

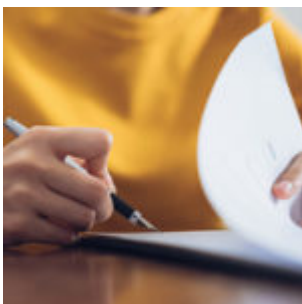
# [The European Parliament Adopts Position on the European Commission's Proposal for the First Major Overhaul of the EU Medicines Regulatory Framework in 20 Years](#)



In April 2023, we published an [alert](#) in relation to two European Commission legislative proposals: new [Regulation 2023/0131](#) and new [Directive 2023/0132](#), to replace the current EU regulatory framework for all medicines (including those for rare diseases and children). On April 10, 2024, the European Parliament adopted its position on the European Commission's legislative proposals with respect to (i) Regulation 2023/0131 that can be found [here](#) and (ii) Directive 2023/0132 that can be found [here](#). For certain key areas covered in the proposed EU legislation, we have set out a brief summary of (i) the European Commission's original proposals and (ii) the European Parliament's proposed amendments. You can read more [here](#).

---

## [Some Much-Needed \(Applicant-Friendly\) Clarification on Priority Claims at the European Patent Office](#)

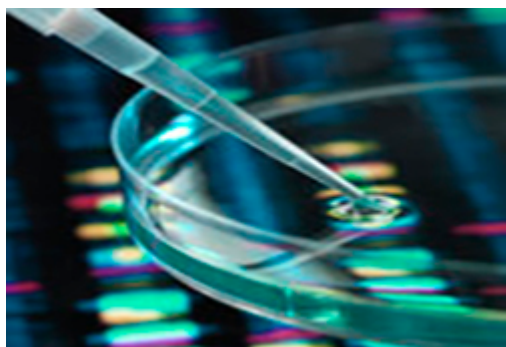


On October 10, 2023, the Enlarged Board of Appeal of the European Patent Office (EPO) issued a [consolidated decision in cases G1/22 and G2/22](#) clarifying a common issue regarding the validity of a priority claim made at the EPO. **Per the Board of Appeal, there is a rebuttable presumption that an Applicant claiming priority is entitled to claim that priority.**

Read the full client alert [here](#).

---

# [UK's Medicines Regulator Announces Guidance on the New International Recognition Procedure for the Approval of New Medicines from 1 January 2024](#)



## **Background**

Earlier this year, the UK's medicines regulator, the Medicines and Healthcare products Regulatory Agency (MHRA), announced that a new International Recognition Procedure (IRP) will be put in place for the approval of new medicines from 1 January 2024. On 4 September 2023, the MHRA announced the publication of detailed [guidance](#) on this new procedure, which will replace the [European Commission Decision Reliance Procedure](#) (ECDRP). The [Decentralised and Mutual Recognition Reliance Procedure](#) (MRDCRP), which allows the MHRA to have regard to approvals in the EU through the decentralised and mutual recognition procedures, will be incorporated under the umbrella of the IRP.

## **European Commission Decision Reliance Procedure**

The ECDRP was introduced post-Brexit as a temporary measure to try and ensure continued access to new medicines from the EU for patients in Great Britain until 31 December 2023.

Under the ECDRP, the MHRA may rely on a decision taken by the European Commission on the grant of a new marketing approval in the EU through the centralized procedure, in order to grant a new marketing approval in Great Britain more quickly.

## **International Recognition Procedure**

From 1 January 2024, the MHRA will have regard to decisions already made by medicines regulators in Australia, Canada, the European Union, Japan, Singapore, Switzerland and the United States (Reference Regulators).

The IRP will be open to applicants that have already received a marketing approval for the same product from one of the MHRA's specified Reference Regulators. The MHRA defines "same product" as *"as having the same qualitative and quantitative composition (active substance(s) and excipients), and the same pharmaceutical form, from applicants belonging to the same company or group of companies or which are licensees."*

There are two procedures that can be used for initial applications for a new marketing approval using the IRP:

- **Recognition A** - applications under this procedure will be approved within 60 days (excluding clock stops), unless there are any major objections which cannot be resolved within 60 days. If this occurs, the timetable may revert to Recognition B. To qualify for this procedure, the Reference Regulator must have given approval for the product within the last two years, the manufacturing process must be unchanged and the product must not meet any of the 24 listed conditions of Recognition B.
- **Recognition B** - applications under this procedure will be approved within 110 days (excluding clock stops), unless there are any major objections at day 110. If this occurs, the timetable will then revert to 210 days and formal advice from the Committee for Medicinal Products for Human Use will be sought on approvability. To qualify for this procedure, the Reference Regulator must have given approval for the product within the last ten years, and at least one of 24 listed conditions must apply. The conditions include if the product is: (i) designated as an orphan medicinal product in Great Britain, (ii) an advanced therapy medicinal product, (iii) a cutting-edge technology, or (iv) a first-in-class active substance.

### **Practical Implications**

The IRP will allow the MHRA to take into account the expertise and decision-making of trusted medicines regulators when approving a new medicine from 1 January 2024.

It is unclear if there are any specific requirements for choosing the Reference Regulator if the product is approved by more than one eligible medicines regulator.

As a final note, the IRP will sit alongside the MHRA's current national procedures. Any ECDRP and MRDCRP applications for marketing approval received by the MHRA *after* 1 January 2024 will be assessed under the new IRP. Any ECDRP and MRDCRP applications for marketing approval received by the MHRA *before* 31 December 2023 will be assessed under the current ECDRP and MRDCRP respectively.

---

## **[Spotlight on Life Sciences Collaboration and License Agreements](#)**



Goodwin's Intellectual Property team regularly works on the most important deals in the life sciences and biotech sector. Our close relationship with clients ensures that the best intellectual property strategies are in place to foster company and product growth and minimize risk. We take pride in structuring, negotiating, and executing complex license, collaboration and joint development agreements. Recently, our Cambridge team advised Renaissance Pharma Ltd., in its

launch and exclusive license agreement with St. Jude Children's Research Hospital for the treatment of newly diagnosed high-risk neuroblastoma patients globally - announced on August 01, 2023.

Manchester, UK-based [Renaissance](#), is a rapidly emerging company focused on the development of life changing therapies in paediatric rare disease.

[St. Jude Children's Research Hospital](#) is leading the way the world understands, treats and cures childhood cancer, sickle cell disease, and other life-threatening disorders.

Goodwin partner, [Malcolm Bates](#) said: "We wish Renaissance and St. Jude every success in this very important agreement."

Read the press release [here](#).

---

## [\*\*The European Commission Proposes First Major Overhaul of the EU Medicines Regulatory Framework in 20 Years: Orphan Medicines\*\*](#)



We recently published an [alert](#) in relation to the European Commission's legislative proposals to replace the current EU regulatory framework for all medicines (including those for rare diseases and for children). One of the major elements of the proposals is a change to the legislation governing orphan medicines for rare diseases, which we examine in more detail in the client alert [here](#).

---

## [\*\*The European Commission Proposes First Major Overhaul of the EU Medicines Regulatory Framework in 20 Years: Regulatory Data Protection\*\*](#)



We recently published an [alert](#) in relation to the European Commission's legislative proposals to replace the current EU regulatory framework for all medicines (including those for rare diseases and for children). One of the major elements of the proposals is a change to the period of regulatory data protection for medicines, which we examine in more detail in the client alert [here](#).

---

## [The MHRA Proposes to Extend the Period of Acceptance of CE Marked Medical Devices in Great Britain Beyond 30 June 2023](#)



### **BACKGROUND**

On 28 April 2023, the UK's medical devices regulator, the Medicines & Healthcare products Regulatory Agency (MHRA), announced its intention to extend the acceptance of CE marked medical devices in Great Britain (England, Scotland and Wales) beyond 30 June 2023.

Following the UK's departure from the EU, CE marked medical devices can currently be placed on the Great Britain market under the existing transitional arrangements until 30 June 2023. The proposed extension will support the ongoing safe supply of medical devices to Great Britain and ease the transition to the future regulatory framework for medical devices.

The government intends to introduce regulations in the future that will implement a substantial reform of the current regulatory framework for medical devices in the UK and is now aiming for core

aspects of the UK's future regime for medical devices to apply from 1 July 2025.

## **PROPOSED EXTENSION TO TRANSITIONAL ARRANGEMENTS**

The UK Medical Device Regulations 2002 (UK MDR) currently provide that the acceptance of CE marked medical devices on the Great Britain market will end on 30 June 2023. However, the MHRA intends to introduce legislation before 30 June 2023 which will provide that CE marked medical devices may be placed on the Great Britain market to the following timelines:

- General medical devices compliant with the EU medical devices directive (EU MDD) or EU active implantable medical devices directive (EU AIMDD) with a valid declaration and CE mark can be placed on the Great Britain market up until the sooner of (i) the expiry of the CE mark certificate or (ii) **30 June 2028**;
- In vitro diagnostic medical devices (IVDs) compliant with the EU in vitro diagnostic medical devices directive (EU IVDD) can be placed on the Great Britain market up until the sooner of (i) the expiry of the CE mark certificate or (ii) **30 June 2030**; and
- General medical devices, including custom-made devices, compliant with the EU medical devices regulation (EU MDR) and IVDs compliant with the EU in vitro diagnostic medical devices regulation (EU IVDR) can be placed on the Great Britain market up until **30 June 2030**.

The above extensions will not include class I medical devices and general IVDs (for which the conformity assessment under EU MDD or EU IVDD did not involve a notified body), which can only be placed on the Great Britain market if the involvement of a notified body would be required under the EU MDR or IVDR (i.e., if it is an up-classified device or a reusable surgical instrument Class I device). Similarly, the extensions will not include custom-made devices that are compliant with the EU MDD or EU AIMDD, which can no longer be placed on the Great Britain market.

## **WHAT HAPPENS NEXT?**

The legislation to implement the proposed extension will now be considered by the UK Parliament, and final approval is expected before 30 June 2023.

---

# **The European Commission Proposes First Major Overhaul of the EU Medicines Regulatory Framework in 20 Years**



On 26 April 2023, the European Commission published two legislative proposals - a new [Regulation 2023/0131](#) and a new [Directive 2023/0132](#) - to replace the current

EU regulatory framework for all medicines (including those for rare diseases and for children).

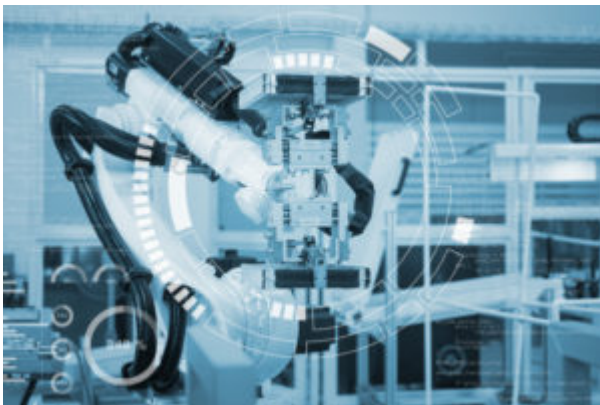
The Directive contains all the requirements for authorisation, monitoring, labelling and regulatory protection, placing on the market and other regulatory procedures for all medicines authorised at the EU and national level. The Regulation sets specific rules (on top of the ones in the Directive) for medicines authorised at the EU level, in particular the most innovative ones.

The proposals aim to reduce costs, expedite the introduction of new medicines and prevent medicine shortages.

Read the key points in the client alert [here](#).

---

## [The European Commission Proposes to Extend the Transition Deadline in the EU Medical Device Regulation](#)



... a major change to the Regulation is needed to prevent shortages of life-saving medical devices...

### **Background**

On Friday 9 December 2022, the European Commission proposed to extend the transition deadline in the [Medical Device Regulation \(EU\) 2017/745 \(MDR\)](#). According to the European Commissioner for Health and Food Safety, Stella Kyriakides, a major change to the Regulation is needed to prevent shortages of life-saving medical devices, from implants and prosthetics to ventilators and pacemakers.

Medical devices in the EU are regulated under the MDR, and the MDR replaced the previous Medical Devices Directive 93/42/EEC (**MDD**) and the Active Implantable Medical Devices Directive 90/385/EEC (**AIMDD**) on 26 May 2021. Currently, medical devices can be placed on the EU market under a CE mark certificate issued under the MDD or AIMDD until 26 May 2024 (**Transition Deadline**). After the Transition Deadline, these products will require a CE mark certificate issued under the MDR so that they remain available on the EU market - a potentially costly and time-consuming process.

A broad range of stakeholders in the medtech sector consider the Transition Deadline to be unattainable. The pandemic, shortages of raw materials caused by the conflict in Ukraine and low

Notified Body capacity have collectively put a strain on the ability for medical device manufacturers to meet the Transition Deadline. Without an extension to the Transition Deadline, it is anticipated that a significant number of medical device manufacturers would need to take their products off the EU market due to an inability to comply with the new requirements under the MDR within the required timeline.

## Key Proposals

The European Commission has proposed the following legislative amendments:

- Extension of the Transition Deadline in the MDR based on the risk class of each device:
  - 26 May 2027 for Class III and Class IIb medical devices; and
  - 26 May 2028 for Class IIa and Class I medical devices.
- Extension of the validity of CE mark certificates issued under the MDD and AIMDD if needed for legal and practical reasons (e.g. to access markets outside of the EU that accept products with a CE mark), provided that:
  - the device does not present an unacceptable risk to health and safety;
  - the device has not undergone significant changes in design or intended purpose; and
  - the manufacturer has already undertaken the necessary steps to launch the CE mark certification process under the MDR (e.g. lodged an MDR application with a Notified Body by 26 May 2024).
- Elimination of the “sell-off” date under the MDR and under the [In Vitro Diagnostic Medical Device Regulation \(EU\) 2017/746 \(IVDR\)](#) to avoid safe medical devices and in vitro diagnostics (e.g. blood glucose meters) that are already on the EU market from having to be discarded by 27 May 2025.

## Next Steps

The European Commission intends to provide these legislative amendments to the EU legislature for consideration at the beginning of 2023.

The European Commission also intends to undertake a comprehensive evaluation of the MDR by May 2027. The purpose of the evaluation is to identify structural problems with the MDR and potential medium and long-term solutions to these concerns.

As a final note, except for the elimination of the “sell-off” date, none of the proposed legislative amendments applies to in vitro diagnostics. Given that there are still few Notified Bodies under the IVDR, similar amendments might also be required for in vitro diagnostics in the near future.

---

## [Decision Time: The Unified Patent Court Begins in 2023](#)





The Unified Patent Court (“UPC”) is set to begin on June 1, 2023. Under the UPC framework, a single court proceeding could result in simultaneous revocation of European Patents across multiple European Union (“EU”) countries, including France and Germany.

A three-month “Sunrise Period” is set to begin March 1, 2023. If a request is filed during the Sunrise Period, patent owners can “opt-out” specific patents from the UPC, such that they never become subject to the UPC unless the patent owner decides to withdraw the opt-out. However, the opt-out procedure is not necessarily straightforward. Importantly, if not done correctly **and** completed within the Sunrise Period, any patent challenged by a third party within the UPC will irrevocably be confined to the UPC’s jurisdiction. Given the high stakes, patent owners should begin assessing which patents they would like to opt-out of the UPC and ensure that the necessary parties are involved in the opt-out procedure. Parties to license agreements, collaboration agreements, and the like should evaluate their existing agreements to see if they are UPC ready. Further, parties to future agreements should take the UPC into account when drafting those agreements.

Read the client alert [here](#).