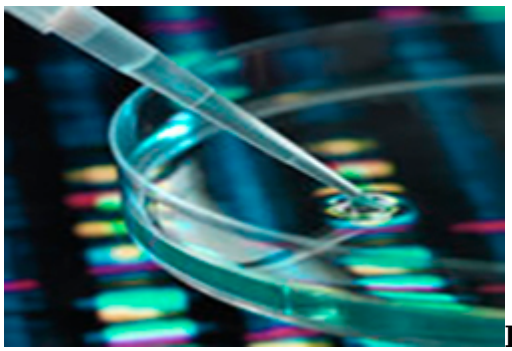
The European Parliament Adopts Position on the European Commission's Proposal for the First Major Overhaul of the EU Medicines Regulatory Framework in 20 Years

 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**.

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.

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

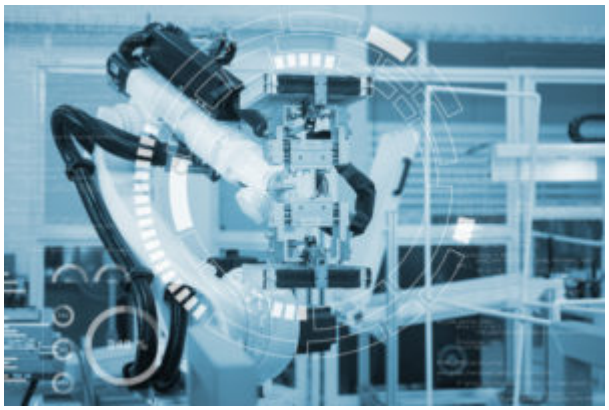
 We recently published an **alert** in relation to the European Commission's legislative proposals to replace the current EU regulatory framework for all medicines (including those for rare diseases and for children). One of the major elements of the proposals is a change to the legislation governing 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

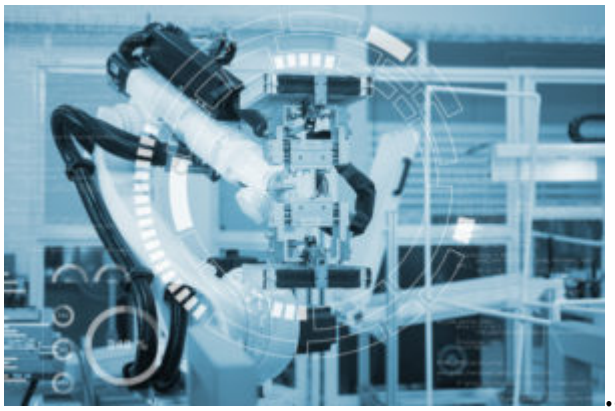
 On 26 April 2023, the European Commission published two legislative proposals – a new **Regulation 2023/0131** and a new **Directive 2023/0132** – to replace the current EU regulatory framework for all medicines (including those for rare diseases and for children).

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.

Is Prescription Support Software Classified as a Regulated Medical Device in Europe?

...the essential criterion for being classified as a medical device is the software's medical objective...

Background

Relying on an unregulated app or piece of standalone software to provide a diagnosis or recommend treatment could have potentially life-threatening consequences. In June 2020, the UK's medical devices regulator, the Medicines and Healthcare Products Regulatory Agency (MHRA) updated its

guidance to help software and app developers in the medical field identify whether their products should be regulated as medical devices.

In particular, the MHRA endorsed the European Court of Justice (CJEU) ruling of **Snitem v Philips France C-329/16** from December 2017. This case considered whether prescription support software which used patient-specific data to detect drug interactions and excessive doses, constituted a medical device.

The CJEU's Judgment

The CJEU held that the prescription support software was a medical device under EU law for the following reasons:

- the software cross-referenced patient-specific data with the medicines that the prescriber had contemplated prescribing;
- the software automatically provided the prescriber with an analysis intended to detect possible drug interactions and excessive dosages; and
- the manufacturer intended the software to be used for one of more medical objectives specified in Article 1(2)(a) of the **Medical Devices Directive 93/42/EEC** (MDD), which include the diagnosis, prevention, monitoring, treatment or alleviation of a disease.

The CJEU further held that it is irrelevant whether the software acts directly or indirectly on the human body. According to the court, the essential criterion for being classified as a medical device is the software's medical objective, examples of which are mentioned above.

Practical Implications

The MHRA guidance provides further certainty that prescription support software and other decision support software in the medical field may be classified as medical devices and thus need to comply with the requirements under the MDD.

As a final point, the MDD is due to be replaced by the Medical Devices Regulation on 26 May 2021. A key implication is that the risk classification of a significant proportion of existing medical device software could change which would mean manufacturers will soon need to obtain regulatory approval to market such software in the EU.

Territorial Licensing in Collaboration Agreements

Life sciences companies often turn to geographical licensing to realise the maximum value from their assets, and to ensure their products reach markets worldwide, particularly where they do not have a global footprint.

In the context of a collaboration agreement, the owner of certain intellectual property rights may collaborate with a licensee to develop a product, and grant such licensee the exclusive right to further develop and commercialise the product, but only in a specific territory. The licensor may reserve for itself the right to develop and commercialise the product in another territory, usually where that licensor has a presence. In certain cases, usually after much of the development of the product has taken place, the licensor may also grant additional licences limited to *other* specific territories to third parties, further dividing up the territory it had reserved for itself in the initial collaboration agreement.

The above deal structures raise many complex issues of coordination between the parties. Some of these issues in relation to geographical licensing in the context of collaboration agreements are:

1. **Product development**: if multiple parties are conducting activities in their own territories to develop a single product, high levels of coordination between those activities are required. No party will want the activities of another party to damage the value of the product being developed. Sharing results of development activities between the parties could avoid duplication of work, and help to ensure compliance with regulatory obligations. However, development results are costly to produce, and some parties may not be willing to disclose this information freely. The development work may also give rise to intellectual property rights, and the licensor will need to consider the degree of access it will need to those intellectual property rights.

2. **Regulatory authorisation and compliance**:
    a. **Pre-approval submissions:** the collaborating parties will also need to coordinate their submissions to regulatory authorities in relation to the product being developed. Inconsistent statements between such submissions must be avoided in order to protect the value of the product worldwide and ensure timely regulatory approvals can be granted.
    b. **Post-approval submissions:** once the product is on the market, each of the parties involved in its commercialisation will have reporting obligations to the regulatory authorities in their own territory. The parties will likely need to share information relating to safety and regulatory matters. If any additional licensees have been brought into the mix, the licensor will also need to consider whether all regulatory information should flow through the licensor, or whether it should flow directly between these licensees.

3. **Intellectual property management:**
    a. **Patents:** licensees who are taking an exclusive licence under certain intellectual property in a territory – particularly if they are developing improvements to such

intellectual property under a collaboration agreement – are likely to want control over the prosecution, maintenance, enforcement and potentially the defence of such intellectual property in their territory. Although this may relieve the licensor of the cost of maintaining the intellectual property in such territory, prosecution of patent applications, and defence of patents, must be coordinated worldwide to avoid inconsistent statements or actions. Such inconsistencies could impede the prosecution of a corresponding patent application, or diminish the validity or enforceability of a granted patent, in another territory.

b. **Trade marks**: if a licensor licenses rights in a centralised trade mark to various licensees, care also needs to be taken to ensure licensees are restricted in their use of the mark. Licensees should be prevented from acting in ways that could damage the value of such trade mark.

The above issues are tricky to navigate in a collaboration agreement, particularly where significant development of the product remains to be carried out, and the identity of any future additional licensees remains unknown.

A carefully considered term sheet at the beginning of negotiations can help to ensure that all relevant issues are raised and discussed as part of an overall package, as well as avoiding any key issue being missed which could potentially derail negotiations at a later stage.

Review of Joint Ventures in Life Sciences Real Estate Deals

The convergence of life sciences companies and traditional real estate developers has led to the emergence of an alternative real estate asset class known increasingly as "**PropSci**".

In this blog, we review:

1. features of the PropSci sector that make the joint venture ("JV") model attractive for market players; and
2. key terms that parties may wish to consider before embarking on a PropSci JV.

Why pursue a JV model?

Cost and scale

The high cost of building PropSci space (usually large-scale, mixed-use schemes sometimes including residential, retail and social spaces) means the ability to pool capital with partners in a JV is appealing.

Shortage of expertise

PropSci requires a marriage of capital and expertise with each party having a particular role in the transaction/project, e.g., funding, asset management, market creation, etc. and there is a relative scarcity of recognized specialist real estate operators in this space.

Public/private partnerships

There are numerous opportunities for private-sector players to partner with government and public sector bodies via public/private JVs as this is a key area of focus for government and public sector bodies (in the U.S., U.K. and E.U.).

Which standard JV terms require a more nuanced approach for PropSci JVs?

Transfer rights

In PropSci JVs, the operator's identity is critical to investors so the investor may wish to restrict any change of control/ownership of the operator or its exit from the venture. This may be further bolstered with "key person" protections. Conversely, the operator may wish to resist 100% ownership requirements and transfer prohibitions to give itself some flexibility.

Control

In investor and operator PropSci JVs, operational control of the assets typically rests with the specialist operator with certain key decisions requiring unanimity.

Default remedies

Removal of a PropSci operator mid-stream (as a default remedy) may not be possible/desirable as the investor may not have the expertise to handle the PropSci operations. Accordingly, alternative default remedies should be considered. The Operator may also wish to consider default remedies in the event of a material default by the investor (e.g. a funding default).

Exit

The parties to PropSci JVs may have different expectations on hold periods for the underlying real estate and, accordingly, the JV arrangements between such parties will need to provide for exit mechanisms.

Exclusivity

In investor and operator PropSci JVs, the investor may desire exclusive access to the operator's PropSci investment pipeline. Conversely, the operator may push for freedom to pursue opportunities independent of the investor provided the relevant key persons are devoting sufficient business time to the JV and there being no conflicts of interest.

The features of the PropSci market lend themselves to JVs, which are familiar to most commercial real estate market players. However, it is worth noting the particular quirks of PropSci and considering the useful tools available to parties to address these nuances and align JV participants.