FONDAZIONE PER LA RICERCA FARMACOLOGICA GIANNI BENZI ONLUS

UNIVERSITÀ DEGLI STUDI DI BARI ALDO MORO

XVI FORESIGHT TRAINING COURSE
Repurposing to cover unmet needs: the current scenario in Europe and the proposed changes to the Pharmaceutical Legislation

Drug repurposing and the revision of EU pharmaceutical legislation

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18 Dec 2023 - Bari, Italy

Starting from the revision of EU pharmaceutical legislation

1. Commission proposal for the Pharmaceutical Regulation
2. Commission proposal for the Pharmaceutical Directive
3. Communication on Pharmaceutical Reform and Antimicrobial Resistance (AMR)
4. Commission proposal for a Council Recommendation on stepping up EU actions to combat antimicrobial resistance in a One Health approach (AMR)
5. Press Release
6. Q&As
7. Factsheets

Why is the EU reforming its legislation?

1. The 3A target: availability, accessibility, affordability
2. Promote better access to effective and affordable medicines
3. Reducing shortages
4. More medicines for children
5. A stronger voice for patients
6. Easier access to information
7. More environmentally sustainable medicines

What is new in the reform?

1. Move away from “one-size-fits-alls” to a flexible systems of incentives that rewards companies that fulfil important public health objectives
2. Faster availability of generics and biosimilars
3. Addressing shortages of medicines and ensuring security of supply
4. Faster authorisations of new medicines:
    - EMA will have 180 instead of 210 days
    - The Commission will have 46 instead of 67 days Commission proposal for the Pharmaceutical Regulation
5. Transferable data exclusivity voucher for priority antimicrobial
6. Temporary emergency market authorisation

The regulatory incentives

Article 81 of the proposed Directive:

«*The regulatory data protection period shall be* ***six years from the date when the marketing authorisation for that medicinal product was granted*** *[...].*

Subject to a scientific evaluation by the relevant competent authority, the data protection period referred to in paragraph 1 shall be prolonged by:

(a) ***24 months****, where the marketing authorisation holder demonstrates that the conditions referred to in Article 82(1) are fulfilled [...] [i.e. supply in all 27 EU member States].*

(b) ***six months****, where the marketing authorisation applicant demonstrates at the time of the initial marketing authorisation application that the medicinal product addresses an unmet medical need as referred to in Article 83;*

(c) ***six months****, for medicinal products containing a new active substance, [...];*

(d) ***12 months****, where the marketing authorisation holder obtains, during the data protection period, an authorisation for an additional therapeutic indication [...]*».

What is not addressed by the reform?

1. Patent protection
2. Digital therapies
3. Rolling review
4. Emergency preparedness

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Article 48 [of the proposed Regulation]

Scientific opinion on data submitted from not-for-profit entities for repurposing of authorised medicinal products

1. An entity not engaged in an economic activity ('not-for-profit entity') may submit to the Agency or to a competent authority of the Member State substantive non-clinical or clinical evidence for a new therapeutic indication that is expected to fulfil an unmet medical need. The Agency may, at the request of a Member State, the Commission, or on its own initiative and on the basis of all available evidence make a scientific evaluation of the benefit-risk of the use of a medicinal product with a new therapeutic indication *that concerns an unmet medical need.*

   The opinion of the Agency shall be made publicly available and the competent authorities of the Member States shall be informed.
2. In cases where the opinion is favourable, marketing authorisation holders of the medicinal products concerned shall submit a variation to update the product information with the new therapeutic indication.
3. Article 81(2), point (c) of [revised Directive 2001/83/EC] *shall not* apply for variations under this Article.

Explanatory memorandum of the proposed reform

- The elements on the environment, regulatory support for non-commercial entities and repurposing of medicinal products included in the preferred option were supported by key stakeholders such as healthcare providers, academia and environmental organisations.
- In addition, the act provides an incentive for repurposing off-patent, added value medicinal products. This supports innovation, resulting in a new therapeutic indication that offers significant clinical benefit in comparison with existing therapies

ENVI amendments

EN - English News MEPs About Parliament Plenary Committees Delegations Other websites

Draft report - ENVI_PR(2023)753550
European Parliament

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DRAFT REPORT
on the proposal for a regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006
(COM(2023)0193 - C9-0144/2023 - 2023/0131(COD))
Committee on the Environment, Public Health and Food Safety
Rapporteur: Tiemo Wölken

3.10.2023

Justification:
Repurposing medicines reduces development costs and can make life-changing treatments available to patients in a shorter time frame. Repurposed medicines' safety profile is often better understood as molecules have already been tested and their use is well-documented. Submission of data for a new therapeutic indication of an off-patent medicine should not be limited to areas of unmet medical need, but it should be possible for all indications and the definition of UMN should be kept rather strict as it is linked to further incentives

European Parliament
2019-2024

Committee on the Environment, Public Health and Food Safety

2023/0131(COD)

21.11.2023

AMENDMENTS
847 - 1061

Draft report
Tiemo Wölken
(PE753.550v02-00)

Laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006

Proposal for a regulation
(COM(2023)0193 – C9-0144/2023 – 2023/0131(COD))

ITRE amendments

Amendment 280
Susana Solís Pérez, Klemen Grošelj

Proposal for a regulation
Article 48 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Article 81(2), point (c) of [revised Directive 2001/83/EC] ***shall not*** apply for variations under this Article.	3. Article 81(2), point (c) of [revised Directive 2001/83/EC] ***may*** apply for variations under this Article.

Or. en

European Parliament
2019-2024

Committee on Industry, Research and Energy

2023/0131(COD)

30.11.2023

AMENDMENTS
350 - 535

Draft opinion
Henna Virkkunen
(PE754.772v01-00)

Laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006

Proposal for a regulation
(COM(2023)0193 – C9-0144/2023 – 2023/0131(COD))

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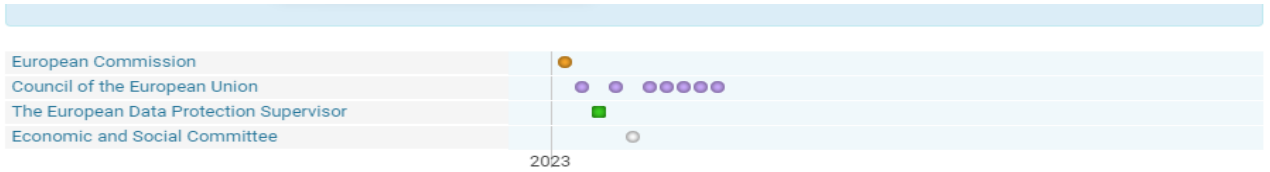

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FIRST READING

European Parliament

Council of the European Union

Discussions within the Council or its preparatory bodies	08/12/2023
Discussions within the Council or its preparatory bodies	29/11/2023
Discussions within the Council or its preparatory bodies	23/11/2023
Discussions within the Council or its preparatory bodies	10/11/2023
Discussions within the Council or its preparatory bodies	27/10/2023
Discussions within the Council or its preparatory bodies	22/06/2023
Discussions within the Council or its preparatory bodies	28/04/2023

OPINIONS

The European Data Protection Supervisor

Economic and Social Committee

HMA/EMA strategy to 2025

- Medical research is increasingly focusing on how existing medicines licensed for use in treating particular conditions can also be investigated for use in treating other conditions.
- This has led to a series of discussions held at the European level via the STAMP Commission Expert Group, of which EMA is a member.
- These discussions focus particularly on seeking new indications for well established, or off patent medicines in areas of unmet medical need, so as to offer additional therapeutic options to patients, to reduce the time and costs of development by building on evidence already generated and to contribute a more sustainable health system.
- Supporting repurposing requires consideration of several areas: the potential incentives and disincentives; the sources of evidence supporting re-purposing; the involvement of academia and not-for profit organisations (including patients organisations); introducing related changes to marketing authorisations as well as off-label use.
- Such consideration can only be achieved through developing ongoing multi-stakeholder discussions in a more formal framework.

The repurposing pilot project

EMA and the Heads of Medicines Agencies (HMA) are launching a pilot project to support the repurposing of medicines as a follow-up to the European Commission's Expert Group on Safe and Timely Access to Medicines for Patients (STAMP) discussions on a proposal for a medicines repurposing framework.

The aim of this initiative is to support not-for-profit organisations and academia to gather or generate sufficient evidence on the use of an established medicine in a new indication with the view to have this new use formally authorised by a regulatory authority. This is a way of making new treatment options available to patients.

As part of the pilot, EMA and the national medicines agencies will provide regulatory support, primarily scientific advice, to help these stakeholders generate a data package robust enough to support a future application by a pharmaceutical company.

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