Medicines for Europe Factsheets on
Removing barriers to equitable access for timely competition

Medicines for Europe is committed to improving access to medicines for all Europeans. Yet, many patients across Europe face restricted access to medicines which undermines public health. The 2019-2024 EU legislature should reshape pharmaceutical policy by prioritising **equitable access to essential medicines** for all Europeans. Equitable access is an achievable goal as the majority of essential medicines are already generic or biosimilar medicines.

Generic, biosimilar and value added medicines are key drivers for access to medicines. Generic medicines provide for almost 70% of dispensed medicines in Europe and have doubled access to medicines for patients with diabetes or cardiac conditions. Biosimilar medicines are drastically increasing access to biological therapies for cancer and auto-immune conditions such as rheumatoid arthritis or psoriasis. Value added medicines are increasing patient quality of life for chronic diseases and offer significant benefits to the healthcare community.

This document develops Medicines for Europe key priorities that should be reflected in the Pharmaceutical Strategy for Europe.

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1. Generic medicines uptake

Problem Statement

The sustainability of healthcare systems is a challenge for many European governments. Multiple factors, such as a growing and ageing population, increased chronic disease burden, the introduction and increased cost of new innovative medicines, have put **pressure on healthcare budgets** across Europe. Increased utilisation of generic medicines presents an opportunity to improve healthcare system value, either by providing access for substantially more patients at the same spending level (higher cost-effectiveness) or by decreasing expenditure at equal treatment rates. However, not all European countries have a high level of generic medicine penetration, so more can and should be done to increase the use of generic medicines and increase the efficiency of healthcare systems.

Policy recommendations

Ensure a cohesive generic policy to increase generic use and patient access

Medicines for Europe encourages governments to focus on **measures to support the use of generic medicines rather than short-term and drastic cost-containment measures**, which endanger medicines supply reliability and ultimately patients' health. Generic medicines are now 70% of prescribed medicines in Europe while only accounting for less than 30% of pharmaceutical expenditure. Governments need to focus their attention on optimising generic use ensuring long-term competition rather than further lowering their price.

Ensure long-term competition

- **Reform procurement processes**, moving away from price-only tendering to the inclusion of MEAT criteria – procurement specialists should take a holistic view when designing **procurement processes** to safeguard that competition is guaranteed in the long run. A well-functioning system would ultimately lead to a more competitive market environment that benefits patients, healthcare professionals and payers.
- **Rethink generic pricing mechanisms to ensure market sustainability** – External Reference Pricing (ERP) and Internal Reference Pricing tools that encourage permanent downward price spirals are not a suitable price control mechanism for ensuring an appropriate and competitive environment for generic medicines and are drivers of market unsustainability.
- **Prevent the application of short-term cost-containment measures** – policy measures such as clawback and payback mechanisms, mandatory discounts and rebates and recurrent or arbitrary price cuts are creating extremely difficult market conditions for generic medicines. These measures, often applied in conjunction, lead to unsustainable price levels and are drivers of market consolidation and consequently increase the risk of medicines shortages.

Ensure fast competition

- Guaranteeing that the **procurement processes reopen** after the entry of the first multisource medicine to ensure a competitive and predictable supply to patients.
- **Accelerating the timelines** for pricing and reimbursement of generic and biosimilar medicines
- National authorities should comply with EU law and immediately remove any form of **patent linkage**, as well as refrain from introducing it in the future.
    - Patent linkage significantly delays the market entry of generic and biosimilar competitors, has a negative impact on patient access, and results in additional costs to be sustained by national healthcare systems, by the generic industry and ultimately by citizens.

Covid-19 suspension of cost-containment measures

During the COVID-19 pandemic, generic medicine manufacturers have worked around the clock to ensure that the supply of medicines to patients continues without interruption. At the onset of the health crisis, many countries either suspended or halted cost containment measures scheduled, giving a clear indication that governments are perfectly aware of the influence these measures may have on the supply of generic medicines. Governments must therefore rethink their approaches to ensure that pharmaceutical policy helps drive generic penetration while ensuring long-term competition to guarantee the long-term sustainability of healthcare systems.

Relevant documents

Medicines for Europe position paper on best procurement practices

Medicines for Europe position paper on The Anti-Competitive Effects of Patent Linkage

2. Biosimilar medicines uptake

Problem Statement

The sustainability of healthcare systems is a challenge for many European governments. Multiple factors, such as a growing and ageing population, increased disease burden, the introduction and the high cost of new innovative medicines, have put **pressure on healthcare budgets** across Europe. Biologic medicines take an important part of the pharmaceutical budget and a growing number of new pharmaceutical therapies are biological molecules. Biosimilar medicines have offered patients increased access to these life-altering biologic therapies. 15 years after the first biosimilar approval in Europe, we have reached more than 2 billion patient treatment days of safe clinical experience, accompanied by a growing trust in these more affordable biologic medicines.

Over the next 10 years, many biological medicines are set to lose market exclusivity. This represents an opportunity for the market to harness more competition in the biologic medicines market and offer invaluable opportunities for healthcare systems to **improve patient access, improve healthcare budget sustainability and significantly reduce equity gaps** across Europe. The reduction of treatment costs with biosimilar medicines frees up resources which can then be **reinvested** into better care for patients and sometimes make previously unaffordable innovative therapies, more affordable.

Policy recommendations

- Implement **thoughtful biosimilar medicine policies** that balance the benefits of competition, biosimilar use to increase patient access where necessary, and increase the affordability of treatments allowing reinvestments in health care.

POLICY AREA	SUSTAINABILITY MEASURE	SUSTAINABLE MARKET STATUS
Regulatory environment and clinical guidelines	Time from EMA approval to first biosimilars sales	Instant or very short market entry after approval
	Treatment guidelines for biosimilar use	Publication of multiple guidelines on usage and protocols prior to first biosimilar entry
	Physician switching policies	Authorisation and guidance of physician-led ability to switch to a biosimilar medicine at entry of first biosimilar on the market
	No biologic pharmacy substitution	No biologic pharmacy substitution allowed
Awareness and education	Comprehensive training / education for patient	Access to comprehensive and unbiased training or education prior to first biosimilar entry
	Comprehensive training / education for physician	
Incentives	Patient incentives to promote biosimilar use	Incentives in place to encourage use of most economically advantageous product upon introduction of competition
	Prescription quotas or financial incentives for providers that do not restrict physician choice	An incentive or quota that does not restrict physician choice
Pricing rules and dynamics	Originator price not subject to mandatory price cuts	No forced originator price cuts by central authorities required, market forces to determine price
	Molecule pricing not subject to reference price	No reference price determined by central authorities, market forces to determine price
Purchasing mechanisms	Length of contracts	12- to 24-month contracts ensure market competitiveness and avoid patients are switched often
	Tender timing relative to biosimilar availability	Tender opens upon introduction of competition
	Time from tender award to delivery	4-6 months lead time to allow necessary preparations and stock build-up
	Number of winners	Consistently award multi-winner tenders to allow of market sustainability
	Winner decision criteria beyond price	Decision based on the most economically advantageous tender offers (e.g. incorporating sustainability, price, product characteristics, continuity of supply)

- Design a **biosimilar policy framework** capable of delivering value for all stakeholders, building on the vast European experience. The **core components** of such framework are outlined here:
    - Political vision, will, action and targets towards healthier communities.
    - Involvement of all relevant stakeholders to build trust.
    - Implementation roadmaps allowing time for tangible results.
    - A coordinated and holistic design with multiple comprehensive policies.
    - A biologic market driven by level-playing field competition.
    - Resilience and continuous improvement reflecting contextual changes.
- Strengthen **shared decision making** and the **physician-patient relationship** has a central role throughout the course of biologic treatment (therapy selection, patient information/education and clinical oversight over time).

Sustainability examples

- In **Denmark**, Amgros (secures the supply of drugs to public hospitals) divided the country into two different regions when procuring Adalimumab after biosimilar market entry. This allowed two competitors to supply the market, reducing market reliance on a single manufacturer while maintaining fast biosimilar medicines uptake, helping to ensure long-term competition and supply reliability for patients.
- In **France**, authorities set a national target for biosimilar use and created opportunities to implement policies to increase biosimilar prescription. France's objective is to achieve 80% biosimilar market penetration by 2022. In addition, France started piloting policy measures to increase biosimilar penetration in October 2018. While the project is scheduled to run for 3 years, policymakers are already looking to preliminary results based on defined KPIs and assessing and implementing alternative measures (e.g. incentives targeting hospital purchasing and for outpatient prescribers) to reach the target biosimilar penetration.

Relevant documentation

- IQVIA BIOSIMILAR SCORECARD 2020
- Positioning Statements on Physician-led Switching for Biosimilar Medicine
- Medicines for Europe Position on biologic pharmacy substitution

3. Barriers to generics and biosimilar competition

The importance of timely competition

The three main EU institutions have taken a very clear position in support of EU-wide policies to encourage generic and biosimilar competition and use in a future EU pharmaceutical policy.

- In the Health Council Conclusions of 2016, Member States stressed "*the importance of timely availability of generics and biosimilars*".
- In 2017, the European Parliament Resolution on Access to Medicines also urged to ensure timely and effective generic & biosimilar competition.
- In the Pharmaceutical Strategy for Europe, the European Commission highlights the importance of "*greater generic and biosimilar competition, based on the sound functioning of the single market*" and is ready to work for "*the removal of barriers that delay their timely entry to market and increased uptake by health systems*". It also stresses how *"originator companies sometimes implement strategies to hinder the entry or expansion of the more affordable medicines of their generic and biosimilar competitors"* and that *"this lack of competition thus inhibits price savings once innovative products lose their market exclusivities"*.

The barriers to timely competition of generic & biosimilar medicines

Quality of patents – Divisionals – Patent related issue

For healthcare systems to function, it is fundamental that the patent system guarantees the **highest quality of patents** and **of patent granting procedures**. The risk, otherwise, is the creation of a multitude of secondary - often 'weak' - patents (**'patent thickets'**) covering one product, with the effect of keeping competitors off the market. The EC Pharma Sector Inquiry of 2009 shows that individual medicines are covered by around 100 patent families, with up to 1300 patents and/or pending applications across EU countries.

Currently, the **patent granting process at the European Patent Office (EPO)** allows **misuse of divisional patent applications**…

> *i.e.*, whereby the patent holder, after filing a "parent" patent application, files a multitude of divisional patents, with new divisionals popping up right before the previous patent is invalidated. In this way, 'weak' patents are kept alive in order to enforce them in Court and unduly delay generic/biosimilar market entry.

…and this is considered an anti-competitive practice by the Commission in its EC Pharma Sector Inquiry.

Patent linkage – Regulatory related issue

Competition is further delayed by the practice of **patent linkage**…

> *i.e.*, whereby regulatory/market access decisions (marketing authorisations/P&R decisions/tender bids, etc.) for a generic/biosimilar product are linked to the status of patents of the reference product.

…that, despite being considered "*unlawful*" by the Commission in its Sector Inquiry Report of 2009, exists in the several Member States where the entry of generic/biosimilar medicines is systematically delayed. The European Parliament Resolution on Access to Medicines in 2017 urged the Commission to end patent linkage to ensure immediate market entry for generic/biosimilar competitors. This would be in line with the **objective of the EU Bolar to *"ensure that a generic could enter the market as soon as possible after the expiry of patent/SPC protection […] based on the basic rationale that free competition should be allowed as soon as protection expires"*** (European Commission Impact Assessment on the SPC manufacturing waiver).

Market or pricing or procurement-related issues

Competition may also be delayed via **market strategies**…

> *e.g.*, cases in which originators, by using their position of power on the market, change formulation or presentation (*e.g.* intramuscular, cutaneous/transdermal, subcutaneous, *etc.*) of a product to shift patients to the new version and reduce the accessible market for competitors, preventing head-to-head competition of similar products.

…or **pricing strategies**…

> *e.g.*, aggressive price cuts to make the market unattractive or unprofitable for upcoming competitors, with a reduction of competition, as new entrants will struggle to penetrate the market. Reduced or absent competition result in price increases in the medium-long term.

…or **procurement policies**…

> *i.e.*, any form of discrimination of biosimilars vs the originator, which may take the form of slots reserved for originators, with long litigation and subsequent loss of the market for the biosimilar.

Policy recommendations

Medicines for Europe urges the Commission to ensure effective competition in the pharmaceutical sector and immediate (*i.e.* Day-1) generic and biosimilar market entry as soon as IP protections expire. This is the only way to guarantee sustainable healthcare systems.

The European Union is encouraged to:

- Ensure **accountability of the EPO** and the **highest quality of patents.**
- Immediately urge the EPO to change its internal rules to **stop the abuses of divisional patents.**
- **Ban patent linkage in EU legislation** as it systematically delays timely (*i.e*. Day-1) competition.
- Constantly **monitor the market to tackle marketing or pricing strategies or procurement policies** aimed at or with the effect of delaying generic/biosimilar entry.
- Introduce a **mechanism for national authorities to systematically claim damages caused to national healthcare systems**, in compensation for overpaying due to the lack of competition caused by the conduct of dominant companies delaying off-patent entry.
- Ensure **EU harmonization of the Intellectual Property Enforcement Directive on damages** to be paid to companies suffering from practices delaying competition.

Relevant documents

Medicines for Europe **Whitepaper**: *Anatomy of a failure to launch: a review of barriers to generic and biosimilar market entry and the use of competition law as a remedy*

Medicines for Europe **position papers**

4. Bolar exemption

The 'Bolar' Directive

The Bolar exemption was introduced in Europe in Art. 10(6) of the Directive 2001/83/EC.
It allows companies, during the patent/Supplementary Protection Certificate (SPC) protection of the reference product, to conduct studies, trials and the subsequent practical requirements necessary to obtain regulatory approvals for generic and biosimilar medicines, without this being considered patent/SPC infringement. The Bolar also exempts from infringement certain experimental research activities to develop new medicines.

The objective

The primary objective of the Bolar is to "ensure that a generic could enter the market as soon as possible after the expiry of patent/SPC protection […] based on the basic rationale that free competition should be allowed as soon as protection expires". (European Commission Impact Assessment on the SPC manufacturing waiver, p. 15)

The issue

The Directive has been implemented in different ways across the Member States, with some more restrictive and some more open national transpositions of the exemption. This fragmentation across the EU has led to legal uncertainty and confusion for generic, biosimilar, originator and Active Pharmaceutical Ingredients (APIs) developers around what is and what is not allowed by the Bolar. As a result, this has been a factor driving investment in API development and production outside of Europe over the last 15 years.

What has already been done

The European Commission and the Member States have expressed multiple times the intention to tackle the fragmentation in the implementation of an open Bolar exemption that delivers on competition as soon as protection expires:

- The 2015 Single Market Strategy for Europe identified enlargement & harmonisation of Bolar as a priority.
- In 2016, the EC published a Charles River Associate study that highlighted the huge benefits for the entire pharmaceutical sector of an extension of the scope of Bolar.
- In 2017, the EC Roadmap to optimise the IP legal framework explored the Bolar reform and its benefits.
- In 2018 the Commission issued a Max Planck Institute study describing the willingness of EU Member States to harmonise the Bolar interpretation.
- The 2020 pharmaceutical strategy includes Bolar as a priority issue for reform.

Policy recommendations

The Commission, in pursuit of the primary purpose of the Bolar to ensure that generic & biosimilar medicines can enter the market on day-1 after IP expiries, should build on all studies and assessments already conducted and propose a revised & harmonised Bolar covering the following actions:

- the conduct of necessary studies and trials by all partners for the purpose of seeking EU marketing authorisation, independently from who the final applicant/Marketing Authorisation holder is and where the medicine will be authorized (EU/ non-EU).
- the offer, manufacture, sale (incl. by third party API suppliers) and purchase of patented APIs for the purpose of seeking marketing authorisation and for R&D purposes.

- the subsequent administrative actions needed to effectively enter the market on day-1 after IP expiry, i.e., Marketing Authorisations, pricing & reimbursement listing, tender bids, upload of serialised packs for compliance with pharmaceutical regulation against falsified medicines, etc.

The Benefits

Harmonsation

- More equitable distribution of API investments among MS
- Stability & predictability for the whole pharma sector
- More rational strategic business planning for European companies
- Reduced legal uncertainty

Extended scope

- More supply from European APIs suppliers
- Ready to access the market on day-1
- More investments in R&D & manufacturing of API in EU
- Wider choice of API suppliers for European companies

What it means in practice

Bolar exemption: *"...based on the basic rationale that free competition should be allowed as soon as protection expires"*
European Commission Impact Assessment on SPC manufacturing waiver