EXPLANATORY MEMORANDUM FOR EUROPEAN UNION LEGISLATION WITHIN THE SCOPE OF THE UK/EU WITHDRAWAL AGREEMENT AND WINDSOR FRAMEWORK

Regulation (EU) 2025/2645 of the European Parliament and of the Council of 16 December 2025 on compulsory licensing for crisis management and amending Regulation (EC) No 816/2006 (Text with EEA relevance)

Submitted by the Intellectual Property Office (IPO), an executive agency of the Department for Science, Innovation & Technology [21/01/2026]

SUMMARY

On 16 December 2025 the EU adopted a Regulation on compulsory licensing for crisis management. The Regulation makes two main changes to the EU's approach to compulsory licensing legislation.

Firstly, it introduces a new EU-wide compulsory licence (granted by the European Commission) for supplying the EU domestic internal market in a crisis or emergency situation. This change does not relate to legislation listed in the Windsor Framework.

Secondly, it amends existing EU Regulation (EC) 816/2006, which applies to Northern Ireland by virtue of the provisions set out in the Windsor Framework[1]. The amendments to Regulation (EC) 816/2006 automatically apply to Northern Ireland through the operation of Article 13(3) of the Windsor Framework, subject to the democratic scrutiny arrangements set out under Schedule 6B of the Northern Ireland Act 1998. However these amendments include a specific provision which excludes Northern Ireland from the scope of the new EU wide compulsory licence for export granted under the amended Regulation. The UK in respect of Northern Ireland shall continue to ensure that products subject to a compulsory licence under Regulation (EC) 816/2006 are not imported.

This specific exclusion for Northern Ireland addresses potential legal uncertainties which may have otherwise arisen in relation to the operation and scope of the amended EU Regulation, in the context of the UK's existing national compulsory licensing regime, and is considered to maintain the procedural status quo.

There will be no changes as a result of this Regulation to Northern Ireland's access to medicines or any other products covered by the new EU regulation.

SUBJECT MATTER

Patents provide a temporary exclusive right which incentivises innovation and investment required to develop new technologies, including new medicines. Without this incentive, businesses would be less likely to invest in developing new technologies.

A patent owner can stop others from copying their innovation without their permission. However, many patent owners enter into voluntary agreements with other businesses to allow them to use their innovation (for example to allow them to manufacture their patented medicine). These voluntary agreements can increase manufacturing capacity for a new technology and allow other businesses to benefit from the patent owner's technical knowledge and experience.

Patent systems in the UK and other countries also include a safety net for use in situations where voluntary agreements cannot be reached, including in emergency situations. This safety net allows governments to issue a 'compulsory licence' to a third party to allow them to use or manufacture a patented technology without the consent of the patent owner, as long as certain requirements are met.

Compulsory licences generally only allow use primarily for the domestic market. However, in certain circumstances they can also be used to allow production of medicines for export to countries with public health problems where those countries do not have manufacturing capability to produce the medicines that they need. The World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) sets out the requirements that must be met when a compulsory licence is issued.

Patents are territorial, and there is currently no harmonisation of EU compulsory licensing laws for supply to the domestic EU market. National EU compulsory licensing laws do not allow products manufactured under a compulsory licence in one Member State to be supplied to another Member State (or they can only be supplied in limited quantities).

On 16 December 2025 the EU adopted Regulation (EU) 2025/2645 on compulsory licensing for crisis management, which provides a new EU-wide compulsory licensing approach for use in crisis situations and for supplying countries with public health problems. It partially amends existing EU Regulation (EC) 816/2006.

The main objective of the Regulation is to ensure that an EU-wide compulsory licence may be granted in a crisis or emergency affecting the Union.

SCRUTINY HISTORY

The House of Commons (European Scrutiny Committee as it was then) reviewed the EU proposal in July 2023.

The House of Lords (European Affairs Sub-Committee on the Protocol on Ireland/Northern Ireland as it was then) reviewed the EU proposal in September 2023.

MINISTERIAL RESPONSIBILITY

Secretary of State for the Department for Science, Innovation, and Technology Liz Kendall MP holds responsibility for the relevant Department.

Kanishka Narayan MP, Parliamentary Under Secretary of State for AI and Online Safety, has a key interest in this area.

INTEREST OF THE DEVOLVED ADMINISTRATIONS

Intellectual property is a reserved matter.

The devolved governments have been consulted in the preparation of this Explanatory Memorandum and had no comments.

LEGAL AND PROCEDURAL ISSUES

i. EU Legal Base

The adopted Regulation is based on Articles 114 and 207 of the Treaty on the Functioning of the EU ('TFEU').

ii. Voting Procedure

The ordinary legislative procedure applied.

iii. Timetable for adoption and implementation

The Regulation was adopted on 16 December 2025 and was published in the Official Journal of the EU on 30 December 2025. The Regulation is directly applicable in all Member states and will enter into force on the twentieth day following its publication in the Official Journal of the EU (20 January 2026).

POLICY IMPLICATIONS

Patent rights are territorial, including in EU Member States, and the EU has previously had a patchwork of different national systems for compulsory licensing. The current EU Regulation provides a new EU-wide compulsory licensing approach for use in crisis situations. This new EU compulsory licensing approach has two main elements:

1) A new EU-wide compulsory licence (granted by the European Commission) for supplying the EU domestic internal market in a crisis or emergency situation. This provides a single procedure to grant an EU-wide compulsory licence as an alternative to the previous patchwork of national compulsory licensing laws among the 27 EU Member States.

2) Amendments to existing Regulation (EC) No 816/2006. Regulation 816/2006 allows - via national procedures - for compulsory licensing for the purposes of export to countries with public health problems who do not have sufficient manufacturing capabilities. In order to achieve synergies, and avoid situations where multiple Member States issue a compulsory licence, the amendments allow for this to be done at an EU-wide level.

Under both elements, EU-wide compulsory licenses permit both domestic manufacturing in a single country and cross-border manufacturing processes between multiple EU countries[2]. The adopted Regulation confirms that EU-wide compulsory licences should only be used as a last resort measure when other means, including voluntary agreements, could not ensure access to crisis relevant products.

Element (1) is implemented by the new EU Regulation which establishes the proposed EU-wide compulsory licensing system for crisis management at EU level, whilst leaving national compulsory licensing schemes in Member States untouched. This element does not relate to legislation listed in the Windsor Framework.

Element (2) of the new compulsory licensing procedures, set out in Article 24 of Regulation (EU) 2025/2645, introduces amendments to the existing EU Regulation (EC) No 816/2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems.

Regulation (EC) 816/2006 applies to Northern Ireland by virtue of the provisions set out in the Windsor Framework[3]. Amendments to Regulation (EC) 816/2006 also

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[2] Recital 45 of the EU Regulation refers to cross-border manufacturing; Regulation (EU) 2025/2645 of the European Parliament and of the Council of 16 December 2025 on compulsory licensing for crisis management and amending Regulation (EC) No 816/2006 (Text with EEA relevance)

[3] Article 5(4) and Annex 2 (item 7)

apply to Northern Ireland through the operation of Article 13(3) of the Windsor Framework, subject to the democratic scrutiny arrangements set out in Schedule 6B of the Northern Ireland Act 1998.

However, the final adopted EU legislation also now includes a specific exclusion in respect of Northern Ireland which means that the procedure for granting an EU-wide compulsory licence in amended Regulation (EC) 816/2006, and any EU-wide compulsory licence granted through that procedure, do not apply to Northern Ireland. Pre-existing provisions in Regulation (EC) 816/2006 continue to apply to Northern Ireland, maintaining the existing procedural status quo on these aspects.

The specific exclusion for Northern Ireland helps to address potential legal uncertainties which may have otherwise arisen in relation to the operation and scope of the amended Regulation. There will therefore be no changes as a result of this Regulation to Northern Ireland's current access to medicines or any other products covered by this EU regulation.

The specific exclusion for Northern Ireland in amended Regulation 816/2006 states that the UK in respect of Northern Ireland shall ensure that products manufactured under EU-wide compulsory licences issued under the amended Regulation 816/2006 are not imported from outside the EU. This is considered to maintain the procedural status quo.

The existing UK patent system (like those of many other countries) already includes compulsory licensing provisions and details the processes to invoke them. These existing UK provisions are considered to be appropriate and there are no plans to amend them at this time.

The EU Regulation is not expected to impact on Northern Ireland's participation in the UK's Free Trade Agreements or Northern Ireland's participation in UK Common Frameworks.

The UK Government engaged with the European Commission prior to the EU's adoption of the Regulation to understand how the new EU system will operate and in relation to the amendments in the final published Regulation. The Government will continue to engage with the European Commission after the implementation of the Regulation as required.

CONSULTATION

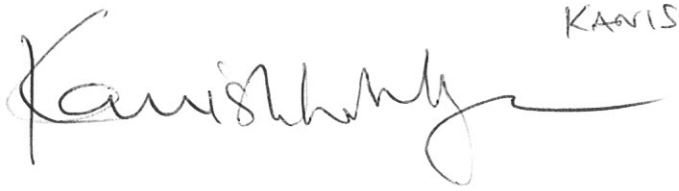
The UK Government has not been involved in the European Commission's consultations for the proposal or the development of the European Commission's impact assessment. The Government has not prepared a separate impact assessment about the proposal.

FINANCIAL IMPLICATIONS

The proposal is not expected to have specific financial implications for the UK.

MINISTERIAL NAME AND SIGNATURE

KANISHKA NARAYAN



Kanishka Narayan MP, Parliamentary Under Secretary of State for AI and Online Safety

Department for Science, Innovation and Technology