# Trialogues on Pharmaceutical legislation: Medicines for Europe's position on regulatory exclusivities

## Support the Council general structure of regulatory incentives and maintain the modulation of market protection

**RDP baseline + 1 year fixed (MP) + 1 year modulated (MP) if the conditions are met + 1 year modulated MP for a new indication bringing significant clinical benefit= TOTAL regulatory (market and data) protection no longer than 11 years**

**Baseline regulatory data protection (RDP)**
Support for a **reasonable** baseline that rewards innovation but also equity of access. A 2024 independent study[1] shows that, between 1995 and 2020, 91% of oncology products recouped R&D investments within 8 years. The EU has the longest Pharma IP protection in the world[2].

**Market protection <u>by default</u>**
+ 1 year of market protection (fixed, applicable to all new originators)

**Modulated market protection <u>if conditions are met</u>**
+ up to 1 modulated year of market protection if product addresses unmet medical need or meets 3 criteria (HTA/comparative trials + clinical trials in more than 1 MS + first or early EU MA application)

**Total Regulatory (market and data) protection: no longer than 11 years** Any extension beyond 11 years would cost healthcare systems billions without any clear benefit for society. Our simulation, based on the originator extension claims (13 to 18 years), for only 15 molecules shows that the costs for healthcare budgets would be between €20billion and €100billion[3].

Economic impact of extension of regulatory protection beyond 11 years on only 15 blockbuster molecules

| | EU | Germany | France | Spain | Poland | Czech Republic |
|---|---|---|---|---|---|---|
| 13.5 years of total regulatory protection | 19.5 BN EUR | 5 BN EUR | 5.35 BN EUR | 2.25 BN EUR | 552.8 MN EUR | 141.6 MN EUR |
| 18 years of total regulatory protection | 99.5 BN EUR | 23 BN EUR | 24 BN EUR | 13.2 BN EUR | 3.8 BN EUR | 1 BN EUR |

**Why is it important to support the Council structure on the modulation of regulatory incentives?**

- Supports the **ACCCESS GOAL** by potential earlier entrance of generic and biosimilar medicines, ensuring predictability both for Member States and the industry
- Supports the **EU COMPETITIVENESS GOAL** by addressing reward for research to cover patients' unmet needs and boosting investments in the EU by stimulating clinical trials in the EU, timely filing/ granting of MAs in the EU in comparison with other jurisdictions, studies supporting HTA decisions

**WHAT SHOULD BE IMPROVED IN THE TRILOGUES?**
To deliver on the objectives of access and competitiveness, generic and biosimilar medicine suppliers should be able to **file their dossier at year 6 of the data protection baseline under <u>all</u> scenarios** - both if the originator company will not supply a specific country or if they do not get their extra years of modulated market protection- to enable the off-patent medicines **to deliver access in that country in time to meet the legally defined deadline (article 56a)**. This is due to the time necessary for generic and biosimilar medicines to finalise their MA and PR procedures (around 2 years).

**Without such clarification,** generic and biosimilar medicines will be artificially delayed where an originator does not get the +1 year of modulated market protection. Furthermore, this **artificial delay will <u>not</u> stimulate originator companies to invest in EU R&D as they will benefit from the artificial extension in any case**.

Lastly, it is also essential to **maintain modulation of incentives as market** (not data) **protection.**

[1] Added benefit and revenues of oncology drugs approved by the European Medicines Agency between 1995 and 2020: retrospective cohort study | The BMJ
[2] NOTE on Proposals to extend pharmaceutical intellectual property incentives in reaction to US tariffs
[3] Impact of extending the duration of regulatory data protection in the new EU pharmaceutical legislation

## Support the Council's general structure of incentives and maintain the modulation of regulatory incentives as market protection

In order to support both access and competitiveness goals, it is key to support the modulation of incentives such as market protection, which opens an opportunity to provide **earlier access to generic/biosimilar** versions of the originator product if the originator product is not launched or conditions to modulate incentives and gain + 1 year are not met. Generic / biosimilar Marketing Authorisations (MAs) will be "ready", instead of applying for a MA only after the expiry of modulated data protection.

Furthermore, with the **modulation of market incentives,** the **system of incentives will be predictable for all parties** (industry and Member States) and will allow off-patent medicine manufacturers to properly plan their development and filings for marketing authorisation applications. It will also allow better planning for the competent authorities to allocate a slot and necessary resources for assessment. This would have no impact on the originator industry unless they fail to meet the criteria such as supplying all markets or investing in research in the EU or in unmet medical need. With modulated data protection, the protection drops (if the conditions for reward have not been met or maintained), the generic or biosimilar would not be approved, and its launch would be delayed. This would nullify the incentive for the originator to comply with the criteria as there would be no threat of generic or biosimilar competition.

Finally, the modulation of market incentives—while ensuring rewards for research that addresses unmet patient needs—**will help boost investments in the EU especially considering the current geopolitical momentum**. It will stimulate clinical trials conducted within the EU, encourage the timely filing and granting of marketing authorisations compared to non-EU jurisdictions, and support the generation of studies relevant for HTA decisions.

## What should be improved in the trilogues?

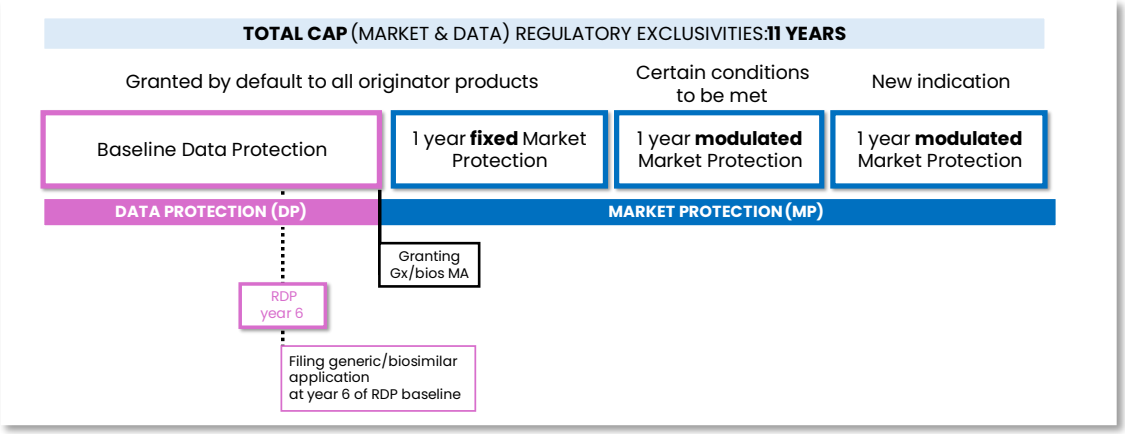
**In line with the principle of "early application"** established by the council in **Article 56.a, to deliver on the objectives of access and competitiveness**, generic and biosimilar medicine suppliers should be able to **file their dossier at year 6 of the data protection baseline under all scenarios** - both if the originator company will not supply a specific country or if they do not get their extra years of modulated market protection- to enable the off-patent medicines **to deliver access in time to meet the legally defined deadline (article 56a)**.

This is due to the time necessary for generic and biosimilar medicines to finalise their MA and PR procedures (around 2 years – see graph below and Annex).

**Without such a clarification, generic and biosimilar medicines will be delayed, leaving some markets unserved by originator medicines. This artificial delay** will **not** stimulate **originator companies in investing in EU R&D for the 1 year of modulated market protection** because they will benefit from such an extension in any case

**Article 56a** of the Directive (Council position) already allows generic and biosimilar medicines to file at year 6 of the RDP baseline in order to supply a Member State that does not receive an originator product. The mentioned article **requires** a further **clarification. In the case where the originator**

**company does not get the extra modulated year of market protection, it is important to allow the generic and biosimilar applicants to submit their authorisation dossier at year 6 of the baseline data protection period**. This would allow sufficient time (on average 2 years as indicated in the Annex below) to complete the regulatory and PR I processes. The marketing authorisation would only be granted once baseline data protection expires. Filing the MA application earlier would then allow the completion of the regulatory and administrative procedures (including pricing and reimbursement processes, etc.). According to an analysis conducted with our membership, around 24 months are necessary to complete the required regulatory procedures (see table and Annex below).

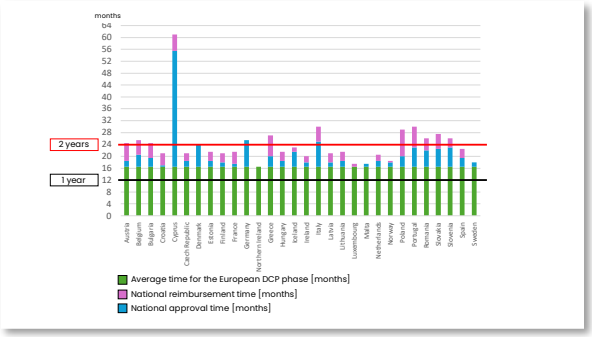



Therefore, we support the council regulatory incentives structure with this clarification of filing at year 6 before the baseline RDP expiry. **Without such a clarification (i.e. without allowing generics marketing authorisation applications earlier before DP expiry), the entry of generic and biosimilar medicines would be automatically delayed, with a consequent impact on unserved markets by an innovative medicine**. **This "artificial" delay will not stimulate originator companies to invest in EU R&D as they will benefit from the extension in any case,** and it will not reward those originator companies investing in UMN or in clinical trials in Europe, particularly in cases where the originator does not meet the modulation criteria to obtain an additional year of market protection or fails to supply smaller or CEE Member States.

## File at year 6 of DP baseline: generics and biosimilars require approximately two years to complete the marketing authorisation process and the pricing and reimbursement (P&R) procedure.

On average, **2 years are needed** (see Annex below) for filing MA applications, assessment by the competent authorities, granting MAs (incl. national MAs), applying for and granting Pricing and Reimbursement (P&R) (the list of necessary steps is not exhaustive).

The Council position allows filing of generic/ biosimilar applications only after expiry of Baseline Data protection. The 1 year of fixed market protection is **not** sufficient to finalise all regulatory and administrative processes for generic/ biosimilar medicines to be ready to launch if the originator has not fulfilled the conditions to be rewarded with a 1year modulated market protection. **Therefore, generic and biosimilars will always be delayed.** It is important to consider that the actual granting of MAs will be allowed after the DP baseline expiry.



**Annex:** Overview of time necessary to finalise Marketing Authorisation and Pricing and Reimbursement (P&R) for generic MA applicants (2024):

| Regulatory Region | Country Code | Country name | National approval time [months] | National reimbursement time* [months] *if in addition to national approval time | National approval time + national reimbursement time [months] | Average time for the European DCP phase [months] | Total time until approval [month] |
|---|---|---|---|---|---|---|---|
| Europe | AT | Austria | 2.0 | 6.0 | 8.0 | 16.5 | **24.5** |
| Europe | BE | Belgium | 4.0 | 5.0 | 9.0 | 16.5 | **25.5** |
| Europe | BG | Bulgaria | 3.0 | 5.0 | 8.0 | 16.5 | **24.5** |
| Europe | HR | Croatia | 0.5 | 4.0 | 4.5 | 16.5 | **21.0** |
| Europe | CY | Cyprus | 39.0 | 5.5 | 44.5 | 16.5 | **61.0** |
| Europe | CZ | Czech Republic | 2.0 | 2.5 | 4.5 | 16.5 | **21.0** |
| Europe | DK | Denmark | 7.5 | 0.0 | 7.5 | 16.5 | **24.0** |
| Europe | EE | Estonia | 2.0 | 3.0 | 5.0 | 16.5 | **21.5** |
| Europe | FI | Finland | 1.5 | 3.0 | 4.5 | 16.5 | **21.0** |
| Europe | FR | France | 1.0 | 4.0 | 5.0 | 16.5 | **21.5** |
| Europe | DE | Germany | 9.0 | 0.0 | 9.0 | 16.5 | **25.5** |
| Europe | XI | Northern Ireland | 0.0 | 0.0 | 0.0 | 16.5 | **16.5** |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Europe | GR | Greece | 3.5 | 7.0 | 10.5 | 16.5 | **27.0** |
| Europe | HU | Hungary | 2.0 | 3.0 | 5.0 | 16.5 | **21.5** |
| Europe | IS | Iceland | 5.0 | 1.5 | 6.5 | 16.5 | **23.0** |
| Europe | IE | Ireland | 1.5 | 2.0 | 3.5 | 16.5 | **20.0** |
| Europe | IT | Italy | 8.5 | 5.0 | 13.5 | 16.5 | **30.0** |
| Europe | LV | Latvia | 1.5 | 3.0 | 4.5 | 16.5 | **21.0** |
| Europe | LT | Lithuania | 2.0 | 3.0 | 5.0 | 16.5 | **21.5** |
| Europe | LU | Luxembourg | 0.0 | 1.0 | 1.0 | 16.5 | **17.5** |
| Europe | MT | Malta | 1.0 | 0.0 | 1.0 | 16.5 | **17.5** |
| Europe | NL | Netherlands | 2.0 | 2.0 | 4.0 | 16.5 | **20.5** |
| Europe | NO | Norway | 1.5 | 0.5 | 2.0 | 16.5 | **18.5** |
| Europe | PL | Poland | 3.5 | 9.0 | 12.5 | 16.5 | **29.0** |
| Europe | PT | Portugal | 6.5 | 7.0 | 13.5 | 16.5 | **30.0** |
| Europe | RO | Romania | 5.5 | 4.0 | 9.5 | 16.5 | **26.0** |
| Europe | SK | Slovakia | 6.0 | 5.0 | 11.0 | 16.5 | **27.5** |
| Europe | SI | Slovenia | 6.5 | 3.0 | 9.5 | 16.5 | **26.0** |
| Europe | ES | Spain | 3.0 | 3.0 | 6.0 | 16.5 | **22.5** |
| Europe | SE | Sweden | 1.5 | 0.0 | 1.5 | 16.5 | **18.0** |