The EU Pharmaceutical Reform

DG SANTE

#EUPharmaStrategy

- Adopted in November 2020
- Ambitious long-term agenda in the field of pharmaceutical policy
- Objective: creating a future proof regulatory framework and at supporting industry in promoting research and technologies that actually reach patients in order to fulfil their therapeutic needs

European Commission

A 4-part package

Chapeau communication

New Regulation

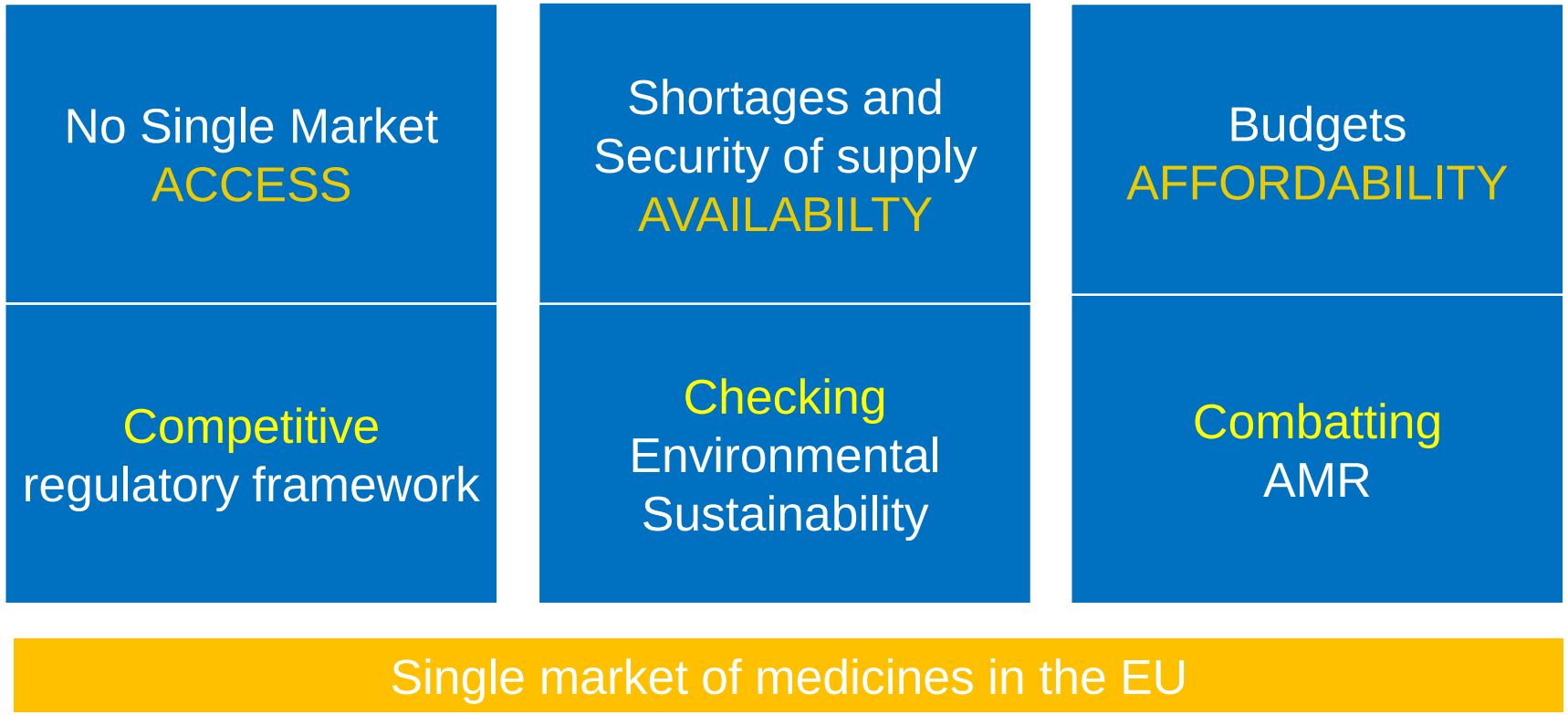
- Specific rules for the most innovative medicines such as orphans, antimicrobials
- Rules on shortages and security of supply
- EMA governance

New Directive

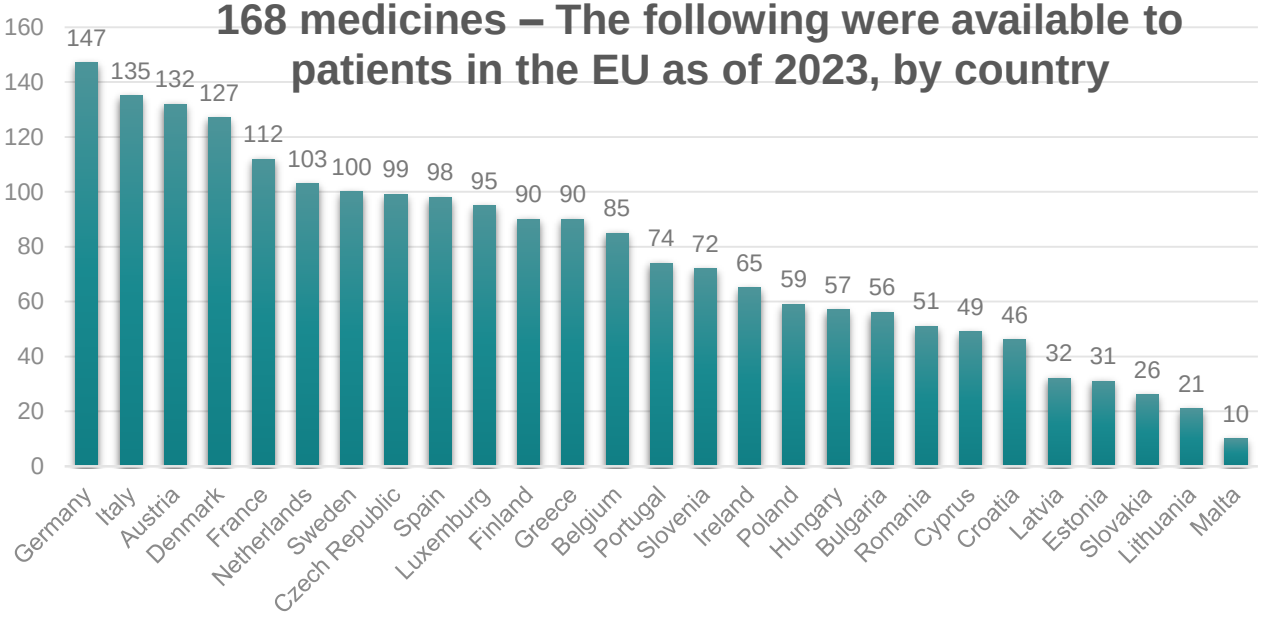
- Placing on the market of all medicines
- Authorisation and labelling requirements
- Strong incentives for access

Council Recommendation on AMR

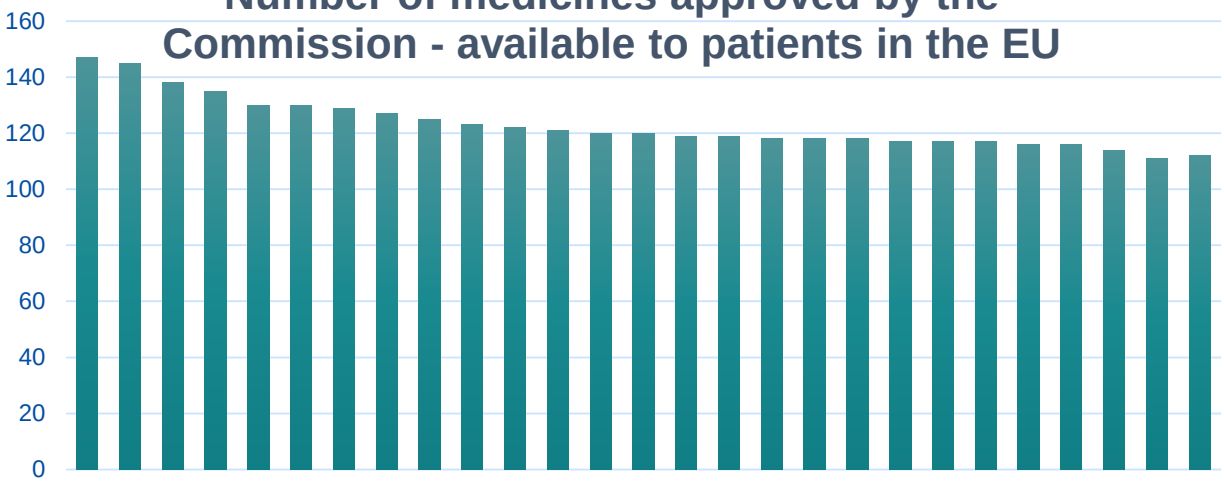
6 key political objectives



Between 2018-2021 the Commission approved 168 medicines – The following were available to patients in the EU as of 2023, by country



#WE CAN DO BETTER
Number of medicines approved by the Commission - available to patients in the EU



TODAY	TOMORROW
Patients are told that the medicine they need is not accessible in their country	**Patients** get treated with the medicine they need
Companies get the same rewards for any medicine	**Companies** are rewarded for medicines that deliver on public health needs
Member States have less benefits for the public money they spend	**Member States** use public money smartly
Continue **business as usual** - not equitable	**Change of paradigm** to benefit patients

European Commission

Main novel elements of the reform

- **Access to medicines:** Move from one size fits all system of incentives (with 10 years of unconditional regulatory protection) to a **modulated system**: incentives to reward **access in all Member States**
- **Affordability: faster availability of generics and biosimilars** e.g. increased transparency; clarification of Bolar exemption.
- **Availability:** shortages monitoring, prevention plans, EU list of critical medicines
- **AMR** specific: vouchers for priority antimicrobials and prudent use
- **Environmental aspects:** strengthened ERA, manufacturing of antimicrobials in ERA
- **Simplification** and optimisation of the regulatory system: faster approvals (180 days, less clock stops), EMA simplified structured
- **Future proofing** of legislation to deal with emerging developments in science & digitalisation (sandbox, adapted frameworks, RWE, platform technologies, decentralised manufacturing, electronic submissions and e-leaflets)
- **Lessons learned from COVID pandemic:** Temporary Emergency Marketing Authorisation, rolling reviews.

Improved clarity and interplay with other EU legislative frameworks

- Improved interplay with Medical Devices
- Improved interplay with the legislation on substances of human origin (‘SoHO’)
- Classification mechanism
- Strengthening of early regulatory support by EMA

Interinstitutional negotiations

- Translations made available on 13 September 2023 → official start of procedure
- Technical meetings with Council and EP
- European Parliament: Adoption of the EP position in 1st reading on 10 April 2024
- Council (discussions ongoing):
  - Political general discussions held in Health Council meeting and in COREPER
  - Council Working Party: technical presentations, formal negotiations in progress – start with shortages and incentives cluster.
  - Reactions from MS: '*good basis for discussion*'

Thank you

European Commission