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Latest legislative developments in the UK on retained EU law

The Retained EU Law (Revocation and Reform) Bill Implications for Healthcare and Life Sciences Industry

On 22 September 2022, the Department for Business, Energy & Industry Strategy published the Retained EU Law (Revocation and Reform) Bill 2022 (the “Bill”) and introduced it to the UK Parliament. The Bill seeks to provide a domestic law basis for amending or revoking over 2,400 well-established retained EU laws (“REUL”) that operate across 21 sectors of the UK economy, including the life sciences sector, by 31 December 2023.

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Background

When the UK was a Member State of the EU for nearly 50 years, it was under a Treaty obligation to give effect to EU-derived legislation. These legal instruments are critical to setting the regulatory standards and requirements for assessing the safety, quality and efficacy or utility of healthcare-related products, including medical technology, medicines, food, human tissues, and blood components. In addition, the European Courts have played a critical role in interpreting provisions and requirements of the EU law governing highly regulated sectors.

REUL is a category of domestic law created by the European Union (Withdrawal) Act 2018 that was preserved at the end of the transition period following the UK’s exit from the European Union. In order to ensure business continuity and legal certainty, EU legislation that still applied in the UK on 31 December 2020 was retained as part of UK domestic law.

The UK Government’s declared position for this legislative proposal is that REUL was not intended to remain on the statute book indefinitely. The Bill, if passed in its current form, will mean that the majority of REUL must either be reformed, adopted, revoked, or left to expire on 1 January 2024.

Key salient points of the Bill and UK Government position

- The Bill will sunset the majority of the REUL on 31 December 2023 unless otherwise preserved. Any REUL that remains in force after the sunset date will be absorbed into the domestic statute book by removing the special EU law features attached to it. Before that date, Government Departments and the Devolved Administrations will either reform EU law, allow EU law to expire, or incorporate EU law into domestic law, either as it is, or in a modified form. A mechanism is included for specified pieces of REUL to be sunset until 2026 where necessary.
- Given its special status, REUL takes priority over domestic UK legislation passed before the end of the transition period when incompatibility arises. The Bill will reverse the order of priority to reinstate domestic law as the highest form of law on the UK statute book. Accordingly, the Bill will end the general doctrine of supremacy of EU law retained in UK statute. However, should there be a need to preserve the current hierarchy between UK domestic and EU legislation in certain specific circumstances, the Bill provides a power to amend the new order of priority to retain particular legislative effects.
- REUL preserved on the UK statute book on 31 December 2023 will become “assimilated law” to reflect that EU interpretive features no longer apply, meaning that the supremacy of EU law and general principles of EU law will be abolished.
- The UK courts should be given greater freedom to develop domestic case law on REUL that remains in force and should not be constrained by the continuing influence of previous EU case law. The Bill addresses this by allowing domestic courts to depart from retained EU case law. The Attorney General and other Law Officers in

the UK and the Devolved Administrations will be given the power to intervene in and refer cases to the courts so that they may be invited to exercise their new discretion to depart from REUL. In practice, whilst interventions and references may not always lead to courts departing from retained case law, it will ensure that courts give full consideration to the appropriate influence of retained EU case law and the continuing development of domestic case law.

- The Bill seeks to correct an anomaly created by the European Union Withdrawal Act which confers on some retained direct EU legislation legislative parity with Acts of Parliament for some purposes. Therefore, the Bill will (a) downgrade the status of retained direct EU law for the purposes of amendment, and (b) modify powers in other statutes to facilitate their use to amend retained direct EU law in the same way they can be used on domestic secondary legislation. According to the Government's position, the purpose of this is to ensure that amendments of retained direct EU law will be subject to an appropriate level of Parliamentary scrutiny. It also simplifies the status of retained direct EU legislation, which is treated as equivalent to domestic secondary legislation, thus clarifying that it may be amended in a similar manner.
- The Bill contains a suite of specific powers to ensure that only those regulations that are appropriate for the UK will remain on the statute book. Therefore, REUL can be revoked, replaced, restated, or updated because the original EU legislation no longer accurately meets the needs of the UK.

Commentaries on implications for life sciences sector

- REUL has been part of the UK domestic law governing many economically important sectors in the UK, e.g. the life science sector, by setting expected industry standards and requirements. These standards and requirements often reflect those that are internationally accepted and which have been adopted by countries beyond the EU. A lack of alignment with these standards could have negative trade implications in the context of transboundary movement of goods such as highly regulated healthcare and consumer products as well as services.
- The UK Government has argued that REUL has not received appropriate parliamentary scrutiny. And yet, many of the retained EU law instruments on the statute book were the subject of extensive consultation amongst the EU Member States with significant input from the UK before they were adopted by the co-decision process involving the European Parliament and European Council.
- The case-law of the European Courts has been instructive in interpreting EU law requirements in many areas that are critical to the management of product life-cycle for medicines, medical devices as well as consumer products. The Bar Council indicated by reference to rulings of the UK Supreme Court that gave no support to any suggestion that there might be circumstances where it would be appropriate for a judgement of the Court of Justice of the EU on a point of EU law to be ignored or treated as irrelevant (see *Pham v Secretary of State for the Home Department* [2015] UKSC 19).
- The Bill adds further uncertainty to the future of Northern Ireland's regulatory landscape. This is because Section 23(1) of the Bill states that the Bill (if passed in its current form) extends to England and Wales, Scotland and Northern Ireland. And yet, the Northern Ireland Protocol requires Northern Ireland to continue to be subject to EU law including the case-law of the European Courts.