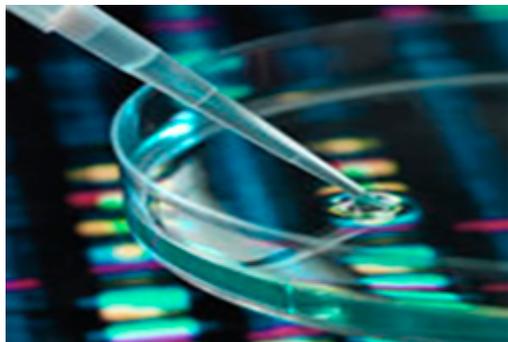


[UK's Medicines Regulator Announces Guidance on the New International Recognition Procedure for the Approval of New Medicines from 1 January 2024](#)



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.

[A Look Ahead in Life Sciences: What We Are Tracking in Q3 2023 and Beyond](#)



As the life sciences industry continues to expand and grow increasingly complex, so does its legal, regulatory, and compliance landscape. To help companies and investors navigate the many evolving and emerging laws and regulations across pharmaceuticals, biologics, medical devices, diagnostics, and laboratory testing, our Life Sciences Regulatory & Compliance team regularly tracks and stays closely connect to a comprehensive list of ongoing legal and regulatory developments in the industry. We update and publish a quarterly tracker detailing these developments. You can read

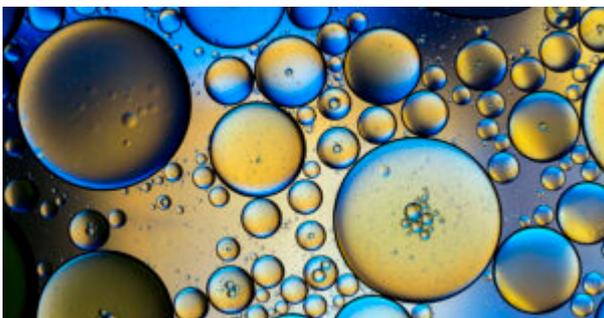
about the Q3 2023 updates [here](#).

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](#).

Psychedelics & Drug Development – Key Considerations for Healthcare Industry and Life Sciences Companies as Congress Seeks to Tap Into Psychedelics' Therapeutic Potential



Based on recent regulatory changes at the state and local level and the efforts by the federal government and certain foreign agencies, investors, clinical trial sponsors, life sciences companies, and investigators operating in the psychedelics industry may have reason to be optimistic about the

future regulatory landscape for therapeutic psychedelic product candidate development, approval, and commercialization. The proposed Breakthrough Therapies Act is one such reason.

On March 8, 2023, US Sens. Cory Booker (D-NJ) and Rand Paul (R-KY) **introduced** an **updated version** of the Breakthrough Therapies Act. If passed, the bipartisan bill would amend the federal Controlled Substances Act (CSA) to enable the Drug Enforcement Administration (DEA) to reclassify from Schedule I to Schedule II drugs and biologics, including therapeutic psychedelics, that receive breakthrough therapy designation or are authorized for expanded access by the US Food and Drug Administration (FDA). Therapeutic psychedelics are Schedule I substances and include LSD, MDMA, and psilocybin. According to the bill's sponsors, the "legislation [would] remove regulatory hurdles that inhibit research and compassionate use access to potentially lifesaving treatments that are heavily restricted by Schedule I of the [CSA]."

The bipartisan effort behind the Breakthrough Therapies Act signals the federal government's evolving position on psychedelic substances, their therapeutic potential, and access. This evolution, discussed in greater detail in our Client Alert, presents an important opportunity for investors, clinical trial sponsors, life sciences companies, and investigators.

Accordingly, we have identified and answered 8 key questions that stakeholders should consider as they develop and innovate in the psychedelic space:

- What Is the Difference Between a Schedule I and a Schedule II Drug?
- What Diseases and Conditions Can Potentially Benefit From Therapeutic Psychedelics?
- What Are the Key Provisions of the Proposed Breakthrough Therapies Act?
- How Does a Drug or Biologic Obtain Breakthrough Therapy Designation From FDA?
- What Is Expanded Access?
- What Are Some Key Limitations in the Proposed Breakthrough Therapies Act?
- What Is the Status of Therapeutic Psychedelics at the State and Local Level?
- What Regulatory Changes Are on the Horizon for Therapeutic Psychedelics?

Read the full 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](#).

US Artificial Intelligence Regulations: Watch List for 2023



Companies are developing, deploying, and interacting with artificial intelligence (AI) technologies more than ever. At Goodwin, we are keeping a close eye on any regulations that may affect companies operating in this cutting-edge space.

For companies operating in Europe, the landscape is governed by a number of in force and pending EU legislative acts, most notably the EU AI Act, which is expected to be passed later this year; it was covered in our prior client alert here: [EU Technology Regulation: Watch List for 2023 and Beyond](#). The United Kingdom has recently indicated that it may take a different approach, as discussed in our client alert on the proposed framework for AI regulation in the United Kingdom here: [Overview of the UK Government's AI White Paper](#).

For companies operating in the United States, the landscape of AI regulation remains less clear. To date, there has been no serious consideration of a US analog to the EU AI Act or any sweeping federal legislation to govern the use of AI, nor is there any substantial state legislation in force (although there are state privacy laws that may extend to AI systems that process certain types of personal data).

Read the client alert [here](#).

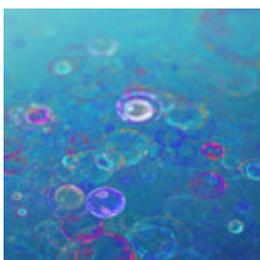
HHS to Create New Potential Medicare Pricing Models for Cell and Gene Therapy, Drugs Subject to Accelerated FDA Approval, and “High-Value” Generics



On February 14, 2023, the U.S. Department of Health and Human Services (HHS) published a [report](#) identifying three models that the Center for Medicare & Medicaid Services' (CMS) Center for Medicare & Medicaid Innovation (CMMI) will test to try to improve the affordability and accessibility of prescription drugs. The report responds to the state of prescription drug costs and access in America, as well as the widespread changes introduced by the Inflation Reduction Act of 2022 and President Biden's [Executive Order 14087](#) (October 2022), both intended to help lower prescription drug costs for Americans. The three selected models will test the feasibility of methods to: (i) offer generic prescription drugs at \$2 or less for Medicare patients; (ii) reduce Medicaid costs for novel cell and gene therapies through outcomes-based agreements with manufacturers on a multistate level; and (iii) improve the safety and efficacy of drugs approved through the FDA's Accelerated Approval Program by aligning payment methods with stakeholders' incentives. More detail on these three models is expected, and Goodwin attorneys will continue to monitor for additional guidance and any opportunities for public comment.

Read the client alert [here](#).

[FDA Announces Total Product Life Cycle Advisory Program \(TAP\) Pilot](#)



The U.S. Food and Drug Administration's ("FDA" or "the Agency") Center for Devices and Radiological Health ("CDRH") recently announced the launch of its Total Product Life Cycle Advisory Program ("TAP") Pilot. The first phase of this voluntary initiative, called TAP Pilot Soft Launch, will be conducted during fiscal year ("FY") 2023 with enrollment beginning on January 1, 2023.

The Agency committed to establishing the TAP Pilot as part of the MDUFA V reauthorization, and the Agency's long-term vision for TAP is "to help spur more rapid development and more rapid and widespread patient access to safe, effective, high-quality medical devices of public health importance." As part of the TAP Pilot, the FDA will provide strategic engagement for such devices by:

- Improving participants' experiences with the FDA by providing for more timely premarket interactions
- Enhancing the experience of all participants throughout the device development and review

process, including FDA staff

- Facilitating improved strategic decision-making during device development, including earlier identification, assessment, and mitigation of device development risk
- Facilitating regular and solutions-focused engagement early in device development between FDA review teams, participants, and other stakeholders, such as patients, providers, and payers
- Collaborating to better align expectations regarding evidence generation, improve submission quality, and improve the efficiency of the premarket review process

Read client alert [here](#).