12.03.2026

ANTWERP

BSAC/NVC congress

Implementation of the IVD Regulation

Ranya Moudallel and Jeroen Poels

famhp

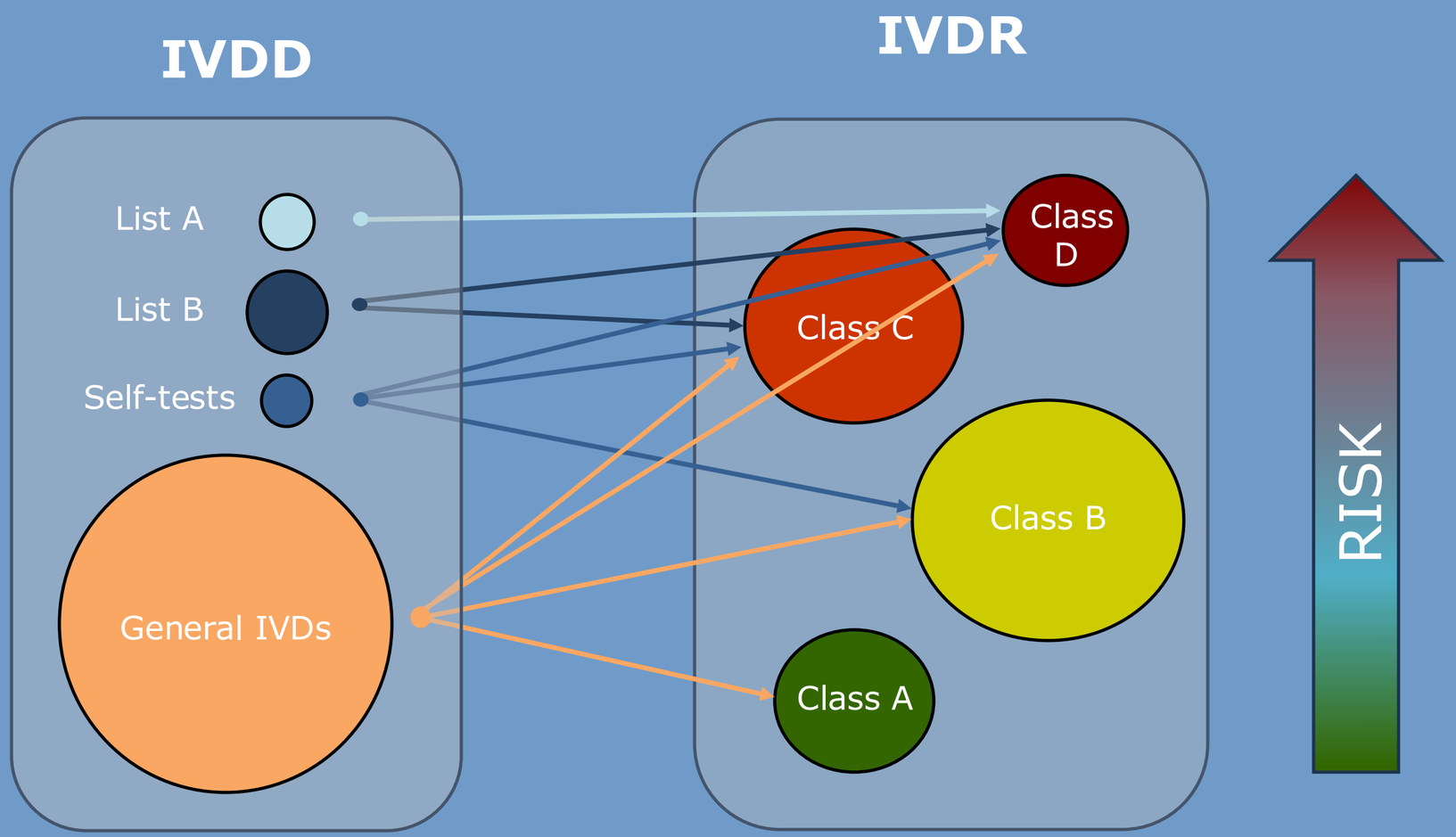
.be

TABLE OF CONTENTS

Some background on IVDR:

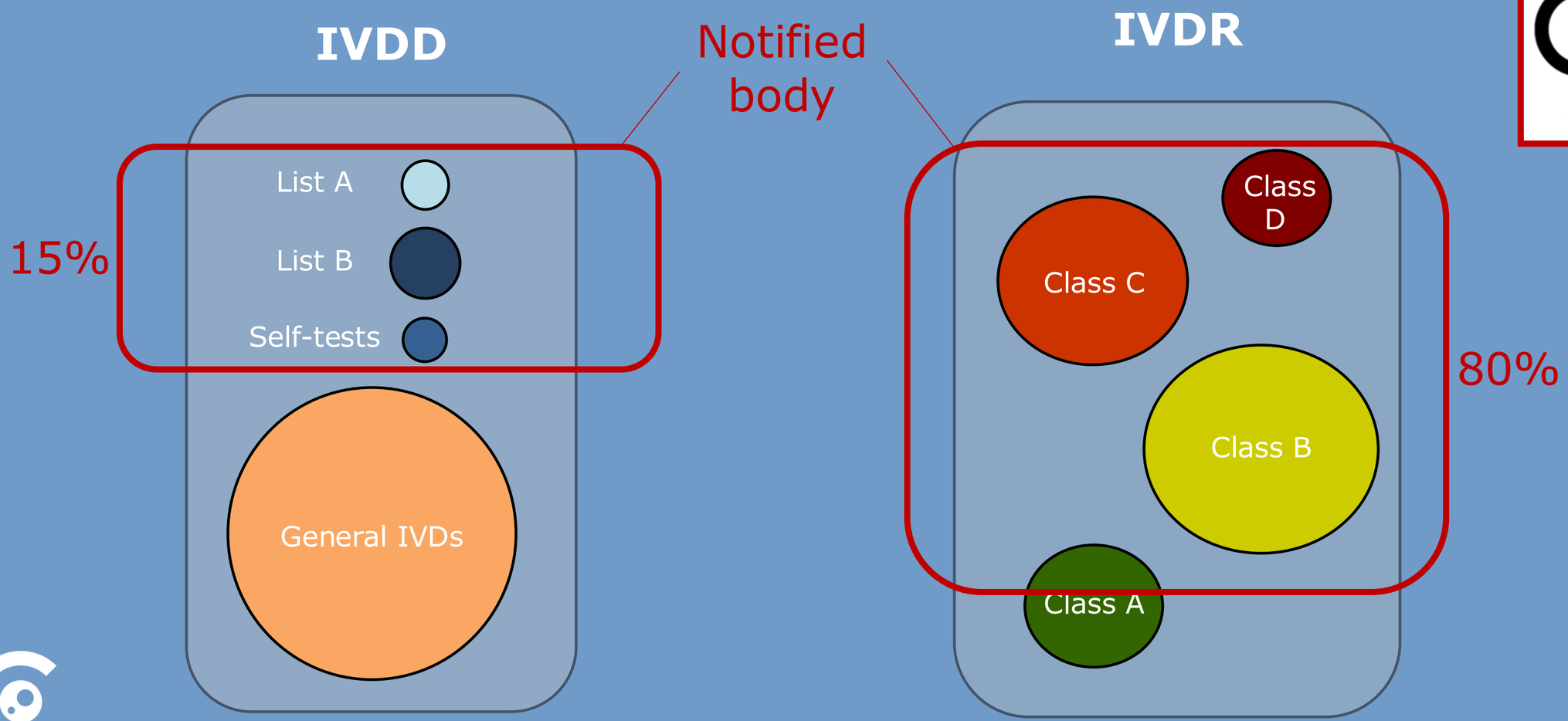
- IVD Regulation (IVDR) published in 2017
- Replaces the IVD Directive (IVDD) from 1998
- Goal: to increase quality, safety and performance, transparency
- Applicable since 26 May 2022
- Major changes: e.g. (1) classification, (2) more actors involved, focus on (3) performance and on (4) transparency

Major changes (1): classification



Major changes (2): actors involved

Notified Bodies (NBs)



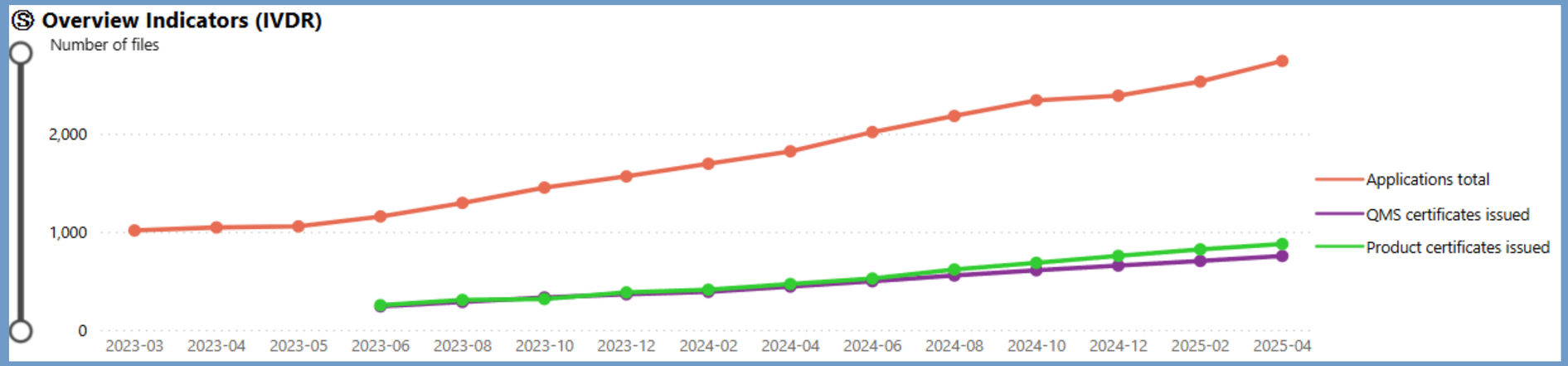
CE XXXX

XXXX = NB number

Major changes (2): actors involved

Notified Bodies (NBs)

- Currently 19 NBs designated for the IVDR, one Belgian (SGS)
- NBs indicate sufficient capacity for new clients
- Steady increase in applications and issued certificates



Major changes (2): actors involved

EU reference laboratories (EURLs)

- EURL tasks: - premarket verification of the performance of class D IVDs
  - test samples/batches of manufactured class D IVDs

- At present, 6 categories of IVDs covered, i.e. detection/quantification of markers of:
  1) hepatitis or retrovirus infection (ISC, PEI)
  2) herpesvirus infection (CQS, ISC, SERMAS)
  3) infection with bacterial agents (CQS, ISC, SERMAS)
  4) respiratory virus infection (PEI, RISE)
  5) parasite infection (ISC, CQS)
  6) blood grouping (PEI, CQS, RISE)

  - State of play after 1st wave of 2nd call:
    - Parasites (2) + blood grouping (3)
    - Implementing act 16 December 2025
    - Transition period for the 2 new scopes: 1 May 2026

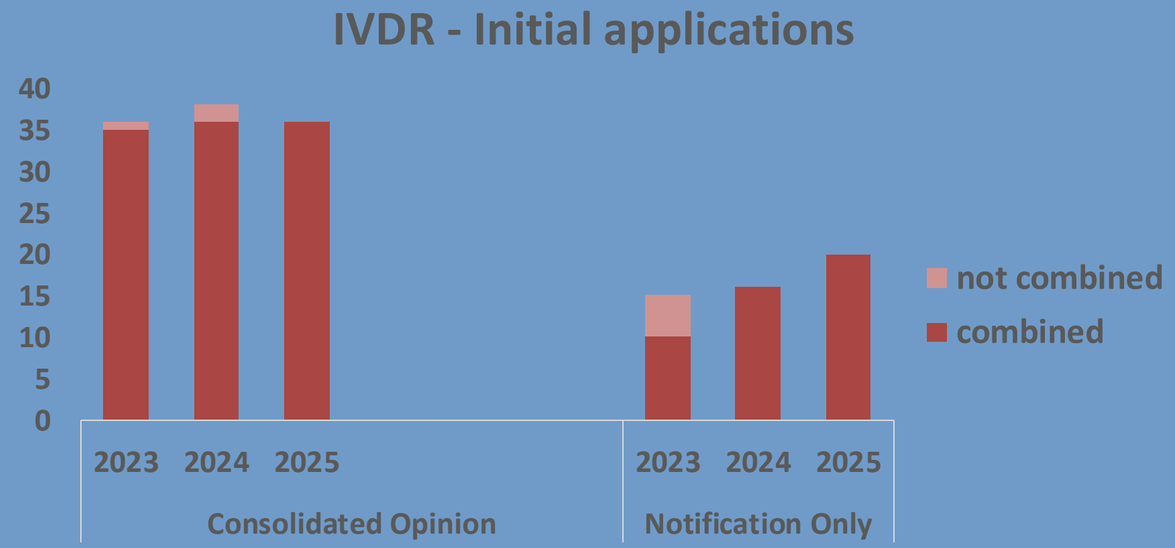
Major changes (2): actors involved

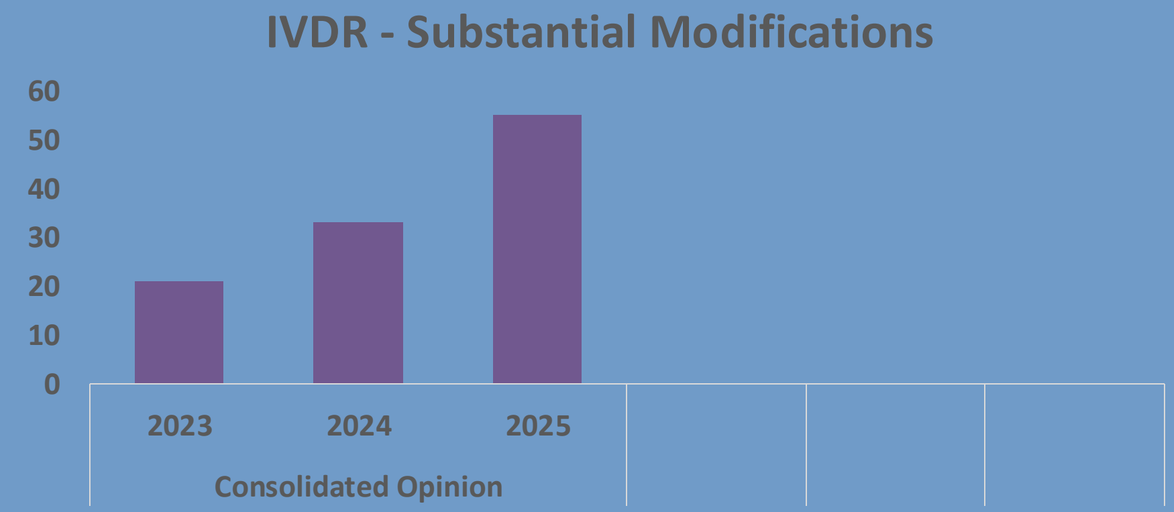
IVD expert panel

- Tasks:
  - review the performance evaluation for certain new class D IVDs
  - scientific, technical or clinical advice, e.g. advice on the down-classification of SARS-CoV-2 tests from class D to class B in 2025
- Reviews of performance evaluations are public
- 22 members (1 from BE), but continuous open call from the European Commission (either for the IVD panel or for a central list of eligible candidates)

Major changes (3): focus on performance (studies)

- Authorisation required for high(er)-risk studies, e.g. interventional performance studies
- Number of applications submitted to FAMHP: graph 2023, 2024 and 2025





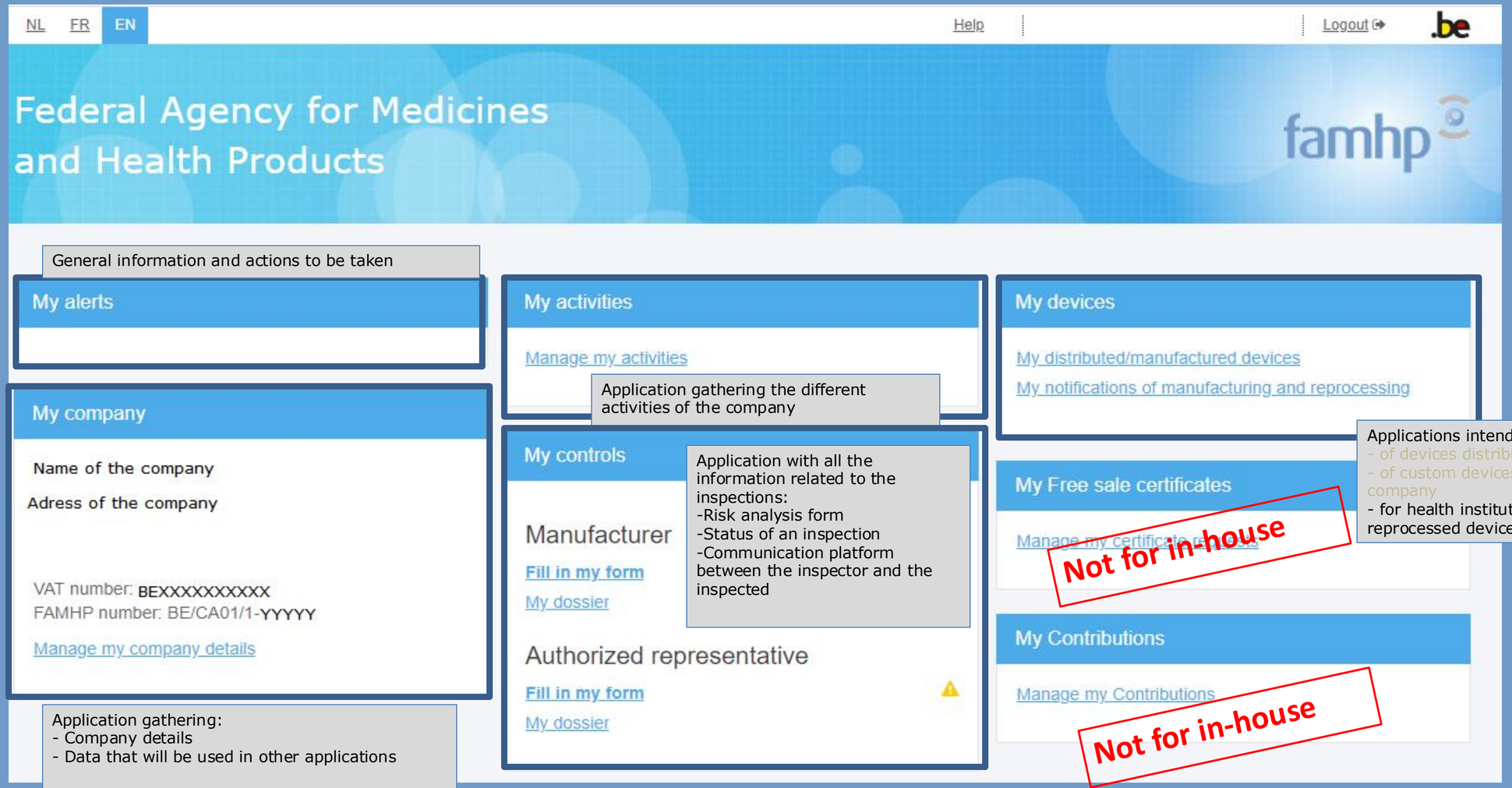
- Almost all those studies are combined: companion diagnostic – medicinal product
- Coordinated EU assessment procedure on the way (pilot phase)

Implementation of IVDR article on in-house IVDs

- Health institutions wishing to develop and use in-house IVDs should follow provisions of Art. 5(5)
- Article 5(5): subsections (a) to (i) are applicable since 26/05/2024, except for subsection (d) on equivalent CE marked IVDs (applicable from 31/12/2030)
- In-house IVDs must meet the General Safety and Performance Requirements (GSPR) of Annex I
- Public declaration from health institutions containing the in-house IVDs and stating their compliance with GSPR

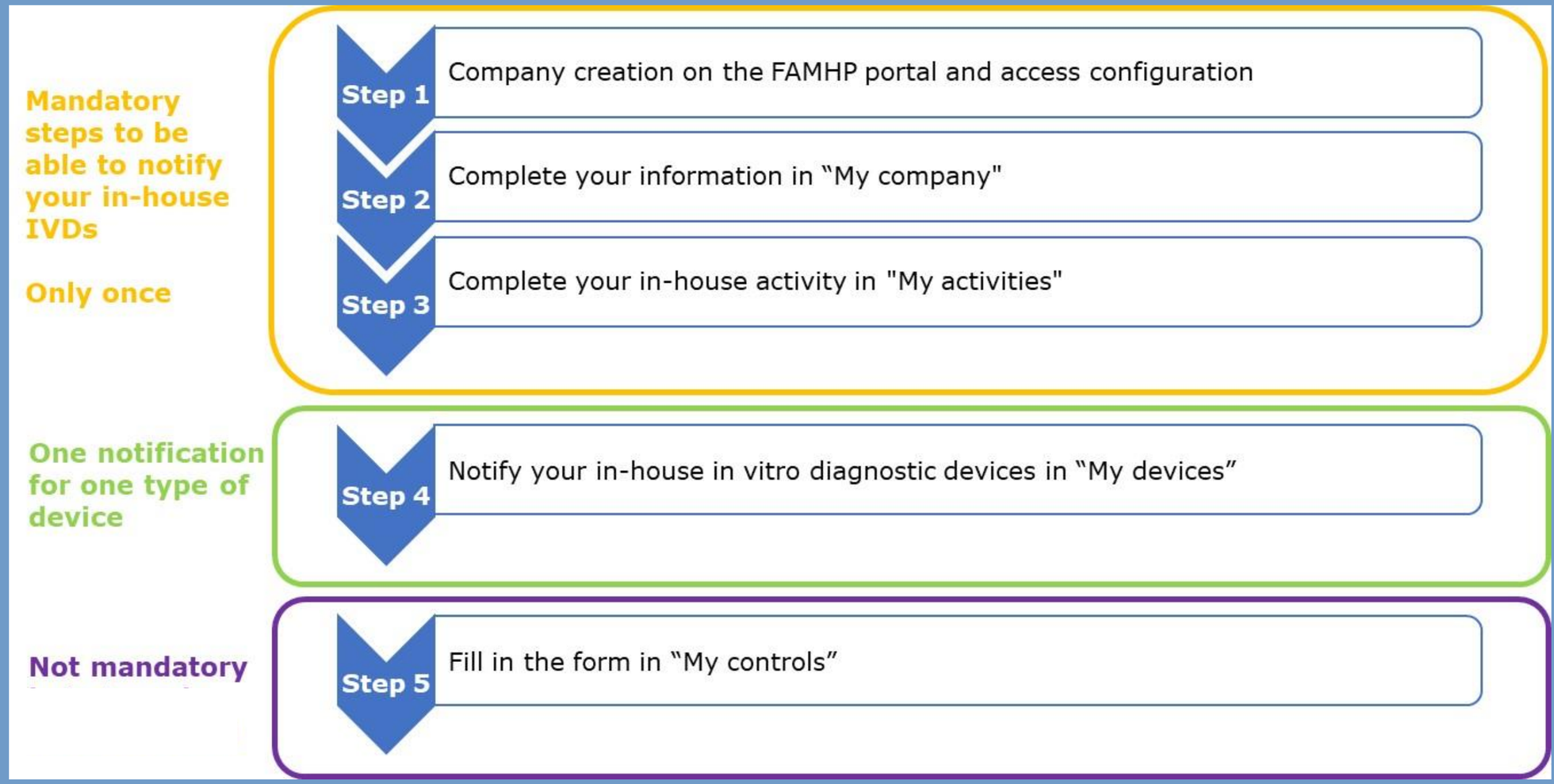
Implementation of article 5(5)

- Public declaration: automatically rendered via FAMHP's web portal



Implementation of article 5(5)

- Steps to register in-house IVDs in the web portal



Implementation of article 5(5)

- **Changes** to existing CE marked IVDs
  - Practical approach followed: only significant changes in intended use or design will yield an in-house IVD (see Q&A document, also available in FR/NL)

- **Inspections (inspection.meddev@fagg-afmps.be)**
  - Take into account reports from Sciensano/BELAC

- **Performance studies (CT.RD@fagg-afmps.be)**
  - Authorisation only needed for high-risk studies (e.g. interventional study). See guideline for the application of a performance study.

- **Vigilance (vigilance.meddev@fagg-afmps.be)**
  - Which incidents should be reported? See decision tree (FR/NL)
  - To whom? Either directly to FAMHP or via the contact point materiovigilance in hospital
  - How? Via form (FR/NL)

- Definition of **legal entity and health institution**
  - See practical interpretation in BE (FR/NL)
  - Upcoming revision of the EU guidance on in-house devices

Proposal IVDR revision

Why?

- Reduce administrative burden
- Enhance predictability and cost-efficiency of notified bodies' certification processes
- Conformity assessments more proportionate to IVD risk-class

What?

Many articles will be revised: focus **Article 5(5)**

- Transfer allowed in specific cases
- CE marked equivalency provison removed
- ISO15189 compliance OR GSPR
- …

- Market access for some IVDs will be stimulated: breakthrough devices + orphan devices

Where to find further information?

- FAMHP's webpage on in-house IVDs :
  - FAMHP's web portal for registering in-house IVDs
  - User guide to register your health institution and your activity (FR/NL)
  - User guides to register your IVDs:
    - notification by notification (FR/NL)
    - by group of notification
    - instructions (FR/NL)
  - Webinar on the full procedure
  - European guidance on in-house devices
  - Q&A document (also available in FR/NL)

- European guidance on IVD classification

CONTACT

Federal Agency for Medicines and Health Products - FAMHP

Galileelaan / Avenue Galilée 5/03
1210 BRUSSELS
tel. + 32 2 528 40 00

welcome@fagg-afmps.be
www.famhp.be

Health Products Division
info.meddev@fagg-afmps.be

Follow the FAMHP on