Norwegian Medical Products Agency

Regulations 2025-26 – Ready or not, here we come…

10/11/2025; ISPOR Europe; Glasgow

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Disclaimer

The views expressed are those of the presenter and should not be understood or quoted as being made on behalf of:

- Norwegian Medical Products Agency (NOMA)
- The European Medicines Agency (EMA) or its scientific committees
- The HTA Coordination Group (HTA CG)

Meanwhile in Europe….

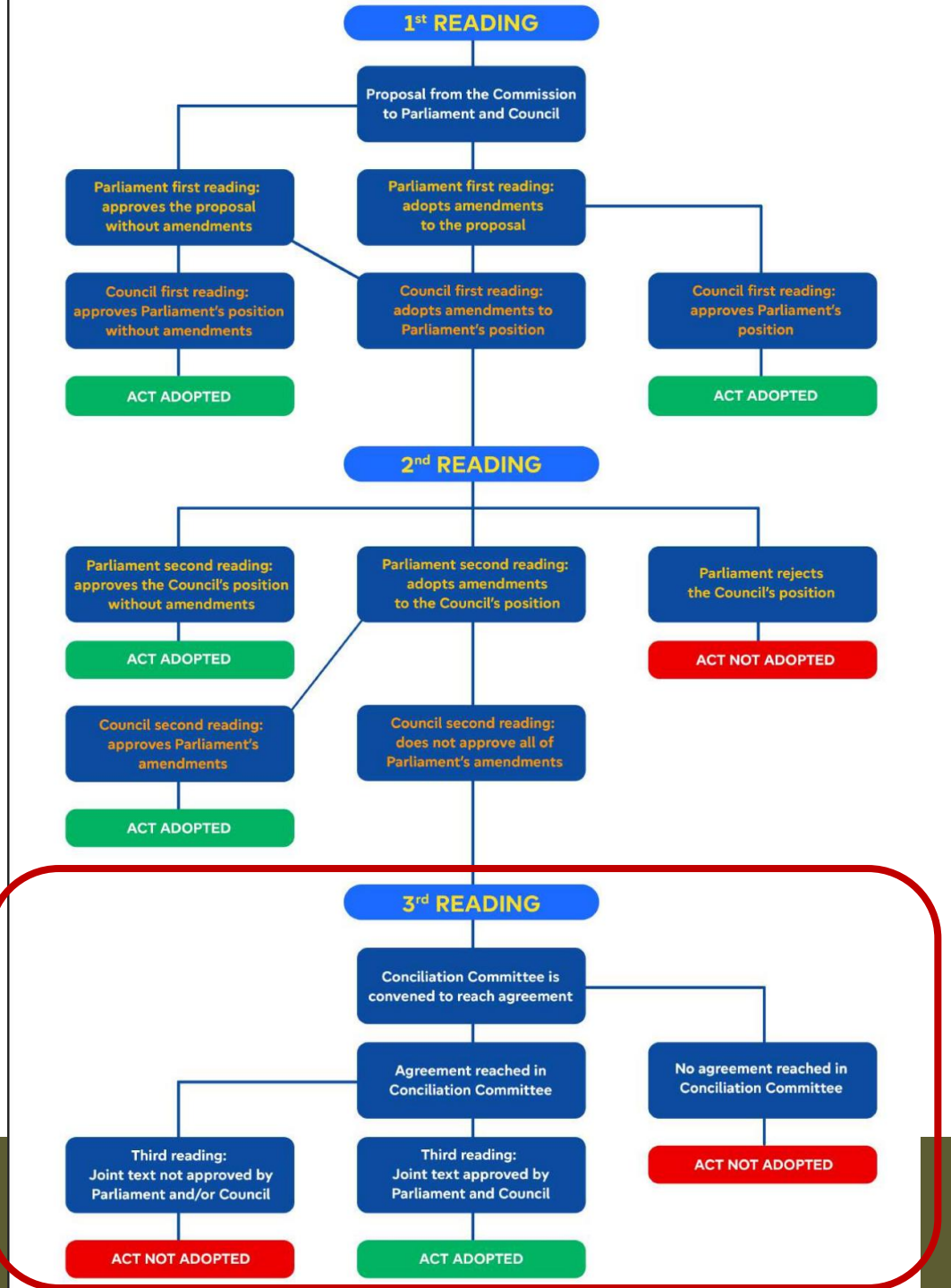
- Revision of the Pharmaceutical legislation (Council Directive 65/65/ECC)
  - Critical Medicines Act – proposal from European Commission
- Regulation on health technology assessment (Regulation (EU) 2021/2282 of the European Parliament and of the Council)
- Biotech act
- Life Science Strategy – call for evidence out now

The two relevant legislations

- Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use **(Pharma Leg)**
- **Superseded:** Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use
- **Superseded:** Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products

The EU process

- The Ordinary Legislative Procedure
  - European Commission (EC): **proposes new laws**
  - European Parliament (EP): represents **EU citizens**
  - Council of the European Union: represents **member states**
- EC proposal published: **26 April 2023**
- ENVI (Parliament committee) adopted reports: **19 March 2024**
- European Parliament adopted its position / reports in plenary: **10 April 2024**
- Council (general approach / position) adopted: **4 June 2025**
- Trilogue / interinstitutional negotiations (first trilogue meeting) opened: **17 June 2025**



Critical Medicines Act

- In March 2025, the European Commission proposed the Critical Medicines Act to improve the availability, supply and production of critical medicines within the EU.

Context

President von der Leyen:
"… we will propose a Critical Medicines Act to reduce dependencies relating to critical medicines and ingredients, particularly for products where there are only a few supplying manufacturers or countries."

- Increasing attention and pressure (COVID-19, geopolitical context)
- Complex and multifactorial root causes
- 23 Member States call for an EU Critical Medicines Act
- Recent and ongoing EU initiatives, *e.g.*:
  - Reform of the EU pharmaceutical legislation (chapter X on shortages)
  - Communication on addressing medicine shortages in the EU
  - Critical Medicines Alliance

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European Commission

Objectives and scope

Strenghtening security of supply and availability of critical medicines	Improved availability and accessibility of other medicines where a market failure exists
Critical medicines on the Union list as envisaged in the Pharma Reform	*Medicines of common interest (e.g. orphans, novel antimicrobials)*

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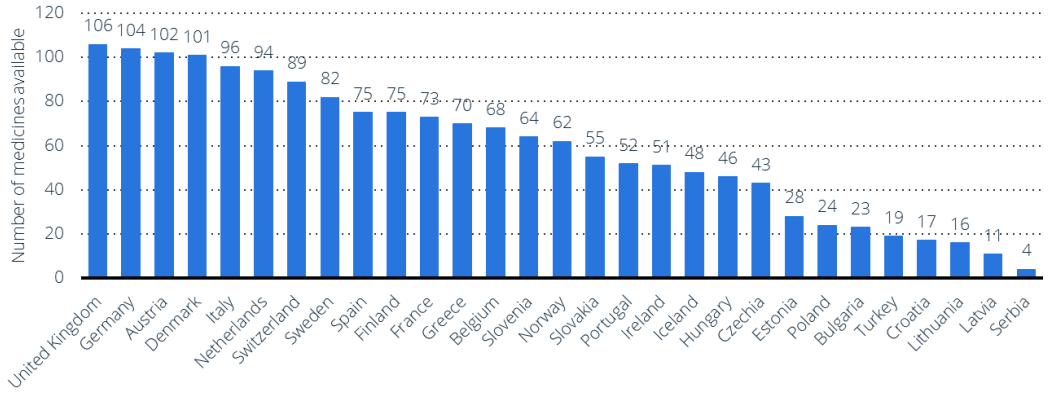
European Commission

Number of medicines approved by the EMA between 2015-17 available to patients in Europe as of 2018, by country

Availability of new medicines in Europe in 2018, by country



Note(s): Europe; 2017
Further information regarding this statistic can be found on page 8.
Source(s): IQVIA; ID 1011132

statista

KEY ELEMENTS OF THE ACT

ENSURING

SECURITY OF SUPPLY AND AVAILABILITY OF CRITICAL MEDICINES

ACCESSIBILITY AND **AVAILABILITY** OF OTHER KEY MEDICINES

STRATEGIC PROJECTS	PUBLIC PROCUREMENT	COLLABORATIVE PROCUREMENT	STRATEGIC PARTNERSHIPS
Facilitate investments in manufacturing in the EU	Incentivise supply chain diversification and resilience	Harness the combined demand and buying-power of Member States	Support the diversification of supply chains

The two relevant legislations

- Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU (Text with EEA relevance)

Public Health

Home > Health technology assessment > Implementation of the Regulation on health technology assessment

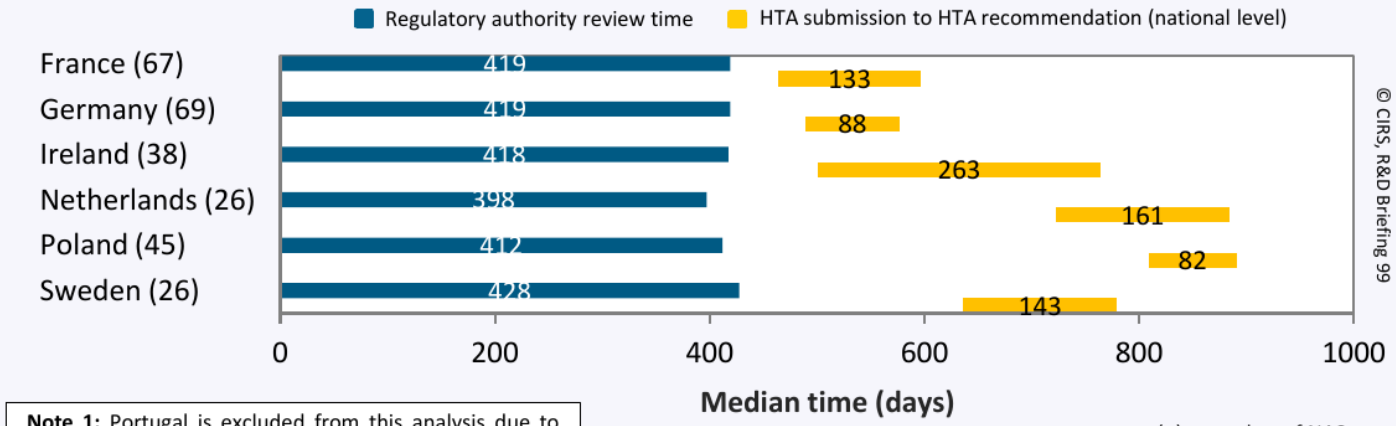
Implementation of the Regulation on health technology assessment

The Regulation (EU) 2021/2282 on health technology assessment (HTAR) entered into force on 11 January 2022 and applies from 12 January 2025.

The two relevant legislations

- Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU (Text with EEA relevance)

Figure 8. Timing from EMA submission to 1st HTA recommendation (oncology EMA approvals between 2018 and 2023 with an HTA recommendation)



Note 1: Portugal is excluded from this analysis due to unavailable HTA submission dates in the public domain.

(n) = number of NASs

Note 2: For Ireland, both rapid and full reviews are included in this analysis. In addition, the HTA review for Ireland time is calculated as (Rapid review completed - Rapid review commissioned) + (NCPE assessment completed - Full submission received from applicant)

The problems we are trying to solve with the HTAR

- ‘Regulatory grade’ evidence isn’t good enough for reimbursement decisions
  - Selected participants
  - Small sample sizes
  - Surrogate endpoints
  - Insufficient study length for long term claims
  - Poor study designs (the famous SAT)
  - What is helpful in terms of RWD/E and what is not
- Agree on ‘basics’
  - Methodological differences are here to stay
  - Minimum requirements for contextualisation and generalisation?
  - Not everyone has the same purchasing power, national prioritisation must be respected -> ATP vs WTP!
  - Opportunity costs are system dependent
- Voluntary collaboration is working better than trying to get a square peg in a round hole
- The 3 S’s (instead of the 3 A’s): Sustainability – Solidarity – Social contract

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Norwegian Medical Products Agency