualitative, semi-quantitative or quantitative;
- (vi) the type of specimen(s) required;
- (vii) where applicable, the testing population; and
- (viii) for companion diagnostics, the International Non-proprietary Name (INN) of the associated medicinal product for which it is a companion test.

Definitions

- Definitions wrt device performance 39-44

- (39) ‘performance of a device’ means the ability of a device to achieve its intended purpose as claimed by the manufacturer. It consists of the analytical and, where applicable, the clinical performance supporting that intended purpose;

- (40) ‘analytical performance’ means the ability of a device to correctly detect or measure a particular analyte;

- (41) ‘clinical performance’ means the ability of a device to yield results that are correlated with a particular clinical condition or a physiological or pathological process or state in accordance with the target population and intended user;

Definitions

- Definitions wrt device performance 39-44

- (42) ‘performance study’ means a study undertaken to establish or confirm the analytical or clinical performance of a device;

- (43) ‘performance study plan’ means a document that describes the rationale, objectives, design methodology, monitoring, statistical considerations, organisation and conduct of a performance study;

- (44) ‘performance evaluation’ means an assessment and analysis of data to establish or verify the scientific validity, the analytical and, where applicable, the clinical performance of a device;

Performance evaluation

- Performance evaluation/clinical evidence (chapter VI, art. 56 – 77)
  - Scientific validity
  - Analytical performance
  - Clinical performance

GSPR
General Safety and Performance Requirements

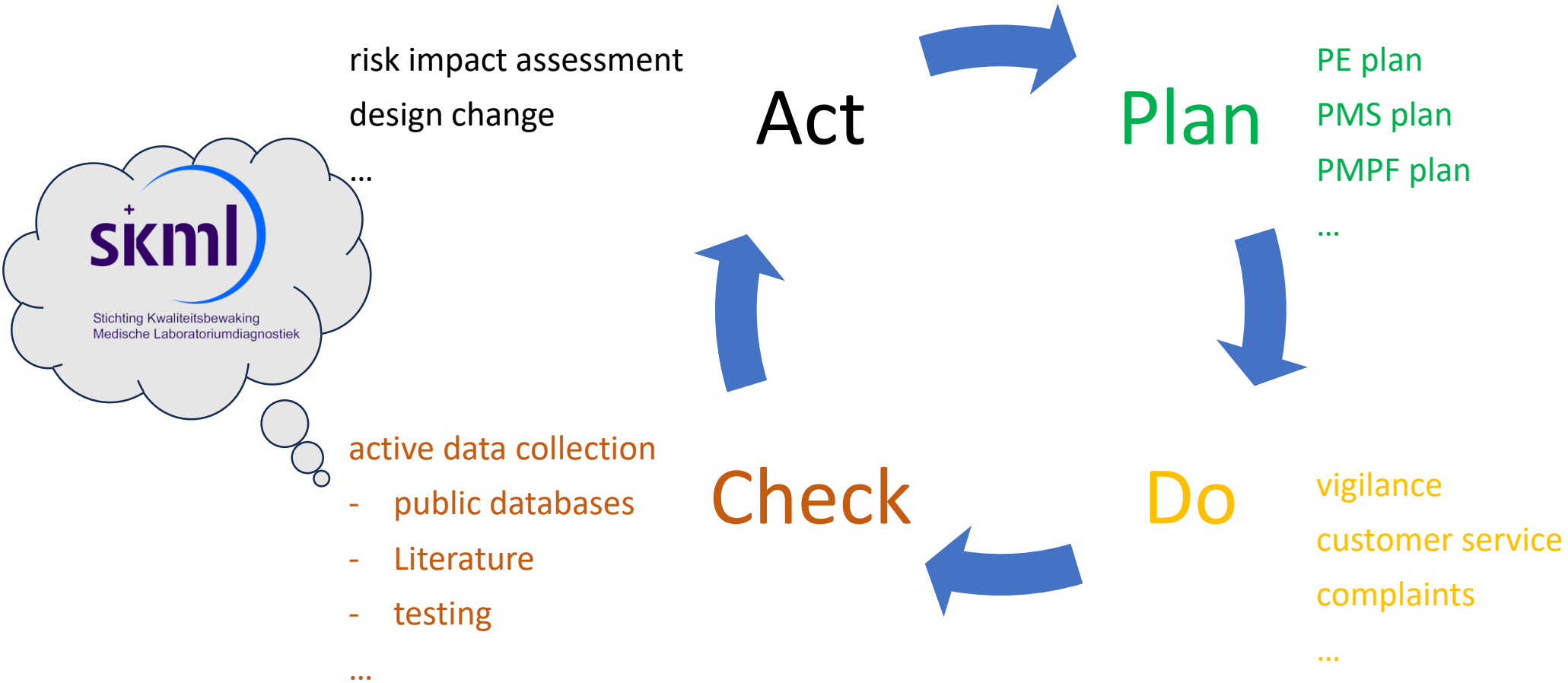
- Annex I, section 9 Performance characteristics
  - Where the performance of devices depends on the use of calibrators and/or control materials, the metrological traceability of values assigned to calibrators and/or control materials shall be assured through suitable reference measurement procedures and/or suitable reference materials of a higher metrological order. Where available, metrological traceability of values assigned to calibrators and control materials shall be assured to certified reference materials or reference measurement procedures.
- IFU contain analytical and clinical performance characteristics
- Performance is assessed by notified bodies against SOTA
  - Common Specifications
  - Harmonized Standards

PMPF Annex XIII, part B

Post-Market Performance Follow-up

- confirming the safety and performance of the device throughout its expected lifetime
- identifying previously unknown risks or limits to performance and contra-indications
- identifying possible systematic misuse

Post-Market Surveillance



Stichting Kwaliteitsbewaking
Medische Laboratoriumdiagnostiek

Disclosure

Presenter is 100% employed by Abbott, a company that manufactures IVDs and medical devices.