PUBLISHED REPLACEMENT EU ACT ASSESSMENT OF IMPACT

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Department: Department of Health (DoH)

Published Replacement EU Act

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. OJ L, 2025/2645, 30.12.2025 [link]

This Regulation amends Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems; Protocol Annex 2, Heading 7 on Others.

Summary of the Act

The general objective of this regulation is to enable the EU to respond to crisis situations in a timely manner and to ensure that in a crisis, critical products and components can be made available across EU countries and supplied without delay to EU citizens and firms or even to non-EU countries.

The proposed Regulation also looks to amend Regulation (EC) No 816/2006 to add the option for a Union compulsory licence granted by the European Commission for compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems.

The Regulation establishes a compulsory licencing system for crisis management at EU level with its own triggers, procedure and conditions. It leaves national compulsory licencing schemes in the Member States untouched but ensures coherence with other crisis and emergency instruments at EU level and is compliant with the international requirements for compulsory licencing laid down in the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property (TRIPS).

The published text includes an amendment to the proposal which means an EU-wide compulsory licence would not apply in Northern Ireland (*Article 18c - Applicability to and in the United Kingdom in respect of Northern Ireland*). Therefore, as the EU-wide compulsory licence under the amendment to Regulation (EC) 816/2006 **does not apply** in Northern Ireland, only a national compulsory licence granted by the UK competent authority could apply across the UK.

Department(s) Responsible

- Department of Health (DoH, Interest in amendment to Regulation (EC) 816/2006 only) – Minister Mike Nesbitt

NB - Intellectual property is a reserved matter for the Department for Science, Innovation and Technology (DSIT).

Assessment of Impact

Q: Does it appear likely that the application of the replacement EU act would have a significant impact specific to everyday life of communities in Northern Ireland in a way that is liable to persist?

A: DoH current understanding is that there should not be a significant impact specific to everyday life of communities in a way that is liable to persist in relation to the published amendment to Regulation (EC) 816/2006.

Q: Does it appear likely that not applying the replacement EU act would have a significant impact specific to everyday life of communities in Northern Ireland in a way that is liable to persist?

A: DoH current understanding is that the amendment to Regulation (EC) No 816/2006 will not apply to Northern Ireland and therefore should not have a significant impact specific to everyday life of communities in a way that is liable to persist.

Additional Information

Regulation (EU) 2025/2645 introduces an EU-wide compulsory licence issued at EU level for supplying the internal market in a crisis or emergency situation, and the amendment to Regulation (EC) 816/2006, introduces a compulsory licence granted by the EU for the manufacture of pharmaceutical products for export to countries with public health problems. DoH only has an interest in Regulation (EU) 2025/2645 in relation to the amendment to Regulation (EC) 816/2006.

In June 2023, the UK Government produced an Explanatory Memorandum (EM) on the anticipated impact based on the initial proposals, as detailed below. Consequently, the EM fails to consider the updated finalised text within the Regulation which now excludes Northern Ireland from the scope of any EU-wide compulsory licence granted by the EU under the amended Regulation (EC) 816/2006 (*Article 18c - Applicability to and in the United Kingdom in respect of Northern Ireland*).

UK Government Explanatory Memorandum

The Department for Science, Innovation and Technology (DSIT) published the latest explanatory memorandum (EM) on this topic on the 14 June 2023 – full document attached as **Annex 1**.

This EM was produced by the Intellectual Property Office (IPO), an executive agency of the DSIT and provides subject matter background information on patents and their regulatory systems. It outlines that patent systems in the UK and other countries 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.

The EM clarifies that 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.

The EM states this new EU compulsory licensing approach would have two main parts:

1. A new EU-wide compulsory licence for supplying the EU domestic internal market in a crisis or emergency situation.
2. An EU-wide compulsory licence for producing medicines for export to countries with public health problems where those countries do not have manufacturing capability to produce the medicines, they require themselves.

The EM concludes that if the proposals were to apply, the DSIT expect a limited impact on the NI market.

Analysis by the European Commission on its Impact Assessment

The European Commission (EC) conducted an extensive impact analysis process for various proposed policy options, producing a comprehensive impact analysis report attached as **Annex 2**. The impacts were assessed for each proposed policy option with stakeholder views and preferences integrated into the decision-making approach to the selection of the preferred policy option.

The EC clarifies their preferred option would create a single procedure to grant an EU-level compulsory licence with the features required to tackle a crisis. The EC activation measure would ensure that conditions are the same across the EU and would avoid national discrepancies likely to slow down or prevent an efficient compulsory licensing scheme from tackling cross-border crises. This single compulsory licence would be applicable in all relevant territories, therefore covering cross-border situations. This would be the case for both the EU market and for export purposes. Consistency with EU crisis instruments would be ensured by the

possibility to use them to trigger the licence procedure and by reference to the (advisory) bodies set-up by those instruments to discuss an EU-level compulsory licence.

The results of the EC public consultation show that a large majority (82%, N=61) of respondents consider that public authorities should be entitled to allow production of critical goods through a compulsory licence. It is unclear whether NI stakeholder's views have been considered, however the consultation process took a two phased approach, first a call for evidence on 1 April 2022 for 4 weeks and then a full open public consultation from 7 July 2022 until 29 of September 2022.

The EC assessment of impact by stakeholder group for their preferred option suggests only one significant negative impact in relation to patent holders, noting "*in the event of a broader geographical scope of a compulsory licence, wider loss of control over patent rights*". The only other suggested minor impacts of this option were attributed by the EC to EU member states, who were expected to notice increased costs of participation and reporting. EU countries would bear limited adjustments costs as the preferred option would provide an EU-level compulsory licence, through a regulation, on top of existing national legislation. They would face some enforcement costs in the event of a crisis, linked to the transparency obligation. However, the benefits of a centralised procedure at EU level would outweigh these costs.

Departmental Engagement

DoH Officials have liaised with colleagues from the Department of Health and Social Care (DHSC) and Intellectual Property Office (IPO). DoH is aware that the published Regulation excludes NI from the scope of any EU-wide compulsory licence granted by the EU under the amended Regulation (EC) 816/2006 (*Article 18c - Applicability to and in the United Kingdom in respect of Northern Ireland*).