Council of the European Union
General Secretariat

Brussels, 17 November 2023

Interinstitutional files:
2023/0131 (COD)
2023/0132 (COD)

WK 15279/2023 INIT

LIMITE

SAN	**ENV**
PHARM	**RECH**
MI	**CODEC**
COMPET	**IA**
VETER	**PI**

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MEETING DOCUMENT

From:	General Secretariat of the Council
To:	Working Party on Pharmaceuticals and Medical Devices (Attachés)
Subject:	Working Party on Pharmaceutical and Medical Devices 16 November 2023 - Commission Presentation

Delegations will find in annex the presentation by the Commission services for the Working Party on Pharmaceuticals and Medical Devices on 16 November 2023.

Revision of the general pharmaceutical legislation

Council Working Party of 16 November 2023

Impact Assessment on the General pharmaceutical legislation

Presentation Outline

Part 1: Context, objectives and key measures proposed on general pharmaceutical legislation

Part 2: Consultations, policy options, methodology

Part 3: Impact assessment of the options, preferred option

Part 4: How key elements of the preferred option translate into the acts

A 4-part package – 26 April 2023

Chapeau communication

New Regulation

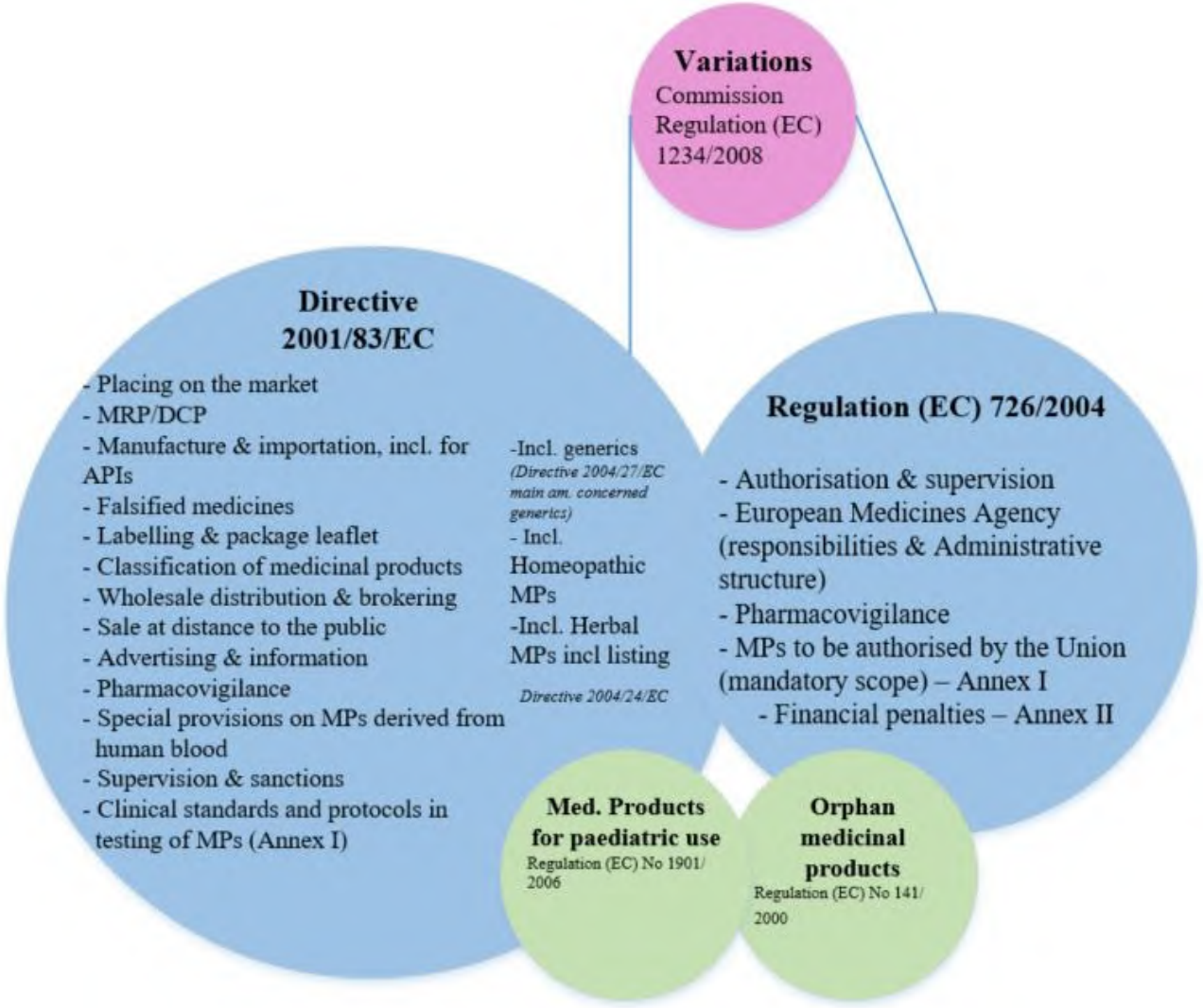
- Specific rules for the most innovative medicines such as orphans, antimicrobials
- Rules on shortages and security of supply
- EMA governance

New Directive

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

Council Recommendation on AMR

Structure of the revision



- Areas not changed:
  - Homeopathic medicines
  - Herbal medicines
  - Falsified medicines
  - Financial penalties
- Areas with minimum intervention:
  - Pharmacovigilance
  - Wholesale distribution
  - Sale at distance to the public
  - Advertising
  - Clinical standards and protocols in testing
- New areas added:
  - Availability – management of shortages and security of supply of critical medicines

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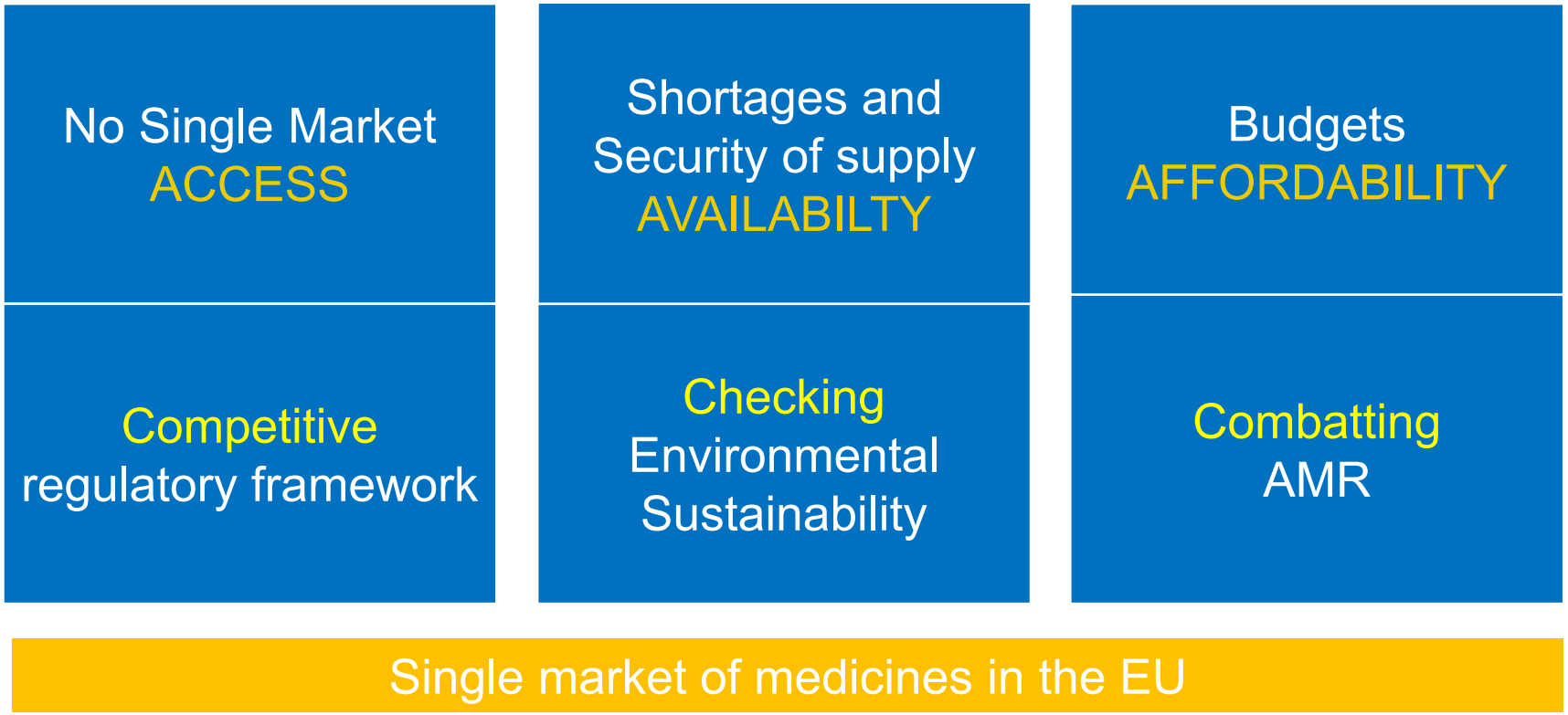
6 Key political objectives



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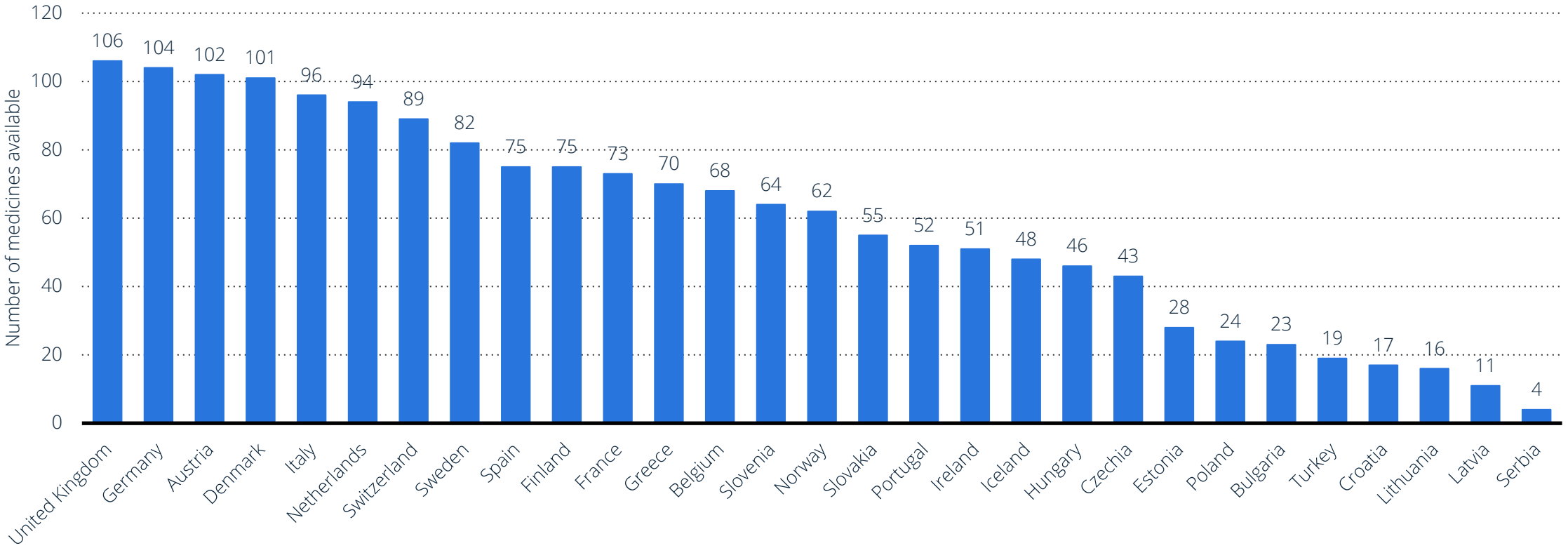
Access to medicines

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



Note(s): Europe; 2017

Further information regarding this statistic can be found on page 8.

Source(s): IQVIA; ID 1011132

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Increasing supply and availability challenges

1. **Shortages and supply challenges in healthcare** systems affecting patient care, identified as a **major public health concern by the European Parliament and Council**.

2. **Existing legislation is limited** in addressing these challenges

3. **Pharma proposal** expands, strengthens and optimises **shortage management** and **ensure the availability of critical medicines**

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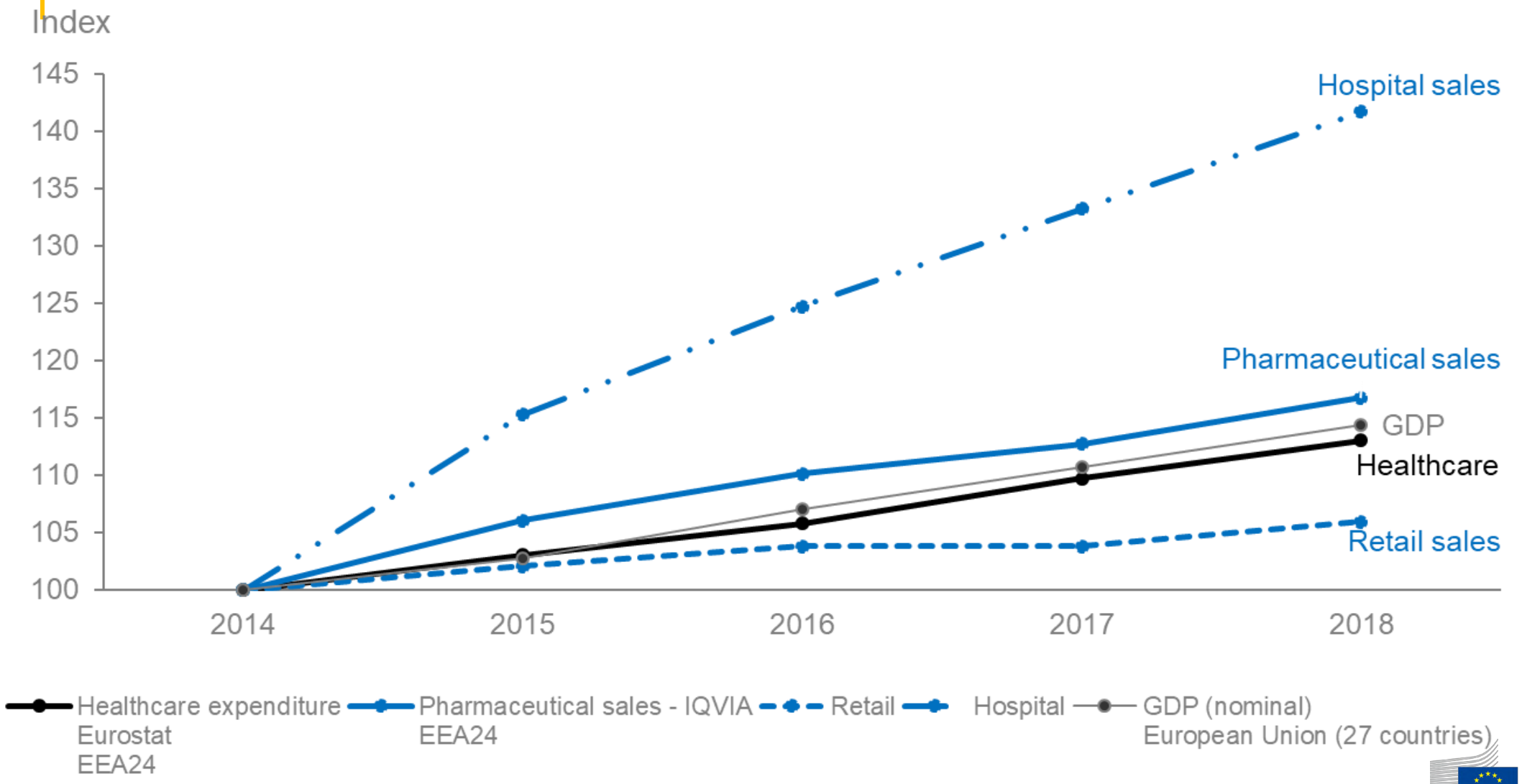
Growing hospital pharmaceutical expenditure



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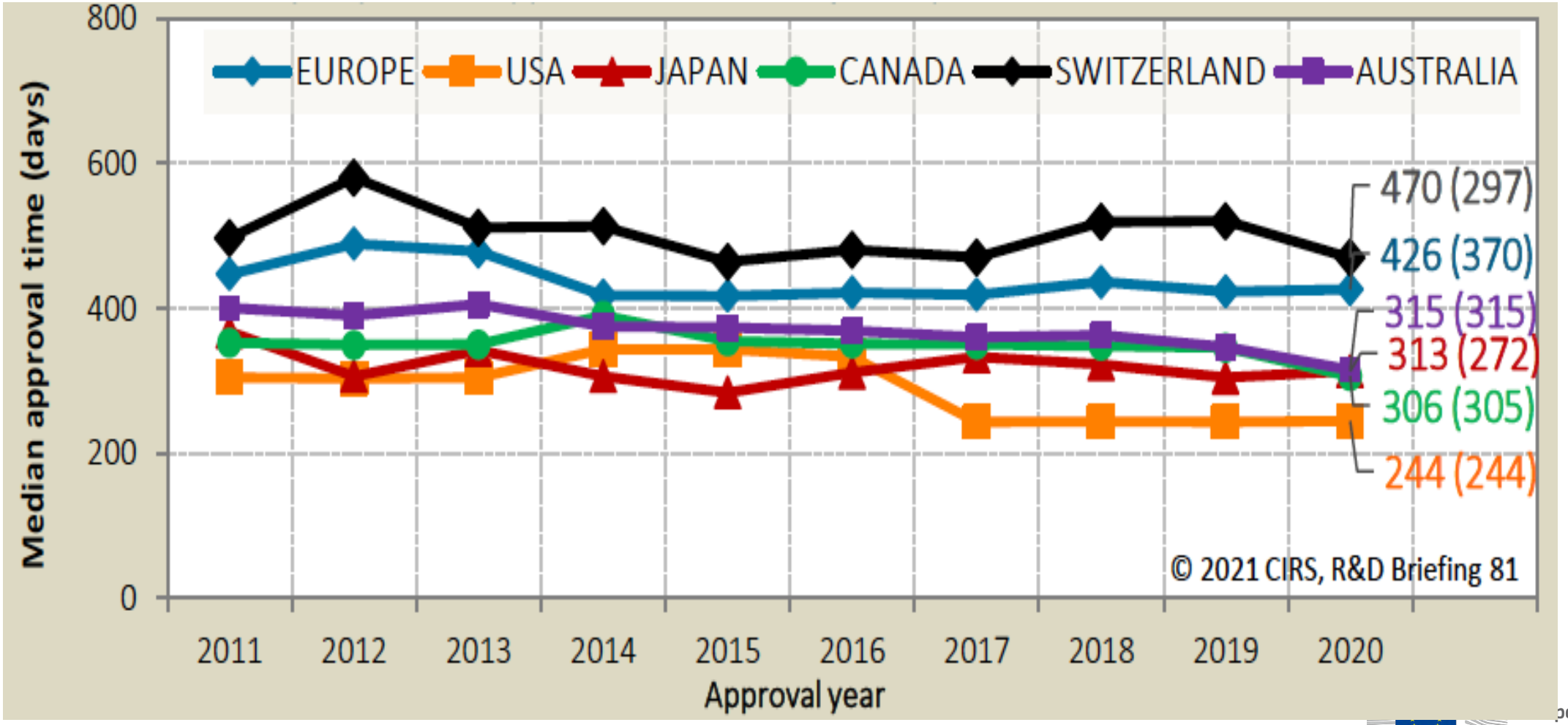
Long approval times



Main provisions on **Access**

Measures	Legal basis
Regulatory protection periods and modulation of data protection incentive: market launch (+24m), unmet medical need (+6m), comparative clinical trials (+6m), additional therapeutic indication with significant clinical benefit (+1yr)	DIR Art 81
Market launch incentive modalities Incentive given if product launched in all MS covered by the marketing authorisation (*not necessarily in all 27* in cases of decentralised applications)	DIR Art 82
Unmet Medical Need criterion based definition	DIR Art 83
Repurposing incentive +4 years DP with respect to additional indication not previously authorised in Union. Off patent and innovative medicines with MA older than 25 yrs.	DIR Art 84
Broadened BOLAR exemption Exemption to cover HTA and P&R activities in addition to studies/trials conducted for a MA	DIR Art 85
EMA **consultation process with downstream actors** and stakeholders	DIR Art 83(3), REG Art 162

Main provisions on **Availability**

Measures	Legal basis
Obligation on **marketing authorisations holder** – **ensure appropriate and continued supplies** of that medicinal product to wholesale distributors, pharmacies or persons authorised to supply medicinal products	DIR Art 56
Obligation on **wholesalers** – **ensure appropriate and continued supplies** of medicines to pharmacies and persons authorised to supply medicinal products	DIR Art 167
Shortage prevention plans to be put in place and updated by MAHs for **all medicines**	REG Art 117
Obligations on marketing authorisation holders (MAH) **to notify market cessations, withdrawals, suspensions and shortages (temporary disruptions), submit additional information,** as requested by national competent authorities or EMA, **take into account MSSG recommendations, comply with national and Union level measures and report on measures taken** and **end date of a critical shortage**	REG Art 116, 118, 125, Annex IV
Shortage monitoring by both national competent authorities (for nationally and centrally authorised medicines) and EMA (for centrally authorised medicines), based on MAH notifications	REG Art 118 (all shortages), Art 124 (critical shortages)
Shortage mitigation plan to be put in place and updated by MAHs for **shortages; risk assessment of impact** of suspension, cessation or withdrawal to be prepared by MAHs	Regulation, Article 119, Annex IV

Main provisions on **Availability** (2)

Measures	Legal basis
Possibility for **other actors to report shortages -** Wholesale distributors and other persons or legal entities that are authorised or entitled to supply medicines and associated obligation on such entities to provide any information requested by NCAs or EMA in a timely manner	REG, Art 120
Publication of shortages by NCAs and EMA	REG, Art 121, 124
NCA requests for information and information sharing with EMA and **SPOC working party activities** to allow for improved coordination and management of critical shortages	REG, Art 121
EMA requests for information, collaboration with SPOC working party and reporting to MSSG and the Commission to allow for improved coordination and management of critical shortages	REG, Art 122, 124
EMA establishment of criteria to adopt and review critical shortages list, specification of tools (including expansion of scope of ESMP), methods and criteria to be used in monitoring and reporting of critical shortages and methods for MSSG recommendations and development of guidance on risk assessments	REG, Art 122
MSSG adoption, review and update of list of critical shortages	REG, Art 123
MSSG may provide recommendations to relevant marketing authorisation holders, the Member States, the Commission, the representatives of healthcare professionals or other entities **on measures to resolve or mitigate a critical shortage**	REG, Art 123
Commission role in implementing measures, taking MSSG recommendations into account	REG, Art 126

Main provisions on **Security of Supply** and the Union List of Critical Medicines

Measures	Legal basis
Member State (national competent authority) identification of **critical medicines at national level** and preparation for Union list of Critical Medicinal Products	REG, Art 127
Proposal by **MSSG** and **Commission** adoption of the **Union list of Critical Medicinal Products** (and updates)	REG, Art 131
Obligation on **marketing authorisation holders** responsible for critical medicines to **submit information** requested by EMA, national competent authorities or MSSG	REG, Art 128, 133
Obligation on **other actors** e.g. other marketing authorisation holders, importers and manufacturers of medicinal products or active substances and relevant suppliers of these, wholesale distributors, stakeholder representative associations or other persons or legal entities that are authorised or entitled to supply medicinal products to the public **to submit information** requested by EMA, national competent authorities or MSSG	REG, Art 129
MSSG recommendations on appropriate security of supply measures to marketing authorisation holders, the Member States, the Commission or other entities. Such measures may include recommendations on diversification of suppliers and inventory management.	REG, Art 132
Responsibility of **marketing authorisation holders** to **take MSSG recommendations into account, comply with measures taken at EU or national level** and **report on measures** they have taken	REG, Art 133
Role of the Commission, including a provision on **Commission** adoption of an **implementing act to improve security of supply of certain medicines on the Union list of Critical Medicinal Products,** directed towards on marketing authorisation holders, wholesale distributors or other relevant entities. This could include contingency stock requirements of active pharmaceutical ingredient or finished dosage forms.	REG, Art 134

Main provisions on **Affordability**

Measures	Legal basis
Broadened BOLAR exemption Exemption to cover HTA and P&R activities in addition to studies/trials conducted for a MA	DIR Art 85
Transparency of public funding of R&D (direct financial support received from public authority/body) to support Member States in their price negotiations with companies	DIR Rec 131, 133, Art. 57 REG Art 138 (2)
Transparency of all direct financial support received for research related to the development of a **priority antimicrobial**	REG Rec 79-81, Art. 40(4)
EMA **consultation process with downstream actors** and stakeholders	DIR Art 83(3), REG Art 162
Recognition of **interchangeability of biosimilars** with their biologic counterparts in recitals promotes uptake of biosimilars	DIR Rec. 27

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Main provisions on **competitive regulatory framework**

Measures	Legal basis
Reduction of assessment/**approval time** from 277 days to 226 days (150 for accelerated)	DIR Art. 30, REG Art. 6, 12, 13
Optimising **EMA's structure** and simplifying regulatory procedures	REG CH. XI SEC. 2
Possibility for regulators to reject **immature applications** to limit endless clock stops that delay the decision.	DIR Art. 29(3), REG Art. 10(2)
Regulatory **sandboxes** to test new and innovative therapies	REG Art. 113-115
Adapted frameworks with specific regulatory requirements tailored to the characteristics of certain novel medicines	DIR Art 28
Improved clarity on the interplay between EU legislative frameworks for **medicines** and **other health technologies** (e.g. medical devices, substances of human origin)	DIR Art 19,20, 21 and 56(5)
Introduction of possibility for a scientific recommendation/decision on **regulatory status** of a product under development	REG Art. 61 and 62
Recognising platform technologies i.e. adjustments to the medicine are made based on the characteristics of the patient or the causing pathogen	DIR Art 15(2)

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Main provisions on **competitive regulatory framework**

Measures	Legal basis
Strengthening the **early regulatory support** by EMA, particularly for promising medicines under development for unmet medical needs + parallel scientific advice and advice involving consultation of other bodies	REG Art. 60, 59 and 58
Electronic submission of applications	DIR Art. 6, REG Art. 5(3) and 6(1)
Support for SMEs and non-for-profit entities (regulatory, procedural and administrative support and reduction, deferral or waivers of fees)	REG Art 164
Facilitate use of **real-world evidence**, and of **health data** for regulatory purposes	DIR Rec. 30, Art. 200(4) REG Art. 166
Possibility for EMA to review **data in phases**, as they become available (rolling or phased review)	REG Art. 6(2)
Abolishing marketing authorisation **renewal in most cases**	DIR Art. 46, REG Art. 17
Simplifying requirements for authorising generic and **biosimilar** medicines	DIR CH. II Sect. 2
Active substance master file to avoid duplication of assessment of chemical active substances (and additional quality master file)	DIR Art. 4(1)(36), Art. 25, 26
Pharmacovigilance risk management plan **not required for off patent medicines**	DIR Art. 21
Promote use of new methodologies to reduce animal testing	DIR Art. 6, Art. 44. REG Art. 6(5), Art. 8, Art. 12(4)(m), |Art. 138

Main provisions on **competitive regulatory framework**

Measures	Legal basis
Facilitate the use of **electronic product information** and **multi-country packages**	DIR Chapt. VI
Facilitation of repurposing through a mandatory variation on the basis of data submitted from not-for-profit entities for repurposing of authorised medicinal products	REG Art. 48
Decentralized manufacturing to enable novel technologies where manufacturing steps need to be performed very close to the patient **(e.g. separate** manufacturing authorisation –not required)	DIR Art 33 and 34
Imposed post-authorisation studies	REG Art. 19-21
Temporary Emergency Marketing Authorisation	REG CH. II Sect. 3
Conditional marketing authorisation	REG Art. 19
Marketing authorisation granted in exceptional circumstances	REG Art. 18

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Main provisions on **combatting AMR**

Measures	Actor and Legal basis
Additional prudent use measures	Art 17
Antimicrobial stewardship plan	DIR Art. 17
Special information requirements (awareness card, educational material)	DIR Art. 69, Annex I, Annex V
Special ERA for antimicrobials	DIR Art. 22(4)
All antimicrobials under prescription status	DIR Art. 51
MS to set appropriate dispensing measures	DIR Rec. 66
Transferable exclusivity vouchers	REG Chapt. III

Main provisions on **Environment**

Measures	Legal basis
Include a **stand-alone ground of refusal** in case ERA does not sufficiently substantiate +address risks to the environment and public health (AMR)	DIR, Art. 47, REG, Art. 15
Add risk to public health due to the release of medicinal products into the environment, including AMR, into the protection goals of ERA	DIR, Art. 4(33)
Compliance with EMA scientific guidelines on ERA becomes mandatory	DIR, Art. 22
Update ERA in light of new information	DIR, Art. 22§6
Obligation to conduct post-authorisation ERA studies at the time of MA and after authorisation	DIR, Art. 44 and Art. 87, Reg, Art. 20
Grounds for suspension, variation, revocation of MA +prohibition of the supply of medicines in case of environmental concerns	DIR, Art. 195, Art. 196
Set up of a **programme for prioritisation of ERA on risk-based approach of those medicinal products authorised before December 2006** + Scientific criteria for the identification of the medicinal products concerned	DIR, Art. 23
Set up of a **monograph** system of the environmental properties of active substances used in authorised medicinal products	DIR, Art. 24

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ERA of medicines containing or consisting of **GMOs**

Measures	Legal basis
Alignment of ERA requirements in the context of marketing authorisation of medicines and authorisation of clinical trials	REG Art 177
Transfer of the ERA requirements for the GMO-IMP assessment from the GMO framework into the pharma framework	REG Art 177
Transfer of the competence for ERA evaluation from national GMO authorities to CHMP one single GMO application (CTIS) and assessment (CHMP) process in the context of authorisation of clinical trials	REG Art 177
The expertise of national GMO authorities is retained though their involvement in the drafting of ERA scientific guidelines and in the potential dedicated CHMP working party	
Environmental risk assessment for medicinal products containing or consisting of genetically modified organisms	REG Art 7
Content of the environmental risk assessment for medicinal products containing or consisting of genetically modified organisms	REG Art 8
Procedure for the environmental risk assessment for medicinal products containing or consisting of genetically modified organisms	REG Art 9

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Presentation Outline

Part 1: Context, objectives and key measures proposed on general pharmaceutical legislation

Part 2: Consultations, policy options, methodology

Part 3: Impact assissent of the options, preferred option

Part 4: How key elements of the preferred option translate into the acts

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Impact Assessment

- Commission published two impact assessments supporting the reform:
  - Impact assessment related to changes of the general pharmaceutical legislation
  - Impact assessment related to changes of the orphan/paediatric legislation
- The impacts assessments considered several policy options and includes a granular analysis of multiple elements supporting the policy interventions
- The impact assessments were supported by two independent studies and stakeholder consultations

Consultation actions

March 2021 to April 2022

- Feedback mechanism on Commission combined evaluation roadmap/inception impact assessment (173 replies)
- Public consultation (478 replies)
- Interviews (38 individuals across all the identified stakeholder groups)
- Two validation workshops (on evaluation findings and on impact assessment findings)

Consultations beyond the Better Regulation requirements

- 13 concept papers from the EMRN network
- Stakeholder's dialogue conference (May 2023)
- 5 thematic workshops on key political issues (Mar. to Jun. 2021)
- Pharmaceutical Committee topical discussions on the revision
- Exchanges in 3rd party conferences and bilateral meetings

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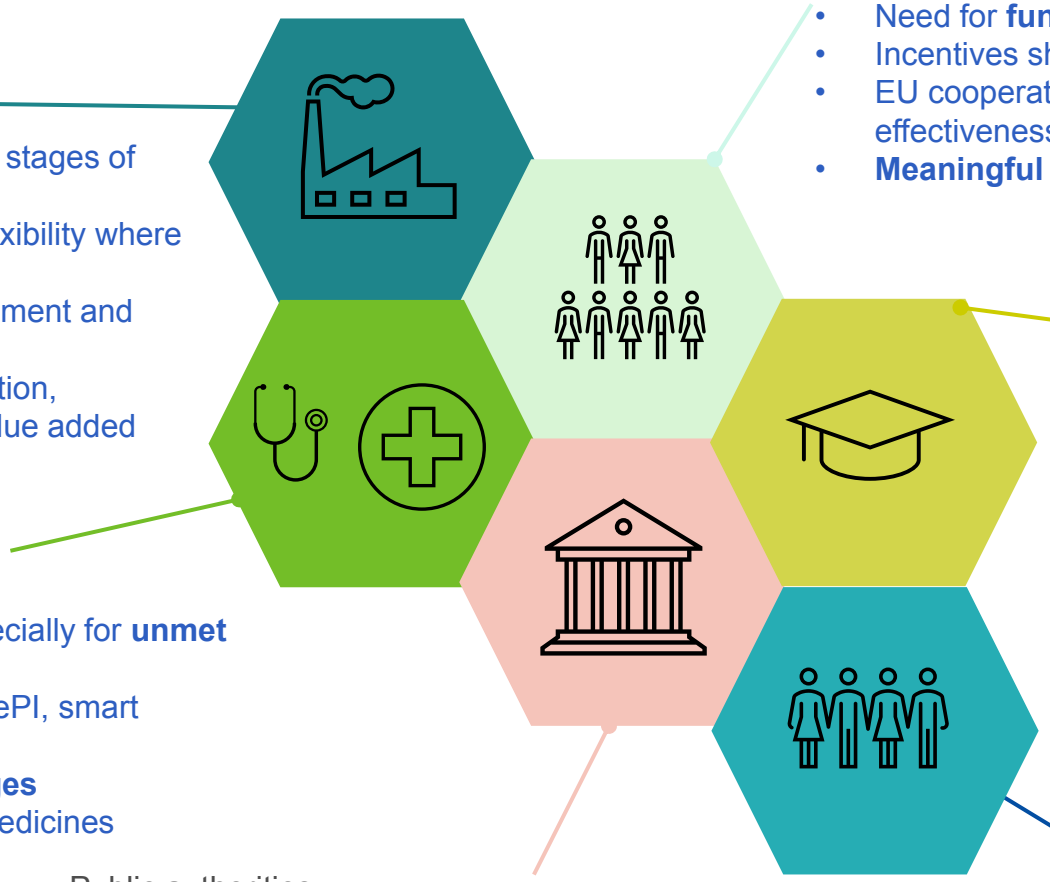
Consultations - Key points

Industry

- Need for **stable incentives** R&D in early stages of drug development
- **Predicable regulatory environment**, flexibility where needed
- Use of RWD and RWE in clinical development and regulation
- **Off-patent sector**: emphasis on competition, procurement criteria, IP, incentives for value added medicines

Civil Society Organisations

- Need for **funding** and R&D
- Incentives should improve **availability** of **treatments**
- EU cooperation on **affordability**, assessment of value, cost effectiveness, P&R, procurement
- **Meaningful patient involvement** in regulatory setting



Researchers, academia and learned societies

- Regulatory recognition of clinical **research conducted by non MAH**
- Promote upskilling & education
- Emphasize patients needs at the centre of drug development

Healthcare stakeholders

- Increase availability of medicines especially for **unmet medical needs**
- Promote the use of **digital** tools (e.g. ePI, smart prescriptions, digital medical records)
- Measures to monitor/**prevent shortages**
- An EU approach to **repurposing** of medicines
- Environmental concerns

Public authorities

- Measures to monitor/prevent **shortages and diversify supply**
- Measures to support **affordability**, access to medicines and financial sustainability of health systems
- Address **regulatory challenges** overlap with medical devices etc.

EU citizens & others

- medicines and tackle high **prices**
- Measures to monitor/prevent **shortages** and diversify supply
- **Competitiveness** and **environmental** concerns

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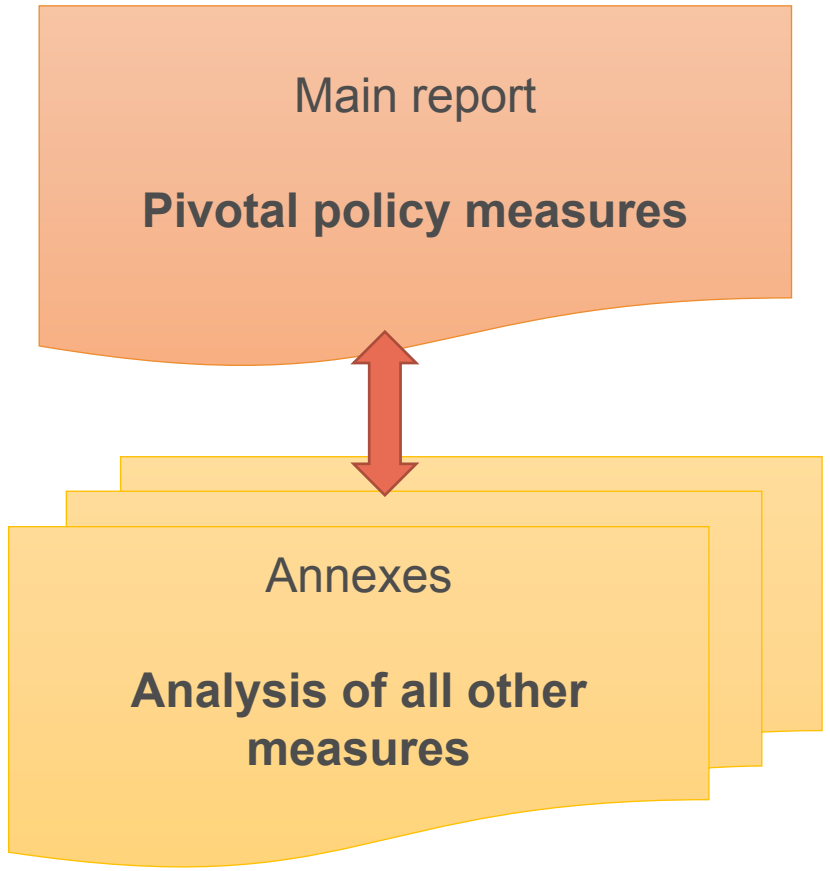
Potential policy measures analysed

- 77 potential policy measures considered
- Each of them analysed for likely impacts
- 16 horizontal measures to reduce regulatory burden and provide a flexible regulatory framework
- Horizontal measures proposed regardless of policy choices
- Costs and benefits of horizontal measures were analysed too

Would not fit in 40 pages of the IA



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Policy options

more incentives

Option A

- **8+2 years standard protection**
- +1 year for UMN
- +6 months for comparative trials
- Transferable AMR vouchers
- +6 months for launch in all EU markets in 5 years
- ⦸ on shortages
- ⦸ on environment
- Horizontal measures to reduce red tape

more obligations

Option B

- **6+2 years standard protection**
- +2 year for UMN or for no return on investment
- Pay or play model for AMR
- Transparency on public funding
- Obligation for market launch in majority of EU markets - 5 years
- Limited additional requirements on shortages
- some environmental obligations
- Horizontal measures to reduce red tape

quid pro quo

Option C

- **6+2 years standard protection**
- +2 years of protection conditional to launch in all EU markets
- +6 months for UMN
- +6 months for comparative trials
- Transferable AMR vouchers
- Transparency on public funding
- Regulatory shortage management and monitoring
- Several environmental obligations
- Horizontal measures to reduce red tape

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Other measures

Systematic multicriteria analysis of the measures

Option A	Option B	Option C
Incentives for innovation, in particular to address unmet medical needs (UMNs)		
A.1.1. PRIME remains under the current scheme (i.e. not included in the legislation). A.1.2. Establish a non-binding system for scientific assessment of evidence for repurposing A.1.3 Add a special incentive bonus (+1 year): of regulatory (data) protection for products with a demonstrated ability to address an UMN A.1.4. Special incentive bonus: if data package includes comparative trial with standard of care (+6 months)	B.1.1. Codification of PRIME in the legislation B.1.2. Establish a binding system for scientific assessment for repurposing B.1.3. Obligation for MAHs to include a new indication when supported by scientific evidence B.1.4. Reduce duration of incentives for originators from 8+2 to 6+2 years B.1.5. Medicines with demonstrated ability to address UMN get +2 years data protection. B.1.6. Breaking market protection in case of urgency B.1.7. Require transparency on any relevant public contribution or funding B.1.8. Give regulators the possibility to impose a post authorisation obligation for additional studies	C.1.1. As B.1.1 Codification of PRIME in the legislation C.1.2. As B.1.2 Establish a binding system for scientific assessment for repurposing C.1.3. Additional data protection period for the new evidence generated to support repurposing **C.1.4. Reduce duration of incentives for originators from 8+2 to 6+2 years (but with +2 years for launch in all markets [C.4.3.])** **C.1.5 As B.1.5 Medicines with demonstrated ability to address UMN get +1-year data protection.** **C.1.6. Same as A.1.4. Incentive bonus: if data package includes comparative trial (+6 months)** **C.1.7 Transparency on public contribution to clinical trials.** C.1.8 As B.1.8. Allow regulators to impose a post authorisation obligation for additional studies C.1.9. Breaking market protection in case of urgency
AMR specific		
A.2.1. Harmonisation of summary of product characteristics for nationally authorised antimicrobials to support prescription practices. A.2.2 Transferable voucher independent and in addition to data/market protection for antimicrobial products A.2.3. Consider adapted system for authorisation of phage therapies and other alternative products	B.2.1 Make central procedure mandatory for new antimicrobials. B.2.2. PRIME like support scheme, including rolling review B.2.3. Optimise package size B.2.4. Stricter rules on disposal B.2.5. Tighten prescription requirements B.2.6. Mandatory use of diagnostics B.2.7. Pay or play model B.2.8. Establish a monitoring system for consumption and use and the environment B.2.9. same as A.2.3	C.2.1. Novel antimicrobials fall in the CAP mandatory scope C.2.2. PRIME like support scheme, including rolling review C.2.3 Require companies to develop AMR lifecycle management plan C.2.4. same as B.2.3: Optimise package size C.2.5. same as B.2.5: Tighten prescription requirements for antimicrobials **C.2.6. Transferable voucher independent and in addition to data/market protection for antimicrobial products.** C.2.7. Consider adapted system for authorisation of phage therapies and other alternative products

Option A	Option B	Option C
Future proofing		
A.3.1. Maintain current exemptions from the scope of the legislation – add some clarifications/conditions *GMO OPTIONS* A.3.2. Clinical trials: a risk-based approach is applied to determine when a specific GMO assessment is required. A.3.3. An environmental risk assessment continues to be performed (by EMA) in the context of the marketing authorisation procedure.	B.3.1. Adapted regulatory framework for certain categories of novel products/technologies *GMO OPTIONS* B.3.2. same as A.3.2 but for clinical trials: Where required, the assessment of the GMO aspects of investigational medicinal products is performed at Member State level B.3.3. Adapt certain definitions, including that of medicinal product and *delink scope from industrial process.* B.3.4. Create a central *classification mechanism* for advice on whether products are medicines or not	C.3.1. Adapted regulatory framework for certain categories of novel products/technologies C.3.2. Clinical trials: a risk-based approach is applied to determine when a specific GMO assessment is required. C.3.3. Same as B.3.3. Adapt certain definitions, including that of medicinal product and *delink scope from industrial process.* For specific cell-based (ATMP) medicinal products [*link with revision of BTC legislation*]: C.3.4. adapted regulatory requirements to facilitate production in the hospital setting C.3.5. less complex cell-based medicinal products to be defined on the basis of clear risk-based approach C.3.6. Introduction of a regulatory sandbox environment, in the context of complex/cutting-edge 'medicinal product' C.3.7. Same as B.3.4. Create a central *classification mechanism* for advice on whether products are medicines or not.
Access		
A.4.1. Facilitate 'multi country packs' with labelling to allow their placing on the market in several Member States. A.4.2. Milestone incentive – +6 months data protection if product marketed in all MS within 6 years. A.4.3. (non-regulatory option) Voluntary reporting of market launches within 2 years of centralised authorisation. A.4.4. Promote placing on the market in all Member States within 5 years	B.4.1. Conditional marketing authorisation: more powers to regulators to enforce obligations for post-market evidence generation. B.4.2. Require MAHs to notify regulators of their market launch intentions. B.4.3. Obligation to place a centrally authorised medicine on the market in the majority of Member States within 5 years B.4.4. Requirement to MAH applying for MRP/DCP to include small markets	C.4.1. Conditional marketing authorisation: UMN incentives are only granted upon switching to standard MA. C.4.2. same as A.4.1. Facilitate 'multi country packs' with labelling to allow their placing on the market in several Member States. **C.4.3. 2 years of protection conditional to launch of all EU markets within 2 years** C.4.4. same as B.4.4.: Requirement to MAH applying for MRP/DCP to include small markets
Competition: generic, biosimilar entry		
A.5.1. New simpler regulatory pathway for generics A.5.2 No change to current situation and no restriction on duplicate marketing authorisations.	B.5.1. same as A.5.1. New simpler regulatory pathway for generics B.5.2. Interchangeability of biosimilars with their reference product will be generally recognised	C.5.1. same as A.5.1. New simpler regulatory pathway for generics C.5.2. same as B.5.2. Interchangeability of biosimilars with their reference product will be generally recognised

Option A	Option B	Option C
	B.5.3. Broaden Bolar exemption B.5.4. Extend Bolar exemption beyond generics B.5.5. Specific (regulatory) incentive for a limited number of first biosimilars B.5.6.a. Reforming the duplicates regime: No auto-biologicals. B.5.6.b. Duplicates restricted to cases of IP protection or co-marketing	C.5.3. same as B.5.3. Broaden Bolar exemption C.5.4. same as B.5.4. Extend Bolar exemption beyond generics C.5.5. same as B.5.6.b Duplicates restricted to cases of intellectual property protection or co-marketing
Security of supply		
A.6.1. Encourage use of HMA/EMA guidance definitions A.6.2. Notifications two months in advance A.6.3. Marketing authorisation offered to another MAH before a permanent withdrawal A.6.4. Use of the Falsified Medicines Directive (FMD) system to monitor shortages A.6.5. EU coordination to exchange information on supply and supply chains	B.6.1. Introduce an EU definition of a shortage B.6.2. Increase notification period to 6 months in advance B.6.3. Shortage prevention and mitigation plans added to GMP for all medicines B.6.4. Stockpiling requirements for MAHs and wholesalers for critical medicines B.6.5. Introduce an EU shortage monitoring system B.6.6. Require specific penalties for breaking supply obligations. B.6.7. Expanded requirements for key suppliers and back-ups to diversify supply chain B.6.8. Increase transparency of the supply chain, including active supply sites.	**C.6.1. Introduce an EU definition of a shortage** **C.6.2.a. Withdrawals: Increase notification period to 12 months** **C.6.2.b and at least 6 months in advance for all shortages (non-withdrawal).** **C.6.2.c Introduce a common template for reporting withdrawals and shortages.** **C.6.3. Stockpiling requirements for MAHs for unfinished critical medicines, as appropriate** **C.6.4. same as A.6.3 Marketing authorisation offered for transfer to another MAH before a permanent withdrawal** **C.6.5. MAHs to have shortage prevention and mitigation plans for all medicines** **C.6.6. Monitoring remains at MS level, with information exchange based on national monitoring, using a common format** **C.6.7. Same as B.6.7. Expand requirements to diversify supply chains.** **C.6.8. Establish a mechanism of information exchange to identify bottlenecks / vulnerabilities** **C.6.9. same as B.6.8. B.6.8. Increase transparency of supply chains**
Quality and manufacturing		

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Description of horizontal measures - simplification

- Active substance master file (common assessment of manufacturing data across products)
- More efficient repeat use procedure
- Sunset clause and renewal of MAs after five years abolished
- Base for reduction in the number of notifiable variations
- Simplification of the environmental risk assessment of medicines that contain or consist of GMOs
- Applying the digital by default principle, notably through electronic submissions of applications, variations to MAs and electronic product information

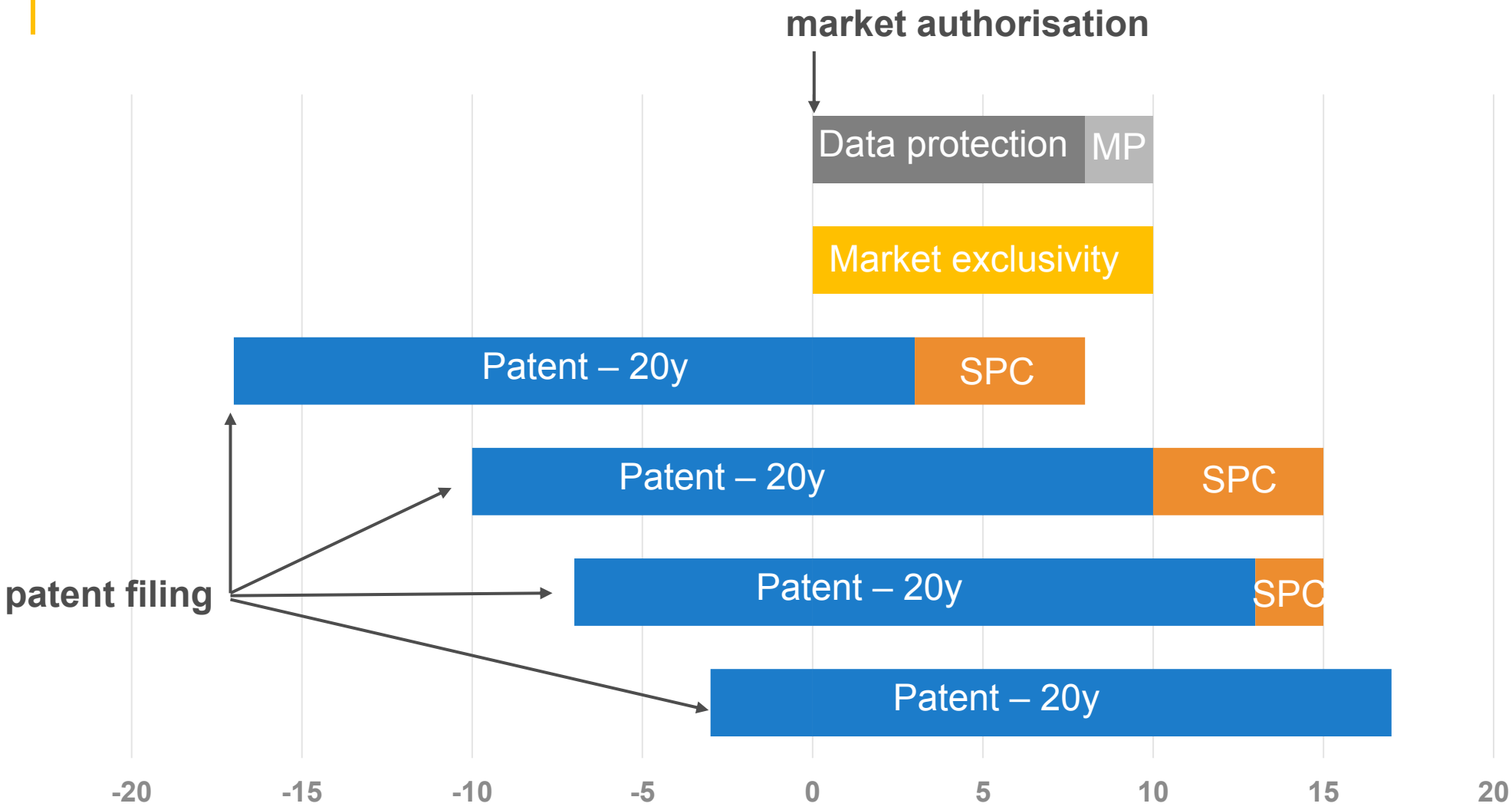
Description of horizontal measures - simplification

- Electronic product information (taking into account needs of patient)
- Simplified structure and working methods of EMA
- EU-wide centrally coordinated process offering early dialogue among clinical trial, marketing authorisation, health technology assessment bodies and pricing and reimbursement authorities
- Combination products (e.g. where medicines are coupled with medical devices, software, or AI)
- New concepts integrated, such as adaptive clinical trials
- Full use of health data (real world evidence)

Methodology and data

- Multiple data sources and related analytical methods were used to strengthen the IA's evidence base
- Commissioning state-of-the-art proprietary data: IQVIA MIDAS, IQVIA Ark Patent, Informa Datamonitor, Informa Pharmaprojects, EMA databases
- Quantification where possible, multi-criteria analysis based on triangulation of qualitative and quantitative data
- Regulatory Scrutiny Board, European Parliament and even the Dolon report recognised the robust data and solid economic analysis

Protection types

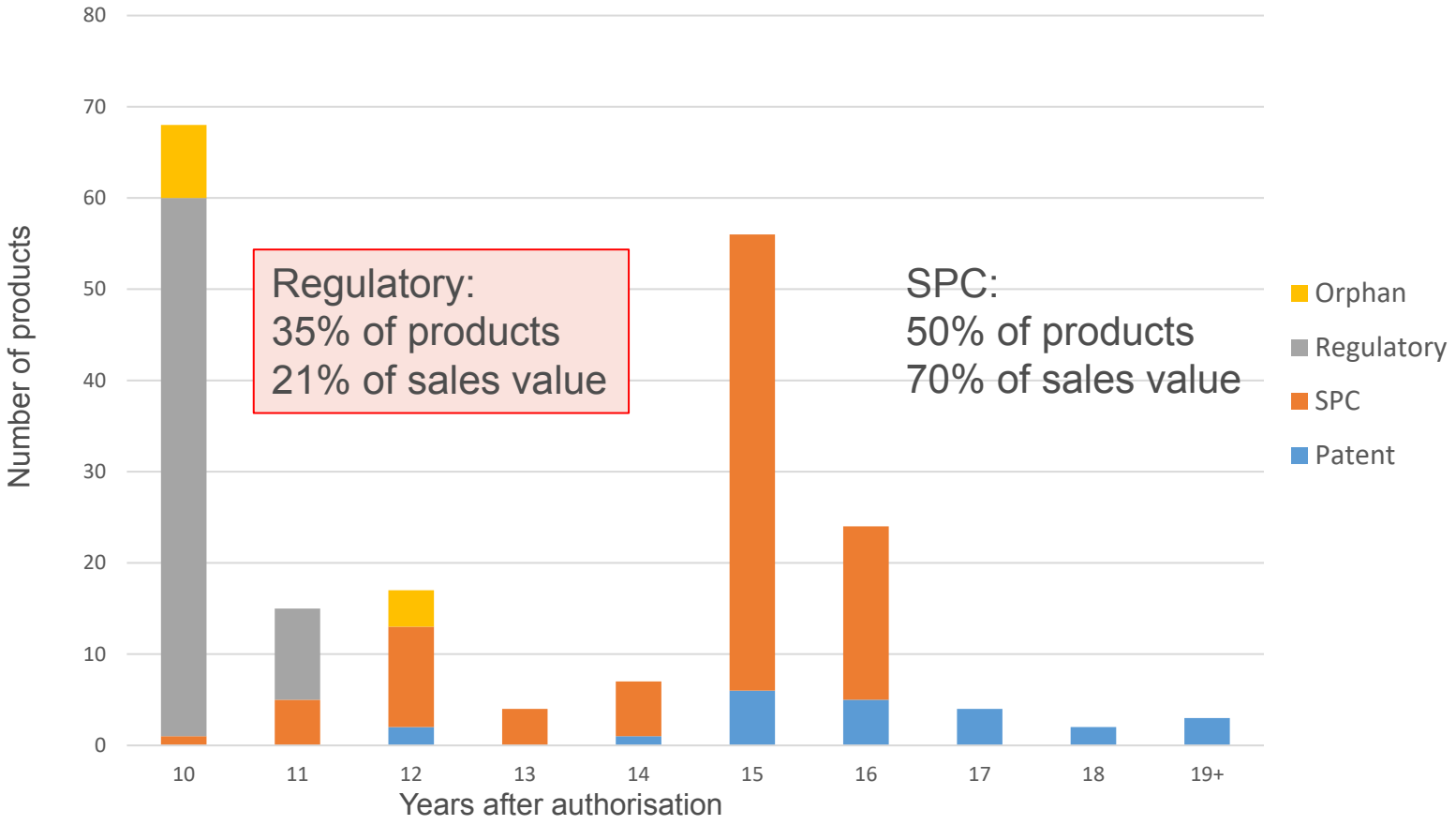


Years of protection 0 = EU market authorisation

European Commission

Scope of pharma legislation

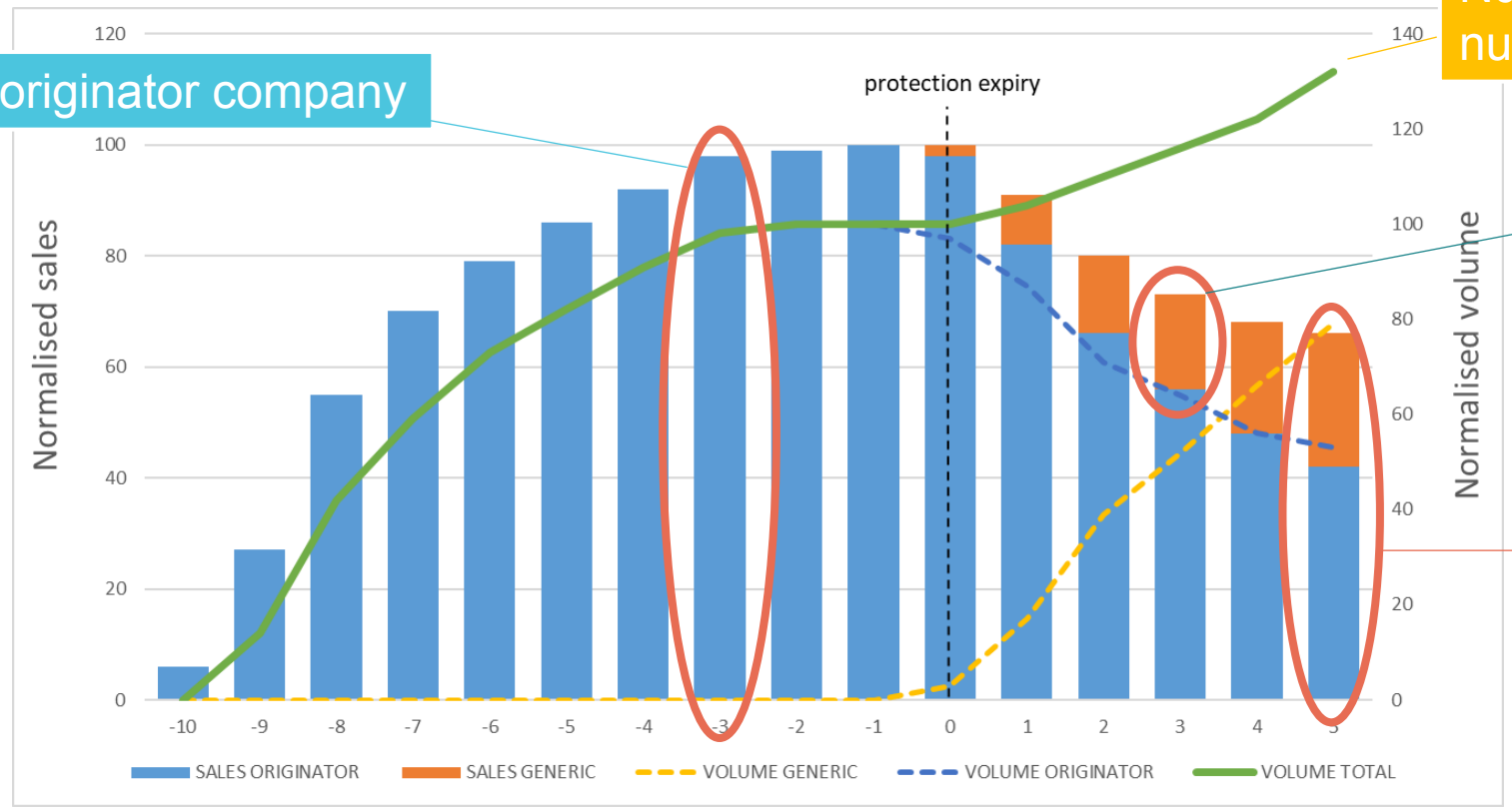
Current distribution of regulatory, SPC and patent protection based on a basket of 200 products, with protection expiry between 2016-2024



Protection type	Proportion	Avg peak sales
Orphan	6%	42 M
Regulatory	34.5%	158 M
SPC	48%	358 M
Patent	11.5%	257 M

European Commission

Baseline
Model for RDP protection and generic entry



Revenue of originator company

Number of treatments = number of patients treated

Revenue of generic companies

Public payer pays

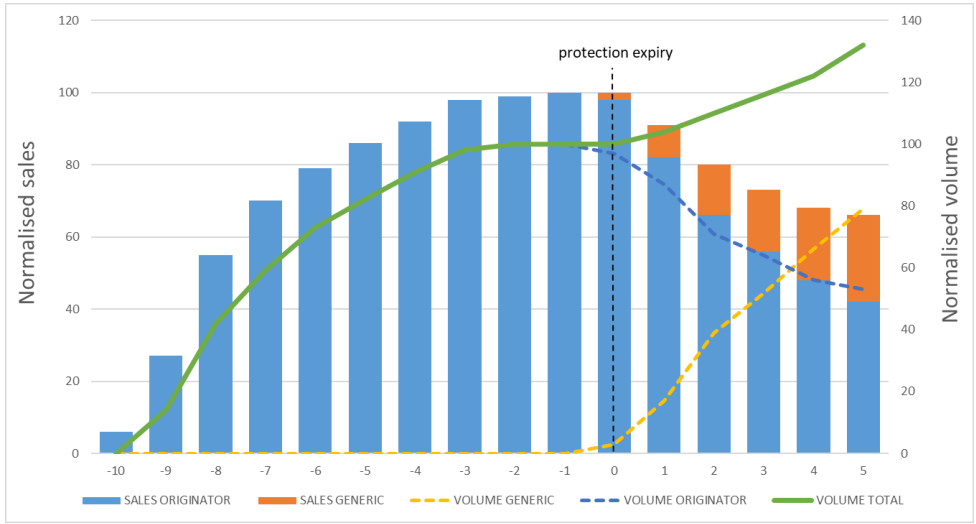
Normalised sales and volume for products with 8+2 years of RDP protection (baseline)

European Commission

Baseline
Model for RDP protection and generic entry

What is value for stakeholders?

- **Patients** – number of **patients treated** ~ total volume, originator + generics together
- **Health payer** – **cost of medicines** ~ total sales value, originator + generics revenues together
- **Industry** – **gross profit**, revenues minus the cost of sales (costs of manufacturing and distribution, but not the fixed costs, such as R&D and investment in infrastructure)
- Protected originator sales – 80% gross profit margin
- Contested originator sales – 50% gross profit margin
- Generic sales – 33% gross profit margin

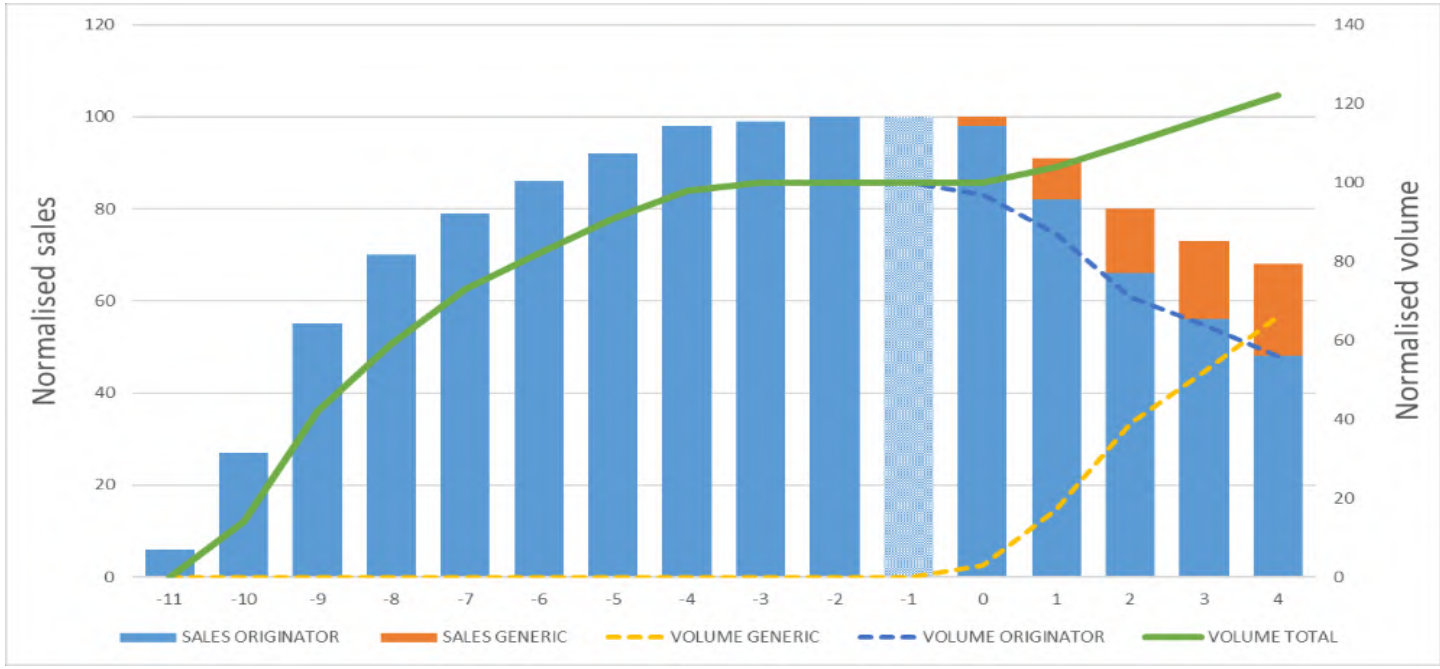


European Commission

Key issue 1 – changes to regulatory protection

Impact of increased protection (Option A & C)

Normalised sales and volume for products with 8+2+1 years of RDP



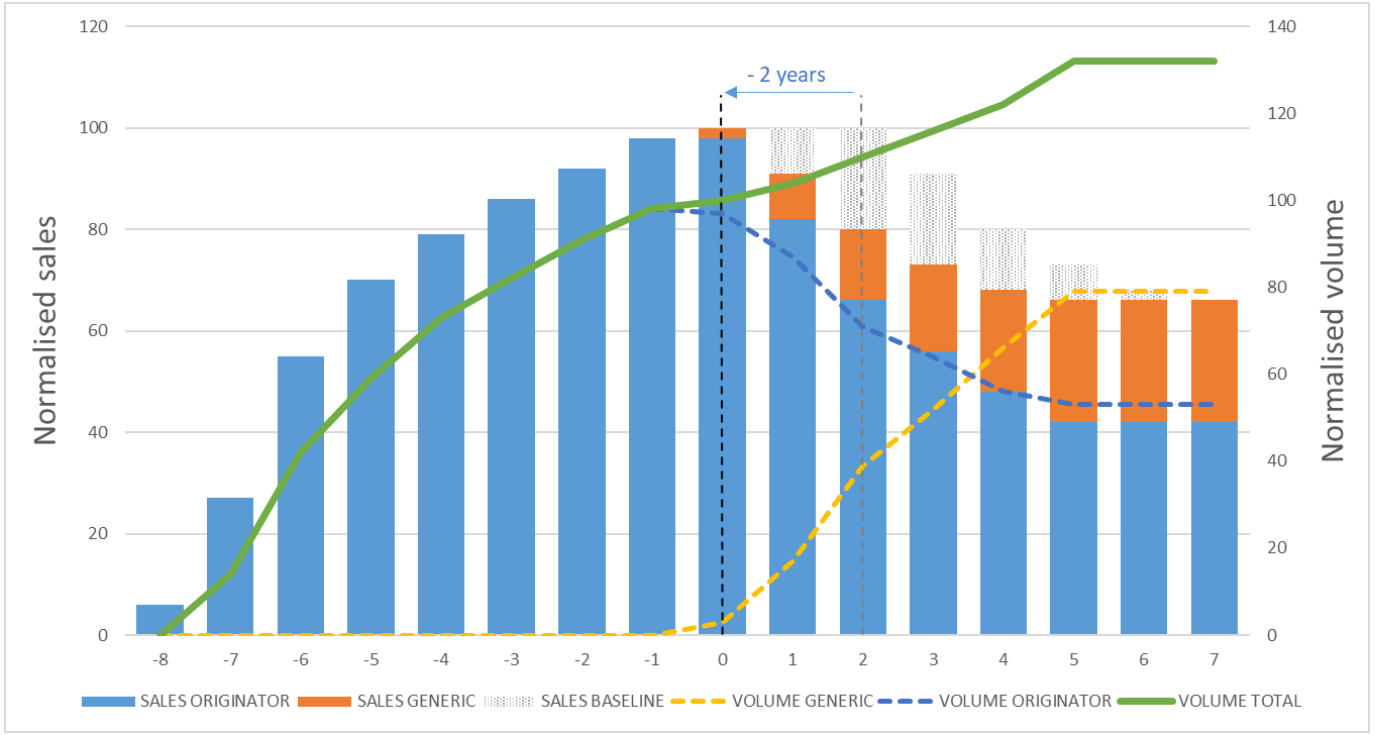
1 year increase in RP	**Product level change**
Originator gross profit	**+€94m**
Generic gross profit	-€13m
Cost to public payer	+€54m
Patients monetised gains/losses	-€28m
Patients + payer monetised gain/loss	**-€82m**

European Commission

Key issue 1 – changes to regulatory protection

Impact of reduced protection (Option B)

Normalised sales and volume for products with 6+2 years of RDP



2 year decrease in RP	Product level change	% change	Systemic change (9-12 medicines)
Originator gross profit	-€188m	**-15%**	**-€1.97 b**
Generic gross profit	+€25m	+56%	**+€266 m**
Cost to public payer	-€107m	-6%	**-€1.13 b**
Δ of patients treated (monetised)	+€71m	+5%	+€745 m
Patients + payer monetised gain/loss	+€178m	+9%	**+€1.86 b**

Less than 1% of EU pharma expenditure

Only affects medicines with no SPC or patent protection beyond 10 years after MA.

European Commission

Would the RP reduction harm EU competitiveness?

An unconditional reduction would probably harm the EU's attractiveness, BUT:

- Incentives reward the products coming to the EU market, not the products originating from the EU
- 20% of new medicines authorised in the EU are from the EU, the others are mainly from US, UK, Switzerland and Japan
- RP reduction only harms medicines that do not have SPC or patent protection after 10 years of MA
- Studies find that other factors, such as taxation, availability of talent and funding, stable legal-political system are more important factors in R&I site selection than incentives.

Country	Protection	Duration
Canada	New Chemical Entity+ Market Protection	6+2 years
EU	New Chemical Entity+ Market Protection	8+2+1 years
Switzerland	New Chemical Entity	10 years
USA	New Chemical Entity (small molecule)	5 years
USA	Biosimilar Application Approval Exclusivity (biologic)	4+8 years
Israel	Market Protection	6 or 6.5 years
China	New Chemical Entity	6 years
Japan	New Chemical Entity	8 years

European Commission

Key issue 2 – market access

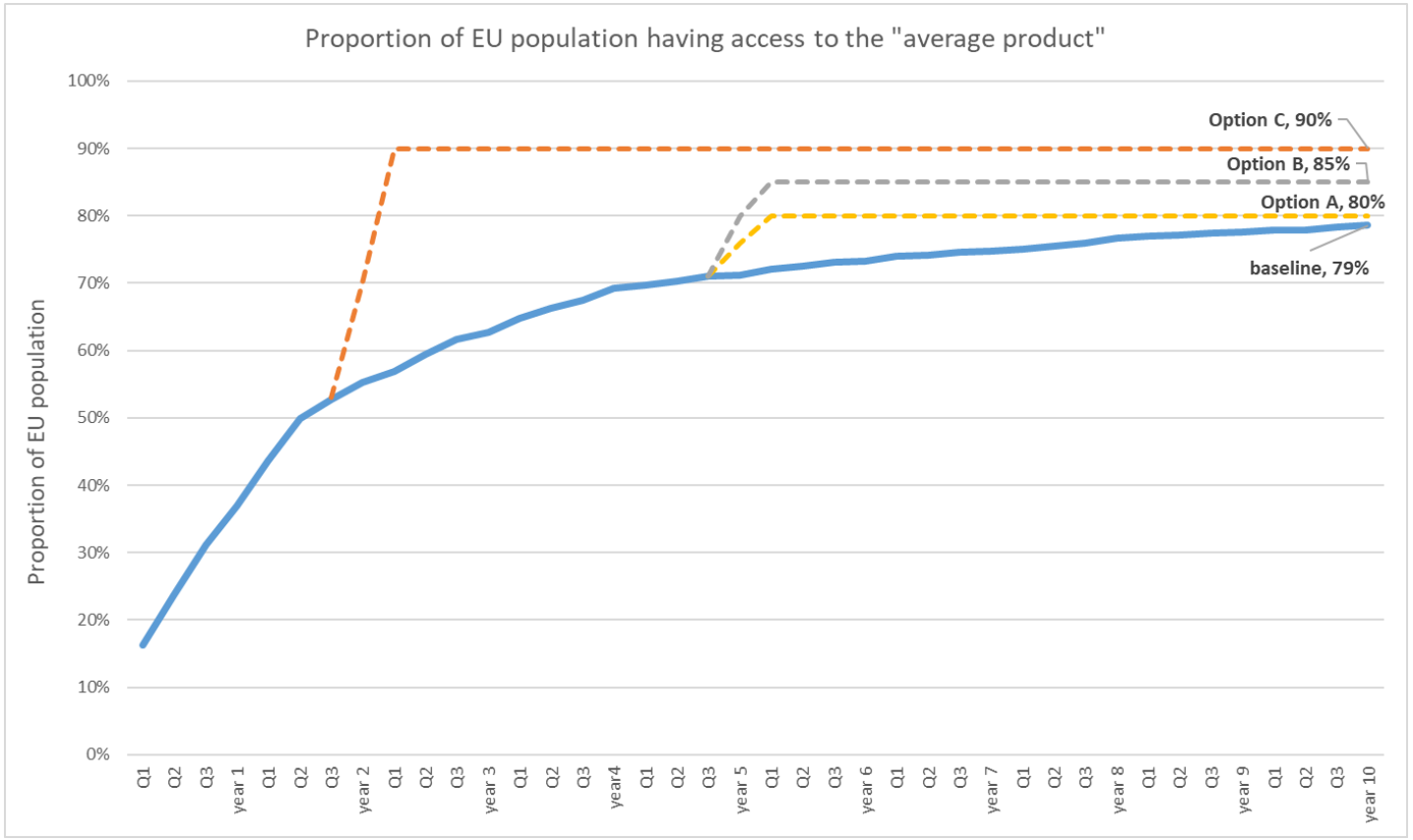
Comparing the impact of the different options

Option	Expected compliance	Originator's reward/loss	Cost/benefit for public
Option A +6 months, if in all EU	50% (6-8 medicines)	+€527 m gross profit +7.5% gross profit for 7 complying medicines	+€455 m public cost
Option B -5 years, if not in majority of MS	75% (11-13 medicines) Majority of markets	-€842 m gross profit -34% gross profit for 4 non-complying medicines	€681 m gain from non-complying medicines
Option C* -2 years, if not in all EU	66% (10-12 medicines)	-€469 m gross profit -15% gross profit for 5 non-complying medicines	€444 m gain from non-complying medicines

European Commission

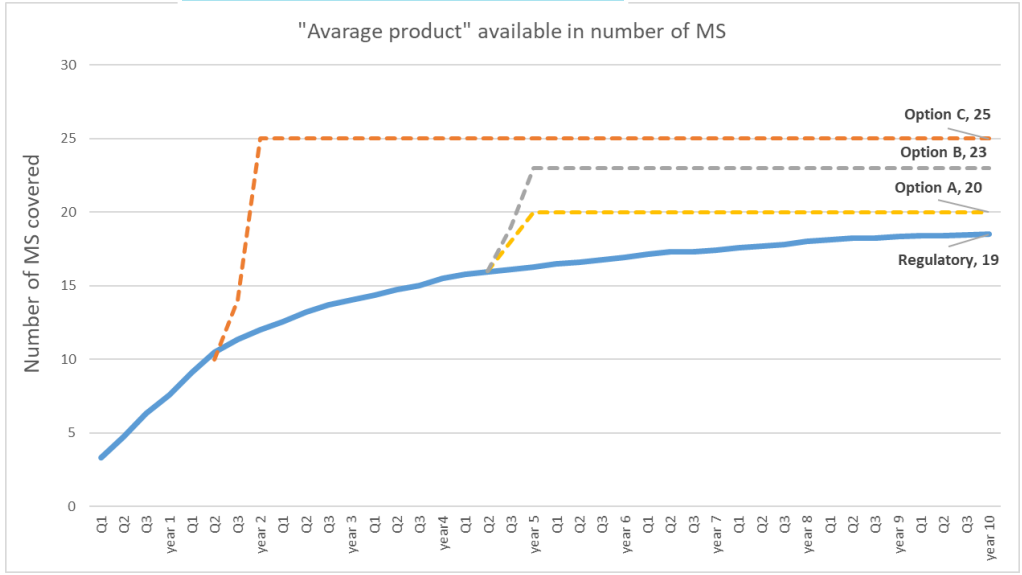
Key issue 2 – market access

Social impact



Avg. coverage over 10 years		
	% population	number MS
Baseline	65.3%	15
Option A	67.6%	16
Option B	70.2%	18
Option C	80.1%	22

+67 million citizens

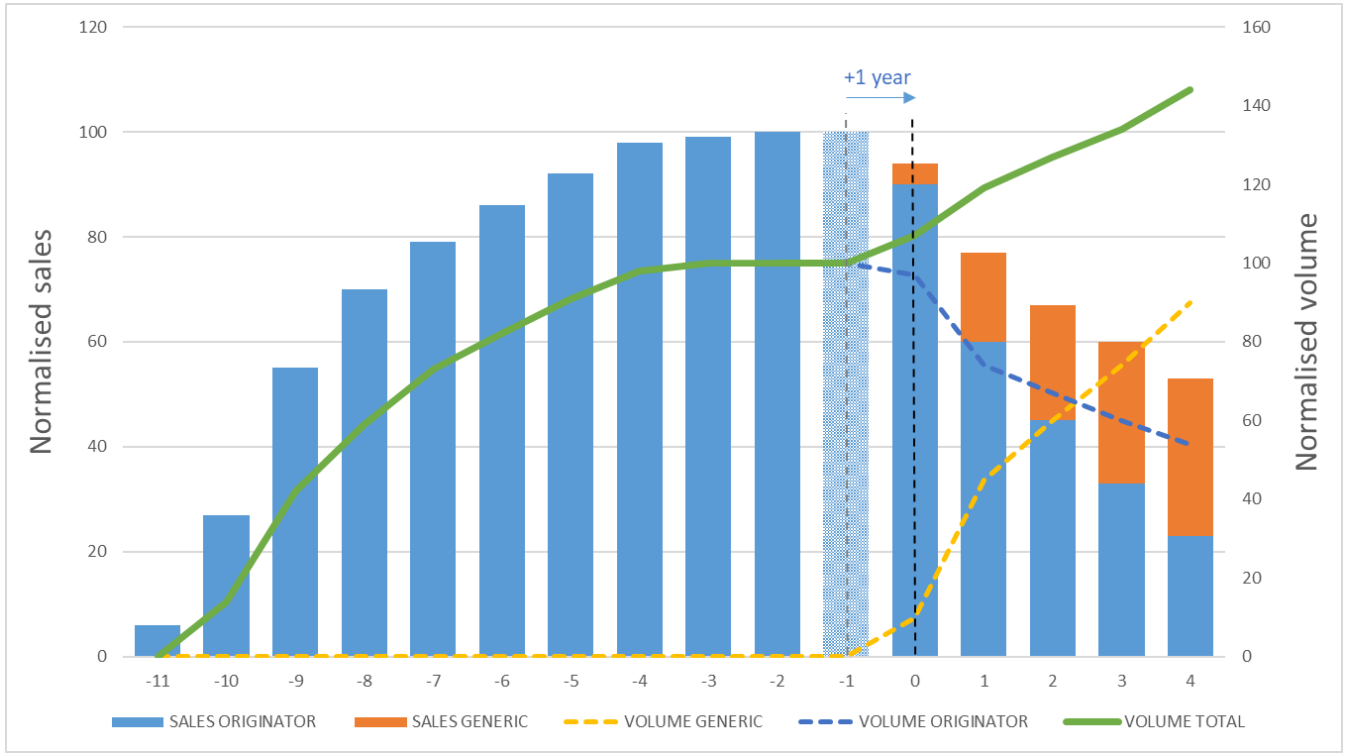


For medicines that has RDP as the last layer of protection

European Commission

Key issue 3 – transferable exclusivity voucher (opt A, C)

Cost and value of voucher



Stakeholder	change	change %
Originator gross profit	**+€387 m**	+10.1%
Generic gross profit	**-€54 m**	-23%
Cost to public payer	**+€283 m**	+4.7%
Patients monetised gain/loss	-€158 m	-3.8%
Patient + payer monetised gain/loss	-€441 m	-7.3%

European Commission

Key issue 3 – transferable exclusivity voucher (opt A, C)

Share between buyer and seller

1 voucher

1 voucher	
Seller rent	**205 M**
Buyer rent	**154 M**
Cost to public in nominal value	**283 M**
Cost to public incl. unserved patients	**441 M**

3 vouchers

3 vouchers	Voucher 1	Voucher 2	Voucher 3	Total
Seller rent	89 M	89 M	89 M	**267 M**
Buyer rent	270 M	97 M	50 M	**417 M**
Cost to public in nominal value	283 M	147 M	109 M	**539 M**
Cost to public incl. unserved patients	441 M	228 M	170 M	**839 M**

European Commission

Benefits of AMR vouchers

- We only bet on the winning horse – only authorised, game-changing antimicrobials are eligible
- It effectively would be a **market entry reward worth €2-300 million** per product
- This regulatory innovation would represent a fair EU share to the global AMR challenge, comparable to industry driven AMR Action Fund or the planned PASTEUR Act in the US.
- Different than direct financing models such as **subscription (Netflix) model** or the **guaranteed revenue model.** The voucher targets **innovation**, the other instruments target **availability** of antimicrobials.

European Commission

Concerns about AMR voucher

- The vouchers are too expensive for health systems
- Middle-men are profiteering from the instrument
- It is not transparent
- It makes the system unpredictable for generic/biosimilar makers
- It does not ensure supply of the authorised antimicrobial

The revision can mitigate the risks

- The vouchers are too expensive for health systems
  - → The novel antimicrobial serves as an insurance policy against cost of AMR
  - → Modulation of incentives creates saving that cover the cost of the voucher
  - → Strict criteria for granting, only game-changers, capping the number of vouchers
- Middle-men are profiteering from the instrument
  - → Limiting the number of vouchers limits profiteering; middle-men not always needed
- It is not transparent
  - → Transparency required on public R&D funding
  - → Details of voucher transactions (buyer, amount) have to be made public
- It makes the system unpredictable for generic/biosimilar makers
  - → The voucher has to be applied well in advance of the regulatory protection expiry
- It does not ensure supply of the authorised antimicrobial
  - → Supply conditions attached

Measures on shortages

Systematic multicriteria analysis of the measures (Annex 11)

C.6.1 EU definition of shortage
C.6.2 increased notification period to 12M
C.6.3 stockpiling requirements
C.6.4. offer transfer of MA before withdrawal
C.6.5. Shortage prev. mitig. Plans
C.6.6. Monitoring at MS level & info exchange
C.6.7. Supplier back-ups for crit. Meds.
C.6.8. Mech. Of exchange on supply chains
C.6.9. increased transparency of suppl. Ch.

Table 61 Option C – Summary assessment of Policy Block F (Security of Supply)

Policy elements	COB	Admin	SMEs	CTI	Int Mar	I&R	PA	H&S	Sust
C.6.1	+/-	+	+/-	+/-	+/-	+/-	+/-	+	+/-
C.6.2	--	--	+/-	+/-	+/-	+/-	+/-	++	+/-
C.6.3	--	--	+/-	--	+/-	+/-	-	+	--
C.6.4	-	-	+/-	-	+/-	+/-	+/-	++	+/-
C.6.5	-	--	+/-	--	+/-	+/-	+	++	+/-
C.6.6	+/-	+	+/-	+/-	+/-	+/-	+	++	+/-
C.6.7	---	---	--	--	-	+/-	+/-	++	--
C.6.8	+/-	+/-	+/-	+/-	+/-	+/-	+	++	+/-
C.6.9	+/-	--	+/-	--	-	+/-	+	++	+/-
Overall impact	--	--	+/-	-	-	+/-	++	+++	+/-

COB=conduct of business; Admin=Administrative costs on businesses; CTI= Competitiveness, trade and investment flows; Int Mar= Functioning of the internal market and competition; I&R= Innovation and research; PA= Public authorities; H&S=Public health and safety; Sust= Sustainable consumption and production. Colour coding: Red=negative impact; amber=neutral; green=positive impact; White=cannot say or depends on actual implementation of the element.

European Commission

Measures on Environment

Systematic multicriteria analysis of the measures (Annex 11)

C.8.1 Include manufacturing in ERA
C.8.2 strengthen ERA requirements/cond. of use
C.8.3 EMA adv. Role on ERA/green manuf.
C.8.4. Include AMR aspects in GMP

Table 65 Option C – Summary assessment of the proposed measures for addressing environmental challenges

Policy elements	COB	Admin	SMEs	CTI	Int Mar	I&R	PA	H&S	Sust
C.8.1.	-	-	-	-	-	+/-	-	+	++
C.8.2.	+/-	+/-	-	-	-	+/-	+/-	+	++
C.8.3.	+/-	+/-	+/-	+/-	+/-	+/-	-	+	+
C.8.4.	-	-	-	-	+/-	+/-	-	+	+
Overall impact	-	-	-	-	-	+/-	-	+	++

COB=conduct of business; Admin=Administrative costs on businesses; CTI= Competitiveness, trade and investment flows; Int Mar= Functioning of the internal market and competition; I&R= Innovation and research; PA= Public authorities; H&S=Public health and safety; Sust= Sustainable consumption and production. Colour coding: Red=negative impact; amber=neutral; green=positive impact; White=cannot say or depends on actual implementation of the element.

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Other measures – example

Overview of the costs and benefits associated with the horizontal measures related to simplification and burden reduction

	Businesses	Businesses	EMA	EMA	NCAs	NCAs
	one-off	recurrent	one-off	recurrent	one-off	recurrent
Streamlining costs						
Enforcement			€1.8m-€3.6m	€3.5m-€7.5m	€15m-€30m	€30m-€60m
Indirect						
Streamlining benefits						
Direct		€15m-€30m		€3.5m-€7m		€30m-€60m
Indirect		€55m-€110m				
Total savings		€1,050m-€2,100m		€-3.9m to €1.8m		€15m-€30m
Digitalisation costs						
Direct						
Enforcement			€20m-€50m	€4m-€10m	€100m-€300m	€20m-€60m
Indirect						
Digitalisation benefits						
Direct		€7.5m-€15m		€7m-€14m		€60m-€120m
Indirect						
Total savings		€112m-€225m		€65m-€70m		€700m-€1,200m

Presentation Outline

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Option A – assessment

Option A

- **8+2 years standard protection**
- +1 year for UMN
- +6 months for comparative trials
- Transferable AMR vouchers
- +6 months for launch in all EU markets
- ⦸ on shortages
- ⦸ on environment
- Horizontal measures to reduce red tape

Innovation ☺☺☺

Provides incentives for UMN, AMR

Affordability ☹☹

Cost of incentives to be borne by the health payer

Access ☺

Provides 6 months incentive, medium compliance expected

Shortages, environment ☺☹

Baseline

Admin burden ☺

No new burden, but benefiting from horizontal measures

European Commission

Impact assessment - option A

Overall impact	Description
Conduct of business	Retaining current RP benefits new medicines, but harms access though delayed off-patent entry; incentives for UMN and security of supply measures have no added burden (status quo).
Public authorities	Extended data protection incurs costs for health systems, delays generics. Comparative trial incentives provide more evidence for HTAs and payers.
Competitiveness	Improved competitiveness and attractiveness of the EU pharmaceutical sector, especially for SMEs
Research and innovation	Increased return on investment for developers and bring additional investment into R&D for UMN, including AMR.
Functioning of the internal market	Increase in the number of new innovative centrally authorised medicines however high prices sustained for a longer period compared to the baseline.
Administrative burden on business	Reduction of administrative burden because of horizontal measures. Increased complexity due to making RP contingent on market launch.
SMEs	Increased support for SMEs from voucher for priority antimicrobials. Market launch incentive more challenging for SMEs compared to big companies.

Cost-benefit table of key measures in Option A

Option A	Cost/benefit for public payer and patients	Cost/benefit for originators	Cost/benefit for generic industry
+1 year extension of RP for medicines addressing UMN	+ €246m cost + 1-2 new UMN addressing medicines	+ €282 gross profit (3 incentives)	- €39m gross profit
+6 months extension of RP for conducting comparative clinical trials	+ €328m cost + faster access and cost saving thanks to improved reimbursement decisions	+ €378m gross profit +€280m cost (8 medicines)	- €52m gross profit
+6 months extension of RP for all EU market launch	+€455 m public cost +3% access	+€527 m gross profit (7 complying medicines)	- €71m gross profit
Transferable exclusivity voucher	+€441m cost + 1 novel antibiotic	+€387m gross profit (1 voucher)	- €54m gross profit
Total balance	**+ €1.470m cost** + 1-2 new UMN medicines +comparative data +3% access +1 novel antibiotic	**+€1.294m gross profit**	**- €216m gross profit**

European Commission

Option B – assessment

Option B

- **6+2 years standard protection**
- +2 year for UMN or for no return on investment
- Pay or play model for AMR
- Transparency on public funding
- Obligation for market launch in majority of EU markets - 5 years
- Limited additional requirements on shortages
- some environmental obligations
- Horizontal measures to reduce red tape

Innovation ☹

Neutral for UMN, AMR compared to baseline, and for other innovators 22% loss of commercial value

Affordability ☺

The reduction saves 0.6-1% of the pharma expenditure

Access ☺☺

High compliance, but only majority of markets, and difficult to predict for generics

Shortages, environment ☺☹

Baseline

Admin burden ☹☺

New burden from transparency, horizontal measure compensate

European Commission

Impact assessment - option B

Overall impact	Description
Conduct of business	Originators adversely affected by reduced RP (22% loss in commercial value), possibly increased prices and rebalancing of innovators' portfolios towards market segments with greater commercial potential. Boost to EU's generic industries. Developers of products addressing UMN would be exempt from the negative impacts. Pay or play model would impose additional costs on EU pharmaceutical businesses.
Public authorities	Benefits to health payers, earlier off-patent entry, more transparency on costs albeit with low implementation feasibility. Increased cost-effectiveness of health systems with a risk of average prices adjusted upwards to offset the shortened protection period. Improved access in small markets. Creating the infrastructure and monitoring shortages will require a significant investment from authorities.
Competitiveness	Weakened global competitiveness of EU and raised costs of business.
Research and innovation	Reduced number of new innovative medicines. Estimated annual €670m loss for R&D due to the reduction in regulatory protection.
Functioning of the internal market	Earlier generic entry and increase in access to medicines through market launch obligations, improvement in access to those medicines marketed in EU.
Administrative burden on business	Absence of ROI from R&D for additional regulatory protection and increased transparency would create administrative costs for businesses which would be offset by horizontal measures to an extent.
SMEs	Difficulty to invest in riskier novel medicines given the reduction in future returns on investment; benefits from the UMN incentive; obligations for market launch in a minimum number of Member States pose challenges to SMEs

Cost-benefit table of key measures in Option B

Option B	Cost/benefit for public payer and patients	Cost/benefit for originators	Cost/benefit for generic industry
2 year reduction of RP (except for UMN)	+€1860m gain innovation loss	-€1.970m gross profit (9-12 medicines)	+€266m gross profit
Loss of RP, if no market launch in majority of EU within 5 years	+€681m gain +5% access	-€842m gross profit (4 non-complying medicines)	+€101m gross profit
Total balance	**+ €2.541m gain** +5% access innovation loss	**- €2.812m gross profit**	**+€367m gross profit**

European Commission

Option C [**preferred option**] – assessment

Option C

- **6+2 years standard protection**
- +2 years of protection conditional to launch in all EU markets
- +6 months for UMN
- +6 months for comparative trials
- Transferable AMR vouchers
- Transparency on public funding
- Regulatory shortage management and monitoring
- Several environmental obligations
- Horizontal measures to reduce red tape

Innovation ☺☺☺

Provides incentives for UMN, AMR

Affordability ☹☺

Cost of incentives to be borne by the health payer

Access ☺☺☺

High compliance, on all EU market, fast access

Shortages, environment ☺☺☺

Several measures

Admin burden ☹☺☺

Some new obligations, horizontal measures compensate

European Commission

Impact assessment - option C

Overall impact	Description
Conduct of business	Increased revenue for the majority (66% compliance rate for ML) of new medicines and a reduction of revenue for remaining products. Incentives for UMN, comparative trials would extend protection periods for certain products. Loss for originators and benefits for off-patent sector. Additional reporting on shortages acceptable under conditions.
Public authorities	Win-win for public authorities, cases with higher costs would come in exchange of access, UMN, comp. cl. Trials. In cases where this is not the case → earlier access, lower costs. Additional costs for verification of UMN, ML, supply reporting. Increased negotiation power from additional transparency on costs and ML incentive.
Competitiveness	Standard incentives remain internationally attractive, Possibility for additional incentives that go beyond today's protection periods. ML incentive would apply to EU/Non EU companies alike → no change to relative competitiveness. Environmental and supply reporting obligations would add burden to EU companies.
Research and innovation	Increased return on investment for developers and bring additional investment into R&D for UMN, including AMR. (similar to Option A)
Functioning of the internal market	Improved patient coverage and functioning of the internal market.
Administrative burden on business	Higher administration costs from ML modulation and increased notification periods and supply obligations which will be significantly offset by horizontal measures.
SMEs	SMEs to benefit from regulatory sandboxes, scientific support from the Agency, fee reductions, incentives for UMN and AMR vouchers. Some increase of burden for SMEs from ERA requirements.

Cost-benefit table of key measures in Option C

Option C	Cost/benefit for public payer and patients	Cost/benefit for originators	Cost/benefit for generic industry
2 year conditional protection for all EU launch in 2 years	€444 m gain +15% access	-€469m gross profit (5 non-complying MP)	+€63m gross profit
+6 months extension of RP for medicines addressing UMN	+ €123m cost + 1 new UMN addressing medicines	+ €141m gross profit (3 incentives)	- €20m gross profit
+6 months extension of RP for conducting comparative clinical trials	+ €328m cost + faster access and cost saving thanks to improved reimbursement decisions	+ €378m gross profit +€280m cost (8 medicines)	- €52m gross profit
Transferable exclusivity voucher	+€441m cost + 1 novel antibiotic	+€387m gross profit (1 voucher)	- €54m gross profit
Total balance	**+ €448m cost** + 1-2 new UMN medicines +comparative clinical data +15% access +1 novel antibiotic	**+€157m gross profit**	**- €63m gross profit**

Simplification measures will bring annually up to **€204m savings for authorities** and up to **€70m** savings for companies

European Commission

Comparison of the options

Criteria	Baseline	Policy Option A	Policy Option B	Policy Option C
Effectiveness: contributing to achieving the policy objectives				
Promote innovation,	0	++	-	+
in particular for unmet medical needs	0	+++	0	+++
Create a balanced system for pharmaceuticals in the EU that promotes affordability for health systems while rewarding innovation	0	--	++	+
Ensure access to innovative and established medicines for patients with special attention to enhancing security of supply across the EU	0	+	++	+++
Reduce environmental impact of the pharmaceutical product lifecycle	0	+	++	+++
Reduce regulatory burden and provide a flexible regulatory framework	0	+++	++	++
Effectiveness: other impacts				
Competitiveness, SME, single markets	0	+	+	++
Social impacts (patients, public health and safety)	0	++	+	+++
Environmental impacts	0	+	++	+++
Efficiency				
Administrative and compliance costs	0	++	++	+
Savings and benefits	0	+	++	+++
Coherence	0	+	++	++
EU added value	0	++	++	+++
Proportionality and subsidiarity	0	+	+	++
Overall	**0**	**+**	**+**	**+++**

Preferred option - impact on **SMEs**

- Small and medium-sized enterprises (SMEs) play a fundamental role in the 'EU pharmaceutical ecosystem'
- SMEs would benefit from the introduction of regulatory sandboxes to support the development of innovative products, scientific support from EMA, and fee reductions
- Biopharmaceutical SMEs in particular are expected to benefit from the incentives scheme for unmet medical needs and AMR
- The burden of increased environmental and shortage reporting requirements, as well as the market launch conditionality are likely more challenging for SMEs than big firms.

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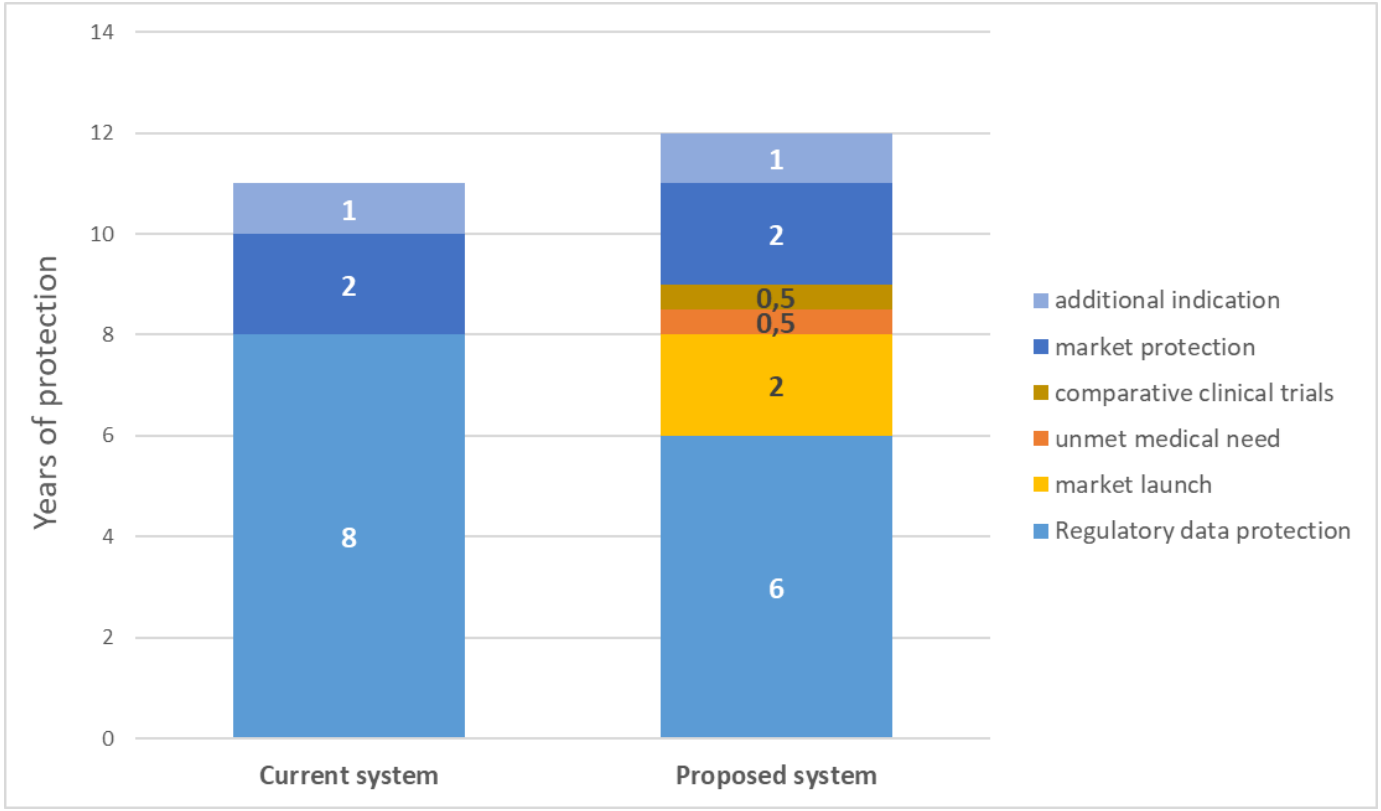
Modulation for the majority of innovative medicines

Regulatory data and market protection today and as proposed



Current system, max 11 years protection

Proposed system, max 12 years protection

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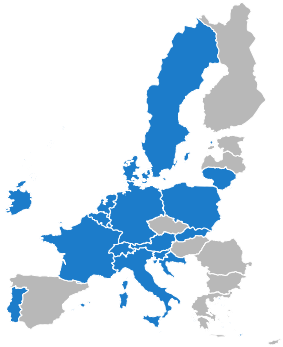
Market launch conditions

- Launch in all Member States where the marketing authorisation is valid (CP and DCP)



- **Actual placing** on the market and continuous supply for the needs of the patients in each MS (incl. presentations, quantities)
- **MS has 4+1 options**:
  - Positive/negative confirmation of actual supply
  - Waiver
  - Tacit [or]
  - positive pricing and reimbursement decisions (Transparency Directive)

Unmet medical needs

All rare diseases-orphan medicines automatically considered UMN

Indication criterion: Therapeutic indication must relate to a *life threatening [*OR] *severely debilitating* condition

Comparison to authorised medicines:

- *No medicine is authorised* in the EU

[OR]

- A medicine *is authorised* in the EU but disease is associated with remaining *high morbidity / mortality*

Effect criterion: Use of the medicine results in *meaningful reduction in disease morbidity / mortality* for the relevant patient population

EMA to set *scientific guidelines* for the application of the article + consultation process of downstream actors and stakeholders (HTA/P&R bodies (possibility to include patients, industry, others).

European Commission

Regulatory incentives with transferable exclusivity vouchers under strict conditions

Transferable data protection voucher: allow the developer of a novel antimicrobial to benefit from **additional year of data protection** on a product in their portfolio, or sell the voucher to another company to use

Strict conditions e.g. only novel antimicrobials that address AMR, full transparency of all funding, obligation of supply, 1 time transfer etc.

Max **10 vouchers in 15 years**, review after 15 years.

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Thank you

Photos slide 40 AI generated by ChatGPT

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