# Procedure file

## Basic information

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| COD - Ordinary legislative procedure (ex-codecision procedure)<br>Directive | 2023/0132(COD) | Awaiting Council's 1st reading position |
| Medicinal products for human use<br><br>Repealing Directive 2001/83 1999/0134(COD)<br>Repealing Directive 2009/35 2008/0001(COD)<br><br>Subject<br>4.20.01 Medicine, diseases<br>4.20.04 Pharmaceutical products and industry<br><br>Legislative priorities<br>Joint Declaration 2023-24 | | |

## Key players

### European Parliament

| Committee responsible | Rapporteur | Appointed |
|---|---|---|
| ENVI Environment, Public Health and Food Safety | | 15/05/2023 |
| | WEISS Pernille | |
| | Shadow rapporteur | |
| | BEŇOVÁ Monika | |
| | AMALRIC Catherine | |
| | AUKEN Margrete | |
| | TARDINO Annalisa | |
| | KOPCIŃSKA Joanna | |
| | KONEČNÁ Kateřina | |

| Committee for opinion | Rapporteur for opinion | Appointed |
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| BUDG Budgets | The committee decided not to give an opinion. | |
| ITRE Industry, Research and Energy | | 05/10/2023 |
| | VIRKKUNEN Henna | |
| IMCO Internal Market and Consumer Protection | The committee decided not to give an opinion. | |
| JURI Legal Affairs<br>(Associated committee) | Chair on behalf of committee | 14/12/2023 |
| | VÁZQUEZ LÁZARA Adrián | |

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| Council of the European Union<br>European Commission | Commission DG | Commissioner |
| | Health and Food Safety | KYRIAKIDES Stella |
| European Economic and Social Committee<br>European Committee of the Regions | | |

## Key events

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| 26/04/2023 | Legislative proposal published | COM(2023)0192 | Summary |
| 14/09/2023 | Committee referral announced in Parliament, 1st reading | | |
| 14/09/2023 | Referral to associated committees announced in Parliament | | |
| 19/03/2024 | Vote in committee, 1st reading | | |
| 21/03/2024 | Committee report tabled for plenary, 1st reading | A9-0140/2024 | |
| 10/04/2024 | Debate in Parliament | | |
| 10/04/2024 | Decision by Parliament, 1st reading | T9-0220/2024 | Summary |

## Technical information

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| Procedure reference | 2023/0132(COD) |
| Procedure type | COD - Ordinary legislative procedure (ex-codecision procedure) |
| Procedure subtype | Legislation |
| Legislative instrument | Directive |
| | Repealing Directive 2001/83 1999/0134(COD)<br>Repealing Directive 2009/35 2008/0001(COD) |
| Legal basis | Treaty on the Functioning of the EU TFEU 114; Rules of Procedure EP 57; Treaty on the Functioning of the EU TFEU 168-p4 |
| Other legal basis | Rules of Procedure EP 159 |
| Mandatory consultation of other institutions | European Economic and Social Committee<br>European Committee of the Regions |
| Stage reached in procedure | Awaiting Council's 1st reading position |
| Committee dossier | ENVI/9/11861 |

## Documentation gateway

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|---|---|---|---|---|---|
| Legislative proposal | | COM(2023)0192 | 26/04/2023 | EC | Summary |
| Document attached to the procedure | | SEC(2023)0390 | 26/04/2023 | EC | |
| Document attached to the procedure | | SWD(2023)0191 | 26/04/2023 | EC | |
| Document attached to the procedure | | SWD(2023)0192 | 26/04/2023 | EC | |

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| Document attached to the procedure | | SWD(2023)0193 | 26/04/2023 | EC | |
| Committee draft report | | PE753.470 | 03/10/2023 | EP | |
| Amendments tabled in committee | | PE754.916 | 21/11/2023 | EP | |
| Amendments tabled in committee | | PE754.917 | 21/11/2023 | EP | |
| Amendments tabled in committee | | PE756.260 | 21/11/2023 | EP | |
| Amendments tabled in committee | | PE756.261 | 21/11/2023 | EP | |
| Specific opinion | JURI | PE758.884 | 13/02/2024 | EP | |
| Committee opinion | ITRE | PE754.773 | 22/02/2024 | EP | |
| Committee report tabled for plenary, 1st reading/single reading | | A9-0140/2024 | 21/03/2024 | EP | |
| Text adopted by Parliament, 1st reading/single reading | | T9-0220/2024 | 10/04/2024 | EP | Summary |

## Additional information

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| Research document | Briefing | 03/04/2024 |

# Medicinal products for human use

PURPOSE: to review pharmaceutical legislation with a view to establishing rules on medicinal products ensuring the protection of public health and the environment as well as the functioning of the internal market.

PROPOSED ACT: Directive of the European Parliament and of the Council.

ROLE OF THE EUROPEAN PARLIAMENT: the European Parliament decides in accordance with the ordinary legislative procedure and on an equal footing with the Council.

BACKGROUND: EU pharmaceutical legislation has enabled the authorisation of safe, efficacious and high-quality medicinal products. However, patient access to medicinal products across the EU and security of supply are growing concerns. There is also a growing problem of shortages of medicinal products for many EU/EEA countries. Consequences of such shortages include decreased quality of treatment received by patients and increased burden on health systems and on healthcare professionals, who need to identify and provide alternative treatments. While the pharmaceutical legislation creates regulatory incentives for innovation and regulatory tools to support timely authorisation of innovative and promising therapies, these medicinal products do not always reach the patient, and patients in the EU have differing levels of access.

Moreover, innovation is not always focused on unmet medical needs, and there are market failures, especially in the development of priority antimicrobials that can help address antimicrobial resistance. Scientific and technological developments and digitalisation are not fully exploited, while the environmental impact of medicinal products needs attention.

The Pharmaceutical Strategy for Europe marks a turning point with the addition of further key objectives and by creating a modern framework that makes innovative and established medicinal products available to patients and healthcare systems at affordable prices, while ensuring security of supply and addressing environmental concerns.

The proposed revision of the pharmaceuticals legislation consists of this proposal for a new directive and a proposal for a new regulation, which will also cover orphan and paediatric medicinal products.

CONTENT: the overall pharmaceutical framework needs to be simplified, adapted to scientific and technological changes, and contribute to reducing the environmental impact of medicinal products. This proposed reform is comprehensive but targeted and focuses on provisions relevant to achieving its specific objectives; therefore it covers all provisions apart from those concerning advertising, falsified medicinal products, and homeopathic and traditional herbal medicinal products.

The proposed Directive lays down rules for the placing on the market, manufacturing, import, export, supply, distribution, pharmacovigilance, control and use of medicinal products for human use. It will apply to medicinal products for human use intended to be placed on the market. It will also apply to starting materials, active substances, excipients and intermediate products.

Objectives

The objectives of the proposal are the following:

- guarantee a high level of public health by ensuring the quality, safety and efficacy of medicinal products for EU patients;

- harmonise the internal market for the supervision and control of medicinal products and the rights and duties incumbent upon the competent authorities of the Member States;

- make sure all patients across the EU have timely and equitable access to safe, effective, and affordable medicines;

- enhance security of supply and ensure medicines are always available to patients, regardless of where they live in the EU;

- offer an attractive innovation-and competitiveness friendly environment for research, development, and production of medicines in Europe;

- make medicines more environmentally sustainable.

The proposed Directive includes the following main areas of revision:

- promoting innovation and access to affordable medicinal products - creating a balanced pharmaceutical ecosystem;

- introduction of variable incentives related to regulatory data protection and rewarding of innovation in areas of unmet medical needs: companies marketing innovative medicines will benefit from a minimum regulatory protection period of 8 years, including 6 years of data protection and 2 years of market protection. They will be eligible for additional periods of data protection if they launch the medicinal products in all Member States covered by the marketing authorisation (+2 years), if the medicinal product meets an unmet medical need (+6 months) or if comparative clinical trials are conducted (+6 months);

- measures that will facilitate faster market entry of generics and biosimilars, thereby increasing competition;

- increased transparency on the contribution of public funding to research & development costs;

- strengthening the requirements for environmental risk assessment (ERA) in the marketing authorisation of medicines;

- reducing the regulatory burden and providing a flexible regulatory framework to support innovation and competitiveness;

- specific provisions for new platform technologies;

- specific measures related to quality and manufacturing: a flexible, risk-based approach will enable the manufacture or testing of a wide range of medicinal products in close proximity to the patient.

## Medicinal products for human use

The European Parliament adopted by 404 votes to 202, with 16 abstentions, a legislative resolution on the proposal for a regulation of the European Parliament and of the Council on the establishment of 'Eurodac' for the comparison of fingerprints for the effective application of Regulation (EU) No 604/2013 and for identifying an illegally staying third-country national or stateless person and on requests for the comparison with Eurodac data by Member States' law enforcement authorities and Europol for law enforcement purposes (recast).

The European Parliament's position adopted at first reading under the ordinary legislative procedure amends the Commission's proposal as follows:

Creation of Eurodac

The aim of the proposed Regulation is to create a system for comparing biometric data (Eurodac) to help implement the EU's asylum and migration policy. The system should support the asylum system, contribute to the control of illegal immigration into the EU, the detection of secondary movements within the EU and the identification of illegally staying third-country nationals and stateless persons, and contribute to the protection of children, including for law enforcement purposes.

This Regulation fully respects human dignity and fundamental rights and observes the principles recognised by the Charter of Fundamental Rights of the European Union, including the right to respect for private life, the right to the protection of personal data, the right to asylum and the prohibition of torture and inhuman or degrading treatment.

Collection of data

The revised Eurodac Regulation seeks to improve the collection of data on asylum applicants and irregular migrants apprehended in the EU member states territory through biometric data - by adding facial images to existing fingerprinting databases - and additional information, including name, surname, nationality and date and place of birth. Authorities will also include information on decisions to remove and return the person or relocate them.

The threshold for collecting data from a child should be lowered from 14 to 6 years of age, to be taken by trained staff in a child-friendly manner.

The best interests of the child should be a primary consideration in the application of this Regulation. In the event that there is uncertainty as to whether or not a child is under the age of six and there is no supporting proof of that childs age, the competent authorities of the Member States should consider that child to be under the age of six for the purposes of this Regulation.

Eurodac data that pertain to a child under the age of 14 should only be used for law enforcement purposes against such a child where there are grounds to consider that those data are necessary for the purpose of the prevention, detection or investigation of a terrorist offence or other serious criminal offence which that child is suspected of having committed.

Security flags

Authorities will be able to record in the system if a person presents a threat to internal security, only if the person is violent or unlawfully armed, or where they have links to terrorism or a terrorist group, or are involved in offences within the scope of the European arrest warrant.

The Member State of origin which has concluded that the threat to internal security identified following the screening no longer applies should delete the record of the security flag from the dataset, after having consulted any other Member States having registered a dataset of the same person.

New categories

Members supported including people taking part in national and EU resettlement schemes as well as for beneficiaries of temporary protection in the scope of the database.

Statistics

eu-LISA should draw up statistics on the work of Eurodac every month indicating, in particular the number of: (i) applicants and the number of first-time applicants; (ii) rejected applicants; (iii) persons who have been disembarked following search and rescue operations; (iv) persons who have been registered as beneficiaries of temporary protection; (v) applicants who have been granted international protection in a Member State; (vi) persons who have been registered as minors; (vii) persons who have been admitted under a national resettlement scheme.

Cross-referenced, anonymised statistics should be improved with interoperability between Eurodac and other justice and home affairs systems - such as Visa Information System, ETIAS and Entry/Exit System in order to provide useful information to policy makers.

The statistics should be made available to the Member States, to the European Parliament, to the Commission, to the European Union Agency for Asylum, to the European Border and Coast Guard Agency and to Europol. Cross-system statistics alone should not be used to deny access to the territory of the Union.

## Transparency

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| WEISS Pernille | Rapporteur | ENVI | 05/04/2024 | Novo Nordisk A/S |
| WEISS Pernille | Rapporteur | ENVI | 03/04/2024 | Alliance Promotion Microbiote |
| WEISS Pernille | Rapporteur | ENVI | 27/03/2024 | Confindustria |
| WEISS Pernille | Rapporteur | ENVI | 21/03/2024 | Novo Nordisk Foundation |
| WEISS Pernille | Rapporteur | ENVI | 21/03/2024 | Confederation of Danish Industry |
| WEISS Pernille | Rapporteur | ENVI | 11/03/2024 | European Federation of Pharmaceutical Industries and Associations |
| WEISS Pernille | Rapporteur | ENVI | 08/03/2024 | Novo Nordisk A/S |
| WEISS Pernille | Rapporteur | ENVI | 07/03/2024 | European Confederation of Pharmaceutical Entrepreneurs |
| WEISS Pernille | Rapporteur | ENVI | 07/03/2024 | Bayer AG |
| WEISS Pernille | Rapporteur | ENVI | 06/03/2024 | Lægemiddelindustriforeningen |
| ?TEFANEC Ivan | Member | 04/04/2024 | Národný in?titút pre hodnotu a technológie v zdravotníctve | |
| BERNHUBER Alexander | Member | 15/03/2024 | Wirtschaftskammer Österreich | |
| KNOTEK Ond?ej | Member | 08/03/2024 | GSK | |
| BERNHUBER Alexander | Member | 07/03/2024 | Takeda Pharmaceuticals International AG | |
| MONTSERRAT Dolors | Member | 06/03/2024 | Bayer AG | |
| RASMUSSEN Bergur Løkke | Member | 06/03/2024 | The Danish Association of the Pharmaceutical Industry | |
| JARUBAS Adam | Member | 05/03/2024 | The Employers' Union of Innovative Pharmaceutical Companies | |
| POULSEN Erik | Member | 05/03/2024 | The Danish Association of the Pharmaceutical Industry | |

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| MONTSERRAT Dolors | Member | 04/03/2024 | Teva Pharmaceuticals Europe BV | |
| WINZIG Angelika | Member | 04/03/2024 | SANOFI | |