WHO GOVERNS AI WHEN IT ENTERS CARE?

& What does effective AI governance look like?

Shirley Kempeneer · Tilburg University

EUPHA Digital Health & AI · 14 October 2026

The AI Act (+) provides a legal architecture

CLASSIFY THE USE

AI in Healthcare may qualify as high risk. Intended purpose matters.

PROVIDERS

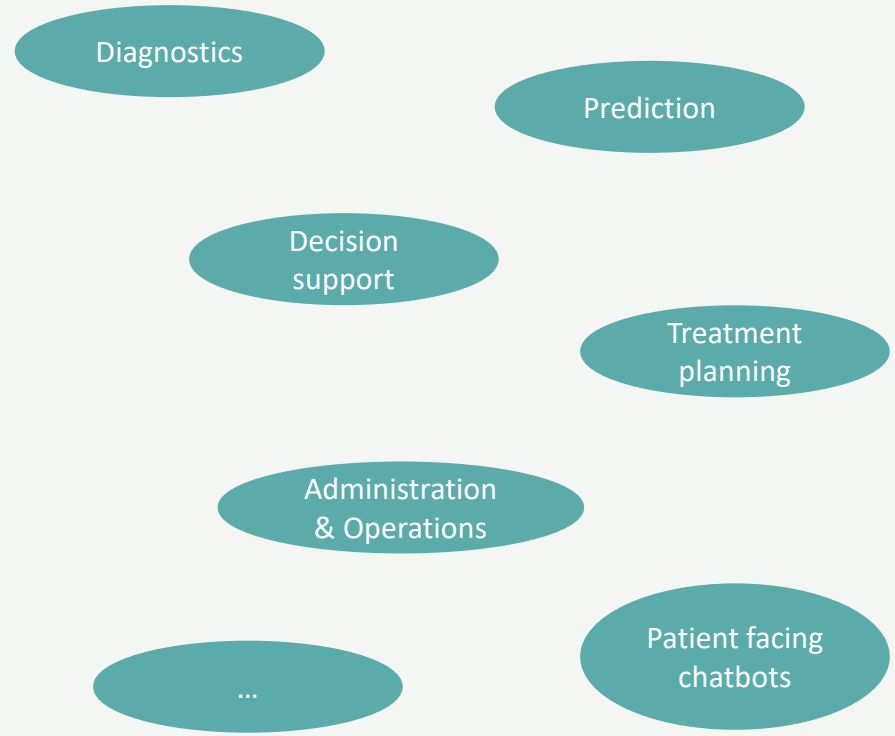
For high-risk AI: manage risks, document, build oversight and monitor performance.

DEPLOYERS

Use it as instructed, assign oversight, monitor use and act on risks.

→ We have the law, we won?

Who governs AI in healthcare?



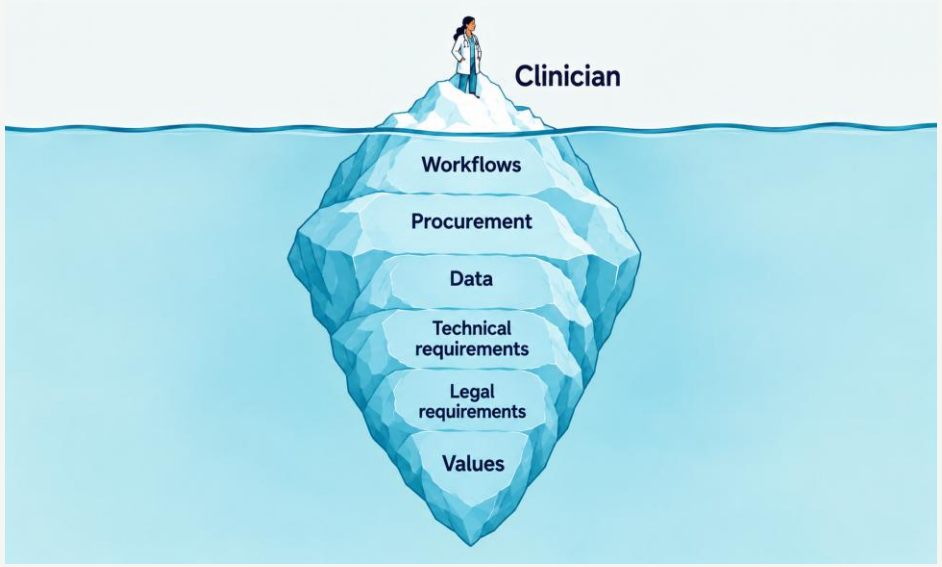
POLL

Who governs AI ?

- Clinician
- (Hospital) management
- Technology developers
- Policymakers
- Other

Who governs AI in healthcare?

Human in the loop



In the loop of what?

- Diagnostics
- Prediction
- Decision support
- Treatment planning
- Administration & Operations
- Patient facing chatbots
- …

How can institutions govern AI in healthcare effectively?

IN THE LOOP OF WHAT?

- Where are decisions being made?
- When?
- Who is at the table?

GOVERNANCE INSTRUMENTS

Make decisions on AI life cycle explicit

IMPACT ASSESSMENTS (FRIA)



CONNECTED RESPONSIBILITY

POLL

Have you heard of Impact Assessments (IA)?

- Not really
- I have a vague notion of the existence of IA
- I am familiar with the Dutch IAMA (specific IA)
- I am familiar with (another) specific IA

How can institutions govern AI in healthcare effectively?

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CONNECTED RESPONSIBILITY

GOVERNANCE INSTRUMENTS

Make decisions on AI life cycle explicit

IMPACT ASSESSMENTS (FRIA)

- Identify risk explicitly
- Consider mitigations
- Improve transparency
- Create dialogue
- Support responsible use



CLEAR AUTHORITY

What does effective AI governance look like?

Connected responsibility

Clear authority

→ Make the law win!

Shirley Kempeneer · Tilburg University

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AI fought the law and the law won: AI Regulation and Governance in Europe

EUPHA 2026 Webinar Series - From hype to hope: public health practice in the age of AI

Sara Roda, *CPME Senior Policy Advisor*

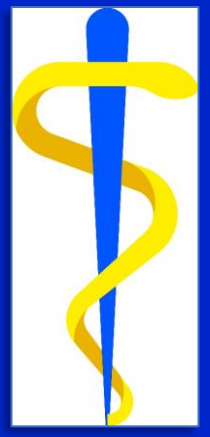
14 October 2026, Brussels

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EUROPEAN DOCTORS

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We are committed to contributing the medical profession's point of view to EU institutions and European policy-making through pro-active cooperation on a wide range of health and healthcare related issues.



We promote the highest level of medical training and practice but also the provision of evidence-based, ethical and equitable healthcare services.

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(Czech Medical Chamber)

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(Danish Medical Association)

Estonia
Eesti Arstide Liit
(Estonian Medical Association)

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Suomen Lääkäriliitto/Finlands Läkarförbund
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(Icelandic Medical Association)

Ireland
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(Irish Medical Organisation)

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(Latvian Medical Association)

Lithuania
Lietuvos gydytojų sąjunga
(Lithuanian Medical Association)

Luxembourg
Association des Médecins et Médecins-Dentistes du Grand-Duché de Luxembourg

Malta
Medical Association of Malta

Norway
Den norske legeforening
(Norwegian Medical Association)

Poland
Naczelna Izba Lekarska
(Polish Chamber of Physicians and Dentists)

Romania
Colegiul Medicilor din Romania
(Romanian College of Physicians)

Slovakia
Slovenská lekárska komora
(Slovak Medical Chamber)

Slovenia
Zdravniška zbornica Slovenije
(Medical Chamber of Slovenia)

Sweden
Sveriges Läkarförbund
(Swedish Medical Association)

Switzerland
Verbindung der Schweizer Ärzte
(Swiss Medical Association)

The Netherlands
Koninklijke Nederlandsche Maatschappij tot Bevordering der Geneeskunst (KNMG)
(Royal Dutch Medical Association)

United Kingdom
British Medical Association

Albania
Urdhri I Mjekeve Te Shqiperise
(Order of Physicians of Albania)

Georgia
Georgian Medical Association

Israel
Israeli Medical Association

Kosovo*
Oda e Mjekëve të Kosovës*
(Kosovo* Doctors Chamber)

Montenegro
Ljekarska Komora Crne Gore
(Montenegrin Medical Chamber)

North Macedonia
Лекарска комора на Република Северна Македонија
(Doctor's Chamber of North Macedonia)

Serbia
Лекарска комора Србије
(Serbian Medical Chamber)

Turkey
Türk Tabipleri Birliği
(Turkish Medical Association)

Ukraine
Ukrainian Medical Association (UMA)

* *References to Kosovo are without prejudice to positions on status. They are in line with United Nations Security Council Resolution 1244/1999 and the opinion by the International Court of Justice on the Kosovo declaration of independence.*

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What the AI regulation means for healthcare professionals and organisations?

Regulation on AI in healthcare

- Ensures patient safety
- Analysis of AI data-driven risks in products
- Increases trust among healthcare professionals
- Implies specific obligations:
  - AI literacy,
  - deployers' obligations, e.g., human oversight, keeping logs for 6 six months, using the system according to the instructions
- Guarantees transparency
- *(…)*

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How do regulatory requirements translate into day-to-day healthcare practice?

POLICY NOVEMBER 2024

Deployment of AI in healthcare: sector specific challenges and accelerators

- Focus on clinical decision-making AI systems;
- Identifies reasons for low uptake on AI in healthcare
- Provides recommendations to improve AI uptake.
- Please find the full policy here.



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POLICY NOVEMBER 2024

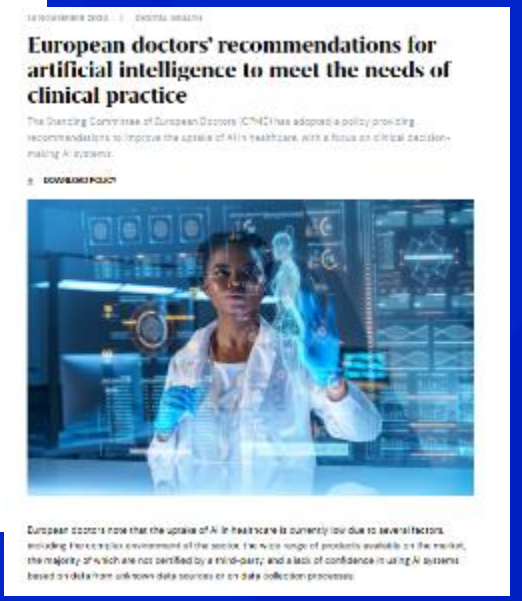
The Standing Committee of European Doctors (CPME) represents national medical associations across Europe. We are committed to contributing the medical profession's point of view to EU and European policy-making through pro-active cooperation on a wide range of health and healthcare related issues.

Deployment of artificial intelligence in healthcare

Sector-specific challenges and accelerators

Main messages:

- Design AI on actual healthcare demands and in a dynamic loop;
- Evaluate AI efficiency and efficacy;
- Compliance of AI systems with medical ethics, data protection and privacy required;
- Certify AI systems to increase trust among healthcare professionals;
- Demystify AI by improving literacy and foster competence development;
- Mitigate deskilling risks and ensure critical thinking;
- Promote adequate tools and methods to interpret and explain AI output;
- Provide detailed and clear instructions for use for deployers;
- Adequate monitoring and oversight with a clear liability regime for AI in healthcare;
- Encourage AI and cyber insurance coverage;
- Coordinate knowledge environment at EU and national level.



European doctors' recommendations for artificial intelligence to meet the needs of clinical practice

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What responsibilities should fall on developers, providers, clinicians and healthcare organisations?

Regulation on AI - responsibilities

- **National guidelines** clarifying responsibilities
- Promote adequate tools and methods to interpret and explain AI output and provide detailed and clear instructions for use for deployers
- CPME supports applying the **strict liability regime for AI systems**, no need for victim to prove fault
- Encourage **AI and cyber insurance cross-border coverage**, include tail coverage
- **Freedom to decide using an AI system**, bearing in mind the best interests of the patient
- **Retain the right to disagree with an AI system** without additional repercussions

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How can regulation support trustworthy adoption rather than create purely procedural compliance?

Proposed amendments to the Digital Omnibus AI

- CPME calls to maintain medical devices within the scope of the AI Act and apply the requirements for high-risk AI systems set out in Chapter III, Section 2 of the AI Act.
- We also call to retain the obligation from providers and deployers to ensure a sufficient level of AI literacy for their staff and persons operating with AI.
- It is necessary to restore the obligation to register in an EU database a high-risk AI system in Annex III when the provider self-exempts it from being a high-risk.
- Read the amendments here.


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AMENDMENTS MARCH 2026

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Proposed amendments to the Digital Omnibus on AI

Proposed amendments

The CPME feedback on the Digital Omnibus Package can be accessed here and the CPME policy on the deployment of AI can be accessed here.

European doctors agree with several amendments proposed by the IMCO-LIBE draft report and the JURI draft opinion, in particular those that reinstate important provisions from the original AI Act (eg. the responsibility of providers and deployers on AI literacy, clarify the interplay with other legislation warranting simplification), or that address new topics which reflect the rapid evolution of the use of AI (eg. introducing agentic AI in the AI definition, banning the instrumentalisation of AI for sexualised content without consent).

CPME strongly advocates for a clear and consistent approach to the AI Act, ensuring that ethics, safety and innovation go hand in hand. The use of electronic health records (EHRs) to train commercial AI systems raises significant ethical and legal questions. CPME calls on EU regulators to provide clarity on the applicable legislation, the authority responsible for oversight, and on how to prevent the treatment relationship from becoming an unpaid resource for commercial product development. The lack of a clear legal framework not only undermines European values such as personal data protection and trust in healthcare but also poses risks to the quality and safety of care.

POLICY MARCH 2026

Proposed amendments to the Medical Devices Regulations Revision

- We propose to safeguard important requirements and safeguards on high-risk AI systems used for medical purposes, such as ensuring human oversight, risk-management system focusing on AI-specific risks relating to outputs, as well as on transparency, accuracy, robustness and cybersecurity.

- We are against the relaxation of clinical evidence requirements for high-risk devices (class III), we emphasise that direct clinical evidence from the manufacturer is essential to ensure patient safety and maintain public trust.

- Read the amendments here.



CPME MEDICAL PERSPECTIVE EUROPEAN DOCTORS

POSITION MARCH 2026

The Standing Committee of European Doctors (CPME) represents national medical associations across Europe. We are committed to contributing the medical profession's point of view to EU and European policy-making through pro-active cooperation on a wide range of health and healthcare related issues.

Proposed amendments to the Commission's Proposal for a targeted revision of EU rules on Medical devices and in vitro diagnostics

The CPME statement on medical devices may be accessed here and the CPME statement on medical devices – electronic instructions for use may be accessed here.

Amendment 1	
Recital 23, page 26	
Text Proposed by the Commission	**CPME Proposed Amendment**
The use of artificial intelligence in medical devices and in vitro diagnostic medical devices can help foster innovation and improve diagnosis and treatment of patients. The parallel application of Regulations (EU) 2017/745 and (EU) 2017/746, as applicable, and Regulation (EU) 2024/168915 of the European Parliament and of the Council could lead to overlaps of requirements and stifle innovation. To prevent those overlaps and to simplify the regulatory framework for artificial	~~The use of artificial intelligence in medical devices and in vitro diagnostic medical devices can help foster innovation and improve diagnosis and treatment of patients.~~ **The parallel application of Regulations (EU) 2017/745 and (EU) 2017/746, as applicable, and Regulation (EU) 2024/168915 of the European Parliament and of the** ~~Council could lead to overlaps of requirements and~~ **stifle innovation.** ~~To prevent those overlaps and to~~

Key recommendations

- Certify AI systems to increase trust among healthcare professionals
- **AI officer to translate regulation into practice, communicate with regulators**
- Enforcement better aligned, more guidelines and dialogue, soft approach in the beginning
- Ensure **patient's awareness and consent** of AI system usage (ethical requirement)
- Coordinate knowledge environment at EU and national level

CONCLUSIONS

- Maintain MDR and IVDR under the AI Act
- “Move fast break things” approach of digital innovation technology does not work in healthcare – **evidence-based sector**
- AI must **not replace or compete** with health professionals, nor diminish patient autonomy and shared decision-making
- Increase capacity and number of active notified bodies
- Support **no-fault liability** regime and mandatory insurance coverage for AI systems
- Ensure long-standing **financial support** for deploying AI in healthcare

Thank you for your attention!

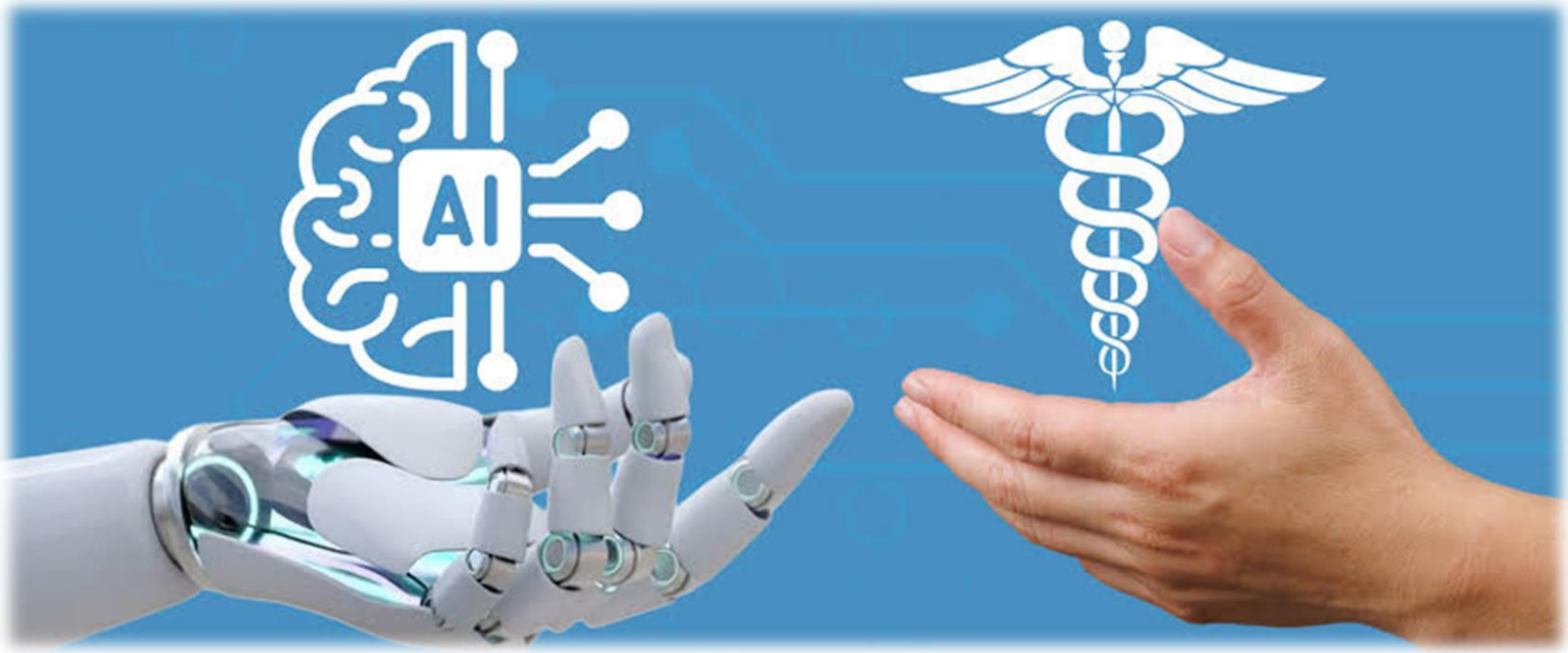
For more information, please contact **CPME Secretariat:**

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AI in healthcare: setting the regulatory scene

Janos Meszaros



Why healthcare AI is distinctive?



- **High stakes**: errors can mean physical harm or death. Safety and performance are central, not optional.



- **Vulnerable people**: patients are ill, dependent and in an unequal position, which makes real choice hard.



- **Sensitive data**: health data is special-category data, so training and use touch core privacy concerns.



- **Trust and relationship**: care rests on trust and shared decisions. AI changes who, or what, takes part in them.

Layered European framework

- **AI Act**: risk-based rules for AI systems and general-purpose models.
- **MDR and IVDR**: safety and performance of medical device software; the route for most clinical AI.
- **GDPR**: legal basis and safeguards for processing health data
- **European Health Data Space**: Primary and secondary use of health data.

How many medical images do you think are generated each year in Europe?

a	10 Millions	**c**	1 Billion
b	100 Millions	**d**	10 Billions

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a	10 Millions
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c	1 Billion
d	**10 Billions**

How many of these medical images are reused for research?

a	Less than 0,1%	**c**	Around 1%
b	Around 0,5%	**d**	More than 1%

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Patient protection and data sharing for scientific research

- **Protecting patients and their data:** purpose limitation, data minimisation and patient control to protect dignity and trust.
- **Sharing data for research**: safe, effective and fair AI needs large, diverse and representative datasets for training, validation and monitoring.
- **Both serve the public interest, and ‘weak’ data sharing can itself harm patients**, through biased or poorly validated AI.

Gaps and tensions



- **Patients at the margins**: the AI Act speaks of 'affected persons', with only limited individual remedies



- **Overlapping regimes**: AI Act, MDR and GDPR overlap. Duplicated procedures risk box-ticking and not better care.



- **Systems that keep learning**: rules assume a product frozen at approval. Post-deployment change needs workable oversight.



- **Unclear accountability:** developers, hospitals and clinicians share the chain. Who answers to the patient is still open.