# Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices

## Entry into application – ways forward

Steering Group on Health Promotion, Disease Prevention
and Management of Non-Communicable Diseases
19 October 2021

# Introduction

Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR)

- Adoption: 5 April 2017
- Entry into force: 26 May 2017
- **Date of application: 26 May 2022**
- Scope of application: devices used *in vitro* for eximination of human body specimens (e.g. HIV tests, pregnancy tests, blood sugar tests, SARS-CoV-2 tests …)
- Replaces Directive 98/79/EC *in vitro* diagnostic medical devices - major changes in the regulatory framework
- Related to Regulation (EU) 2017/745 on medical devices (MDR) that is applicable since 26 May 2021

# State of play

## Insufficient market readiness for date of application (26 May 2022)

- COVID-19 impact
  - resources of national authorities, health institutions and economic operators diverted to addressing pandemic;
  - need for increased availability of vitally important IVD;
  - travel restrictions hindering on-site audits for conformity checks
- Capacity shortage of conformity assessment bodies (‚notified bodies‘)
  - ca. 80% of IVDs subject to notified body control (compared to 8% under IVD Directive)
  - 6 notified bodies designated (compared to 18 under IVD Directive)

# In-house devices

- „*manufactured and used within the same health institution*“ – tests developed in clinical laboratories
  - except for general safety and performance requirements, exempted from IVDR if certain requirements are fufilled (no CE-marking, no notified body involvement; but QMS, ISO 15189, unavailability of CE marked tests, ...)
- health institutions not ready due to focus on COVID-19
  - essential tests may not be available to patients

# Need for action

- EP cross-party letter (EPP, S&D, Renew, ECR, GUE/NGL, Greens/EFA) of 11 May 2021 to EC President
- EPSCO Council Conclusions 15 June 2021
- Stakeholders (industry, notified bodies, health institutions, patients, consumers)
- **Commission proposal for a progressive rollout of the IVDR – COM(2021)627 of 14 October 2021**

# Commission proposal

- Date of application (26 May 2022) maintained
- Extension of transitional provisions (scope and timelines)
  - Devices with a Notified Body certificate under the IVDD and requiring NB assessment under the IVDR (IVDD Annex II List A and B; self-tests) - extend transition period by 1 year until 26 May 2025
  - Devices with a Declaration of Conformity (DoC) under the IVDD and requiring NB involvement under the IVDR – risk-based approach
    - class D – provide transition period until 26 May 2025
    - class C – provide transition period until 26 May 2026
    - class B and class A sterile – provide transition period until 26 May 2027
  - In-house devices - provide transition period until 26 May 2024 (for justification that no equivalent CE marked device available until 26 May 2028)

# Work on infrastructure

- Joint Implementation Plan
  - Notified body capacity
  - Expert panels
  - EU Reference Laboratories
  - Common specifications
  - Guidance

# Thank you



European Commission