THE EUROPEAN REGULATORY FRAMEWORK FOR HEALTHCARE: ZOOM ON AI APPLICATIONS

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Nada Alkhayat
Policy Officer
Unit B.6: Medical Devices, Health Technology Assessment
Directorate-General for Health and Food Safety (DG SANTE)

Health

European Commission

Agenda

1. A new EU Regulatory system for Medical Devices (MDR/IVDR)

2. Horizontal legislation on Artificial Intelligence

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1. A new EU Regulatory system for Medical Devices

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EU legislation on medical devices

- **Current Directives and new Regulations**:
  - Directive 90/385/EEC on active implantable medical devices (AIMDD)
  - Directive 93/42/EEC on medical devices (MDD)

  Regulation (EU) 2017/745 on medical devices (MDR) adopted in April 2017 and entered into force in May 2017, as amended – fully applicable from **26 May 2021**

  Directive 98/79/EC on *in vitro* diagnostic medical devices (IVDMDD)

  Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR) adopted in April 2017 and entered into force in May 2017, as amended – fully applicable from **26 May 2022**
- **Specific transitional provisions** (Articles 120 MDR and 110 IVDR)

Regulation (EU) 202/561 and main consequences

- Regulation (EU) 2020/561 adopted on 23 April 2020 **amending MDR**, as regards the **dates of application** of certain of its provisions

- Commission Implementing Regulation (EU) 2020/666 of 18 May 2020 amending Implementing Regulation (EU) No 920/2013 as regards the renewal of **designations** and the **surveillance and monitoring of notified bodies**

- Commission Recommendation (EU) 2020/403 of 13 March 2020 on **conformity assessment and market surveillance** procedures within the context of the COVID-19 threat

Pillars of the EU regulatory framework for devices (MD / IVD)

- The “New Approach” and the “**New Legislative Framework”** (Regulation (EC) 765/2008, Decision 768/2008/EC, and others)
- **Specific scope and definitions,** roles and responsibilities of economic operators and of national competent authorities
- **Essential requirements** (health, safety and performance) supported by voluntary harmonised European **standards**
- **Classification and conformity assessment** procedures according to risks, with third party conformity assessment bodies (“notified bodies”) and related certificates for medium- and high-risk devices

Objectives of the new EU legislation on medical devices

- establish a **modernised** and more **robust, transparent** and **sustainable** EU regulatory framework on medical devices, while ensuring **free and fair trade** of devices throughout the EU internal market
- **keep up with advances in science and technology whilst supporting innovation ensure a better and consistently**
- **high level of health and safety protection of public health** and patient safety for citizens using medical devices in Europe

To include slides on MDCG 2019-11

- Slides to briefly cover MDCG 2019-11 on qualification and classification of medical device software and clinical evaluation/performance evaluation of software. These EU MDCG guidance cover all MD software (including AI)

2. A new EU Regulatory system for AI

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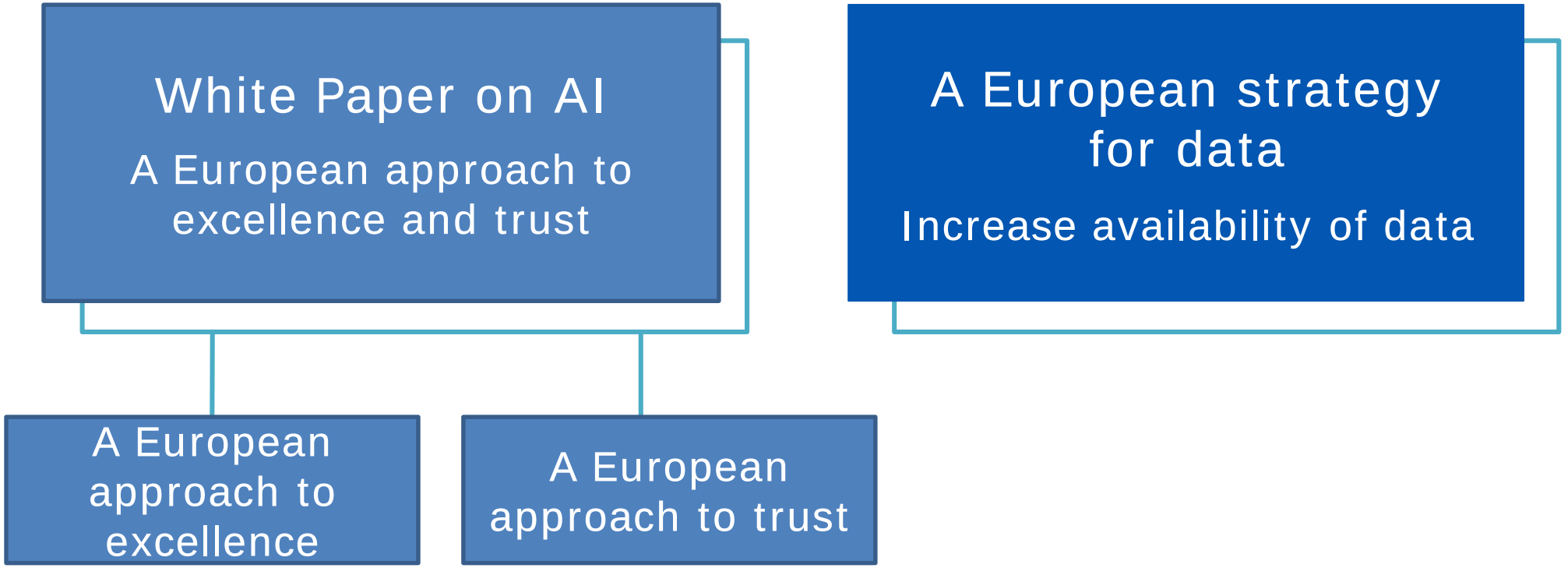
A balanced approach to AI

The Commission presented strategies for AI and data in February 2020



Ecosystem of excellence

Key actions to accelerate AI development, application and use

1. **Join forces between Member States and the EU** - Coordinated Plan on AI
2. **Strengthen research and innovation** – through networks of excellence
3. **Strenghten Industrial research** – new PPP on AI, data and **robotics**
4. **Support testing and experimentation,** through dedicated sites
5. **Help SMEs** - Digital Innovation Hubs, equity funding
6. **Promote AI in the public sector** – Sector dialogues
7. **Improve skills** – Talent

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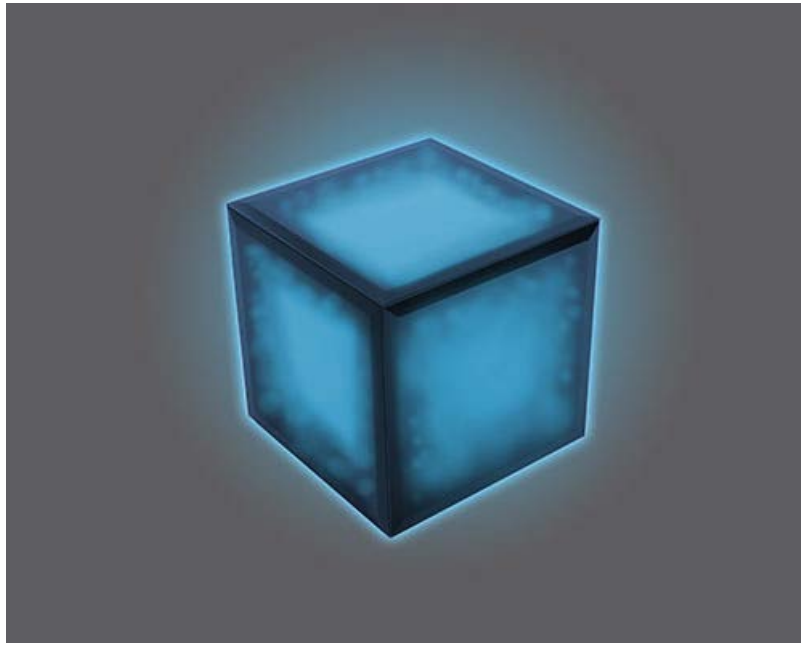
Promote an ecosystem of trust

“The specific characteristics of many AI technologies, including opacity (‘black box-effect’), complexity, unpredictability and partially autonomous behaviour, may make it hard to verify compliance with, and may hamper the effective enforcement of, rules of existing EU law meant to protect fundamental rights.” (White Paper on AI)



A risk-based approach to the ecosystem of trust

Risk-based and proportionate regulatory approach could include:

- Identification of **high-risk AI systems**
- **Mandatory requirements** and **ex-ante conformity assessment** for high-risk AI systems
- For AI systems that are not high-risk, a **voluntary labelling** scheme

Realizing an ecosystem of trust prevents fragmentation of the single market

- AI needs scale
- Member States are already looking at (soft) regulation

Public consultation on the AI White Paper gathered broad participation

Responses received February – June 2020

1 215

406 citizens

352 business and industry

160 civil society

152 academia

73 public authorities

72 other

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Public consultation: Ecosystem of trust

Need for new legislation

- **Only 3%** think that **current legislation is fully sufficient**.
- **33%** find that the **current legislation may have some gaps**.
- **42%** say there is **a need for a new legislation**

Focussed on high-risk?

- **43%** of respondents agree that **compulsory requirements** should be **limited to high-risk AI applications**.
- **31%** do not agree with the limitation to high-risk

Main concerns of respondents:

90% **Breaching fundamental rights**

87% **Discriminatory outcomes**

All respondents, excl. no answer

Next steps

Commission is **analysing** the public consultation results and preparing an **impact assessment**

A **revised coordinated plan on AI** and a proposal for a **regulatory framework** could be proposed early in 2021

CEN-CENLEC Workshop on AI on 22 October 2020

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Contact:

European Commission –
Directorate-General for Health and Food Safety (DG SANTE)
– *Unit B.6: Medical Devices, Health Technology Assessment*

SANTE-MED-DEV@ec.europa.eu

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