PROTOCOL ON IRELAND/NORTHERN IRELAND

SUPPLY OF MEDICINES

12 April 2022

What flexibilities has the European Union implemented to ensure continued long-term supply of medicines to Northern Ireland?

On 12 April, the EU adopted two legislative acts introducing a series of targeted amendments to EU law[1]. To ensure legal certainty and predictability, these acts provide for permanent solutions for the continued long-term supply of medicines from Great Britain to Northern Ireland. In addition, they address outstanding supply concerns in Cyprus, Ireland and Malta. The adopted legislation also includes certain conditions to ensure the protection of the EU's Single Market. These measures apply retroactively from January 2022.

Generic medicines and other medicines authorised at national level	Generics can be authorised under national UK procedures, in compliance with EU law.
Regulatory functions *(e.g. marketing authorisation holder, the manufacturing authorisation holder qualified person for batch testing and pharmacovigilance)*	All regulatory functions can remain in the UK if they are currently located there. No need to relocate any functions or testing facilities to Northern Ireland.
Use of a single pack and leaflet across the UK	The UK regulator may authorise companies located in Great Britain to use a single pack and single leaflet when supplying markets in Great Britain and Northern Ireland.
Batch testing	No need to repeat batch testing carried out in Great Britain or the EU for medicines brought to Northern Ireland from or through Great Britain.

1 Directive (EU) 2022/642 of 12 April 2022: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2022.118.01.0004.01.ENG&toc=OJ%3AL%3A2022%3A118%3ATOC.
Regulation (EU) 2022/641 of 12 April 2022: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2022.118.01.0001.01.ENG&toc=OJ%3AL%3A2022%3A118%3ATOC.

New medicines that are authorised centrally in the EU such as cancer medicines	If a new medicine is authorised in the UK but not yet in the EU, the UK regulator may authorise its supply to patients in Northern Ireland temporarily pending the outcome of the marketing authorisation procedure in the EU.
Manufacturing/import authorisations	No need for wholesalers in Northern Ireland to hold a manufacturing authorisation or import licenses for medicines supplied from Great Britain to Northern Ireland.
Unique identifier on packs of prescription medicines	No need to remove the EU unique identifier ('decommissioned') from prescription medicines for another three years (i.e. until 31.12.2024) when these products enter Northern Ireland from the EU, via Great Britain[2].

2 Commission Delegated Regulation (EU) 2022/315 of 17 December 2021: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022R0315

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