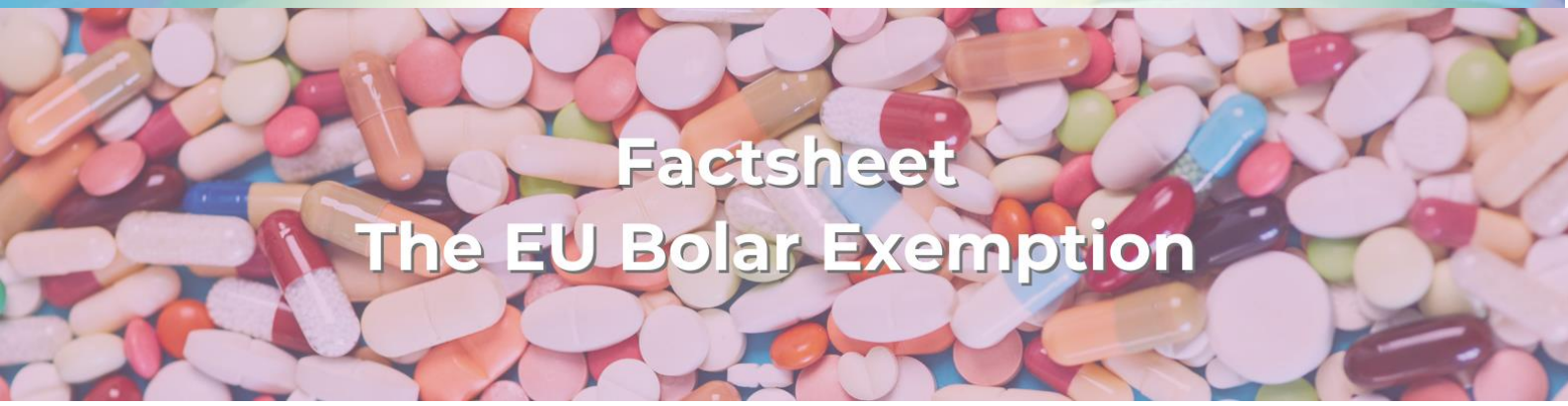


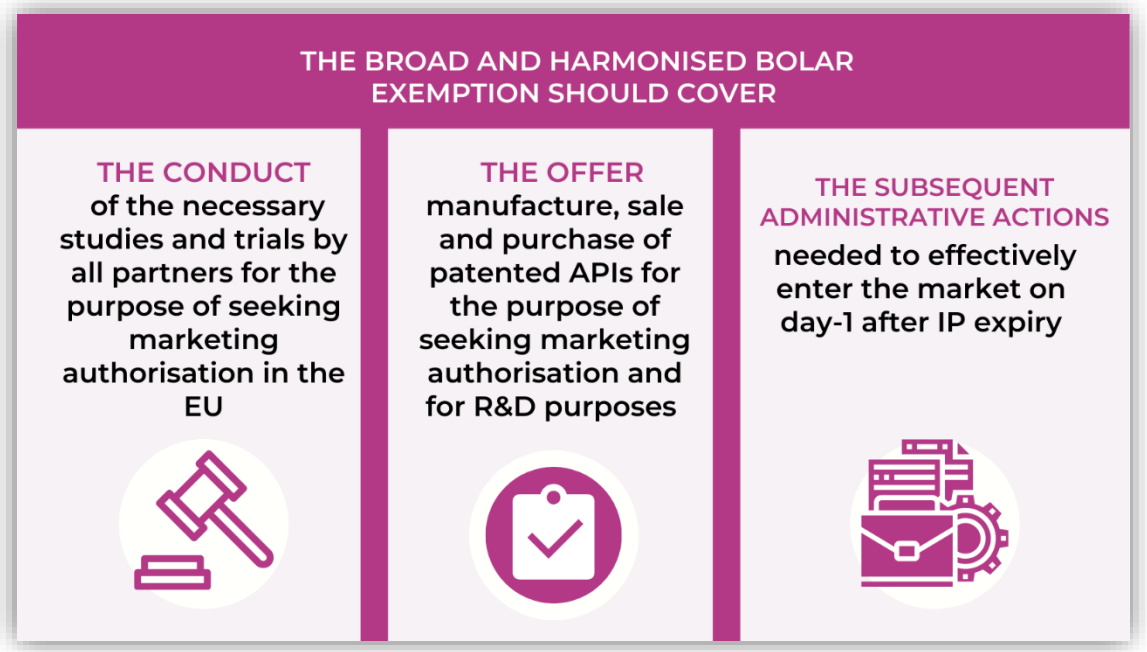
Factsheet
The EU Bolar Exemption

March 2022

The 'Bolar'

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 Member States, with some more restrictive and some more open national transpositions of the exemption. This fragmentation throughout the EU has led to legal uncertainty and confusion for generic, biosimilar, originator and Active Pharmaceutical Ingredients (APIs) developers around what is and what it not allowed by the Bolar. As a result, this has been a factor for driving

investments on API development and production outside of Europe over the last 15 years. In addition, its restrictive interpretation blocks certain administrative procedures that therefore favour patent linkage (defined "unlawful" by the European Commission, p. 315) and delay generic and biosimilar market entry with huge economic consequences for healthcare budgets and patient access to medicines.

What's already been done

The European Commission and 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.
- ✓ The European Parliament Report on the IP Action Plan urges to address Bolar.

The 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, supply, storage, import, export, use, sale (incl. by third party API suppliers) and purchase of patented APIs for the purpose of seeking marketing authorisation and for R&D**.
- ➢ 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