Department of Health (NI) Continuity of Medical Supplies Guidance

Purpose

This Department of Health (DoH) Continuity of Medical Supplies Guidance provides Health and Social Care (HSC) organisations and independent providers with information to help inform their arrangements for the supply of medicinal products into Northern Ireland (NI) following European Union (EU) Exit, the introduction of the NI Protocol and legislative changes introduced by the European Commission (EC) in April 2022.

The guidance is needed because there are now differences between the medicines' markets in NI and Great Britain (GB) which HSC organisations and other service providers need to manage within their operations.

For further information on EU Exit please refer to the Department of Health website and the UK Government website which provides information from Medicines and Healthcare products Regulatory Agency (MHRA) to industry. For further information on the April 2022 EC legislation changes please refer to EC Legislation.

Medicines

Medicines Licensing

Medicines may be licensed for use in NI by the United Kingdom (UK) regulator, the Medicines and Healthcare products Regulatory Agency (MHRA) and EC regulator, the European Medicines Agency (EMA). The MHRA issue national UK authorisations which are generally for generics and other established medicines whilst the EMA issue EC authorisations which include new and innovative medicines and vaccines that fall under the scope of the EU centralised procedure.

HSC organisations and services providers should take note of the different licensing pathways and be aware that NI licensed medicines can be purchased via UK and/ or EU wholesalers. See Annex A.

National UK Authorisations

Marketing Authorisations (MA) that fall outside the scope of the EU centralised procedure can be licensed for use in NI via:

- UK wide national application procedure;
- Decentralised or mutual recognition procedures with UK(NI) as a concerned Member State; or
- MHRA can approve a medicine for use in NI, GB or the whole of the UK depending on the procedure used.

Medicines that have MAs for use in the NI market through national procedures will display PL or PLNI numbers. These products must comply with the requirements of the EU's Falsified Medicines Directive (FMD).

If a MA Holder (MAH) discontinues a product from the NI market and opts for a GB only national licence, their product will display a PLGB number. PLGB products will not be licensed for use in NI and therefore, will not be compliant with FMD. PLGB medicines must not be supplied to NI unless authorised to do so through the NI MHRA Authorised Route (NIMAR), the Centrally Authorised Products (CAP) Bridging Mechanism, or an exemption under Article 63.3 of Directive 2001/83/EC.
MHRA guidance is available at: Supplying Authorised Medicines to Northern Ireland Guidance. Please see the following sections on the NI MHRA Authorised Route (NIMAR) and Article 63.3 exemptions.

Centralised Authorised Products (CAP)

Marketing authorisations issued by the EC through the centralised procedure continue to apply in NI but not GB. For products within the scope of the EU centralised procedure, NI must use a CAP that is authorised for the NI market either with packs containing only NI specific details or multinational packs in which labelling, and leaflets have been amended to reflect NI use.

In addition, if a manufacturer applies for a new product authorisation via MHRA and EU centralised procedure, the EC proposals have included a 'bridging mechanism' to permit MHRA to license these products for use in NI for up to six months, if awaiting EC authorisation or until the EC authorises the product.

HSC organisations and service providers should be aware that there may be withdrawals from the NI market, changes to logistics and medicines packaging that have been authorised via this route and may find the following link useful in determining if a product is a CAP: https://ec.europa.eu/health/documents/community-register/html/reg_hum_act.htm?sort=a.

NI MHRA Authorised Route (NIMAR)

The NIMAR contingency measure became operational on 1st January 2022. This is a legal measure that is designed to ensure that people in NI can continue to access prescription-only medicines (POMs) should clinical need be unable to be met through authorised products or any other existing regulatory routes. "NIMAR provides a route for the lawful supply of POMs in compliance with UK and EU rules, where there is a risk that clinical need in NI for that product cannot be met. This includes supply of medicines that are unlicensed in NI, but which are licensed and approved in GB. Supplying medicines via NIMAR is essential on public health grounds and having this additional route for supply means POMs can be supplied to NI, to meet clinical need, in accordance with their GB marketing authorisation" www.gov.uk/government/publications/the-northern-ireland-mhraauthorised-route-nimar/the-northern-ireland-mhra-authorised-route-nimar.

Inclusion of a medicine on the NIMAR list is determined by assessing patient need and system-wide impact. A decision is taken on whether there may be a clinical unmet need for the medicine in NI. This process is managed by DHSC in partnership with DoH. There is no application process for a medicine to be placed on the NIMAR list and manufacturers should use existing processes to notify DHSC of their intention to discontinue a product in NI or if there is an anticipated shortage of a product specific to the NI market.

Prescribers in NI do not need to do anything different to prescribe or access medicines through this route and as such medicines on the NIMAR list can continue to be prescribed to patients as normal. There is no requirement for end users to identify NIMAR products and they can be supplied to patients on the same terms as medicines with a marketing authorisation valid in NI (PL and PLNI). Medicines

on the NIMAR list do not need to be serialised for FMD, there is no requirement to decommission these products as required by EU Delegated Regulation 2016/161.

The NIMAR list and guidance can be accessed via:

https://www.gov.uk/government/publications/medicines-eligible-for-northern-ireland-mhraauthorised-route.

HSC organisations and service providers do not need to do anything differently to prescribe or access medicines through this route but should note this guidance.

Article 63.3 Exemption

Medicines licensed via EU centralised procedure are licensed for use in NI, however in order to be supplied into NI all packs must be compliant with EU packaging regulations and contain NI details on their packaging and leaflets. As described above these can be packs labelled for specific use in NI or joint packs with NI details added.

There may be occasions where NI compliant packs are not available but packs labelled for use in other EU Member States are. In certain circumstances MAHs may apply to MHRA to allow these packs to be supplied into NI using an exemption under Article 63.3 of directive 2001/83/EC

HSC organisations and service providers should be aware of this exemption and potential use by MAHs if NI compliant packs are not available.

Falsified Medicines Directive (FMD)

Hospitals, Community Pharmacies, General Practices and other end users of medicines in NI must legally comply with FMD. Therefore, steps should be taken to implement processes ensuring to verify and decommission any medicines' packs with FMD safety features (anti-tamper devices and unique identifiers). NI remains connected to the National Medicines Verification System facilitated by SecurMed UK. SecurMed UK have continued to provide end user registration and necessary support to enable the decommissioning of packs with the FMD unique identifier. More information can be found via: https://securmed.org.uk/.

Investigational Medicinal Products (IMPs)

The EU legislation adopted on 20th April 2022 included derogations concerning the supply of IMPs. IMPs manufactured in GB can be imported into NI provided they meet the particulars required, including following EU acquis, Qualified Person (QP) certification in either GB, NI or EU. Batch testing may also be performed outside the EU, including GB or NI and must only be available to participants in NI. IMPs can also be supplied to NI direct from EU Member States.

Prior to the EU derogations, the Public Health Agency (PHA) have been temporarily overseeing clinical trials and the supply of IMPs. With derogations now in place these responsibilities and functions will transfer from the PHA back to the HSC organisations and service providers. HSC organisations and service providers should have in place appropriate arrangements to facilitate their return.

More information can be found via:

https://www.gov.uk/guidance/supplying-investigational-medicinal-products-to-northern-ireland.

Medical Devices (including In Vitro Medical Devices)

NI must follow the EU acquis in respect of medical devices. Medical Devices and In Vitro Medical Devices must comply with the EUMDR 2017/745 and EU IVDR 2017/746 respectively and bear the CE or CE and UKNI markings in order to be placed on the NI market.

Please note that the UK Government recently consulted on the future regulation of medical devices for the UK. The Government response to this consultation can be found here Response to the consultation on the future regulation of medical devices in the United Kingdom. The new regulations are planned to come into force in July 2024. The UK government shall continue to recognise CE marked devices currently on the market in GB for a transitory period. after the new regulations come into force in July 2024.

HSC organisations and service providers should note these regulatory differences and potential for changes in supply.

Reporting Shortage or Discontinuations

There are both national and local arrangements in place that deal with supply disruptions to ensure that patients continue to get the medicines and medical supplies they need. When needed, National Patient Safety Alerts, Medicine Supply Notifications and other forms of communications will provide advice to prescribers, service providers and suppliers about managing medicines or device shortages. There are also other measures that may be used in response to shortages including the prohibition of medicines exports and “Serious Shortage Protocols” that allow flexibility in primary care dispensing of medicines.

In addition to these arrangements teams have been established which are dedicated to investigating the impact of discontinuations or disruptions of medicines and medical devices that are unique to NI. These teams consist of officials from the Department of Health, HSC Trust procurement teams and colleagues from Department of Health and Social Care (DHSC) and MHRA.

During the pandemic, structures and reporting systems were established to assist Trusts and other healthcare providers to escalate issues to the Department. These channels became a useful tool for escalating EU Exit medical supplies concerns. However, in anticipation of these structures being stepped down, it will become necessary for healthcare providers to return to normal business arrangements for escalating concerns to the Department. See Annexes B and C.

Key Messages

HSC organisations and service providers need to be aware of changes to the supply of medicines and medicinal products for NI in regard to their operational arrangements. The key messages for organisations are:

Medicines and IMPs

- **In April 2022 the EC ratified and adopted proposals introducing derogations to support the supply of medicines and IMPs into NI.**
- **Medicines in NI can be licensed by MHRA or the EMA via national UK authorisations or EC authorisations via EU centralised procedure respectively.**
- **Products with UK-wide authorisations will display PL or PLNI licence numbers and must comply with FMD requirements.**
- **Products with GB authorisations will display a PLGB licence number and will not be authorised for use in NI (unless supplied under NIMAR, Article 63.3 exemption or CAP bridging mechanism) and therefore will not be compliant with FMD.**
- **NIMAR products will be PLGB licensed medicines that can legally be supplied to address unmet clinical need and do not need to comply with FMD.**
- **Products with EC authorisations must display NI details on their packs and leaflets and must be compliant with FMD.**
- **NI licensed medicines can be purchased via UK and/ or EU wholesalers.**
- **Other routes of supply include:**
    - **NIMAR**
        - **Products will be unlicensed in NI.**
        - **Products will be GB licensed medicines authorised by MHRA with PLGB licence numbers.**
        - **Products do not need to comply with FMD.**
        - **Products may be obtained via existing supply routes.** ○ **Article 63.3 exemption**
        - **Licensed medicines but without NI details on packaging and leaflets.**
        - **MAH applies for exemption to supply packs labelled for use in other EU Member States.**
- **Hospitals, community pharmacies and general practices must comply with FMD.**

IMPs can be supplied into NI from GB or EU. The interim arrangements with PHA concerning IMPs will come to an end and will be supplied via business as usual channels.

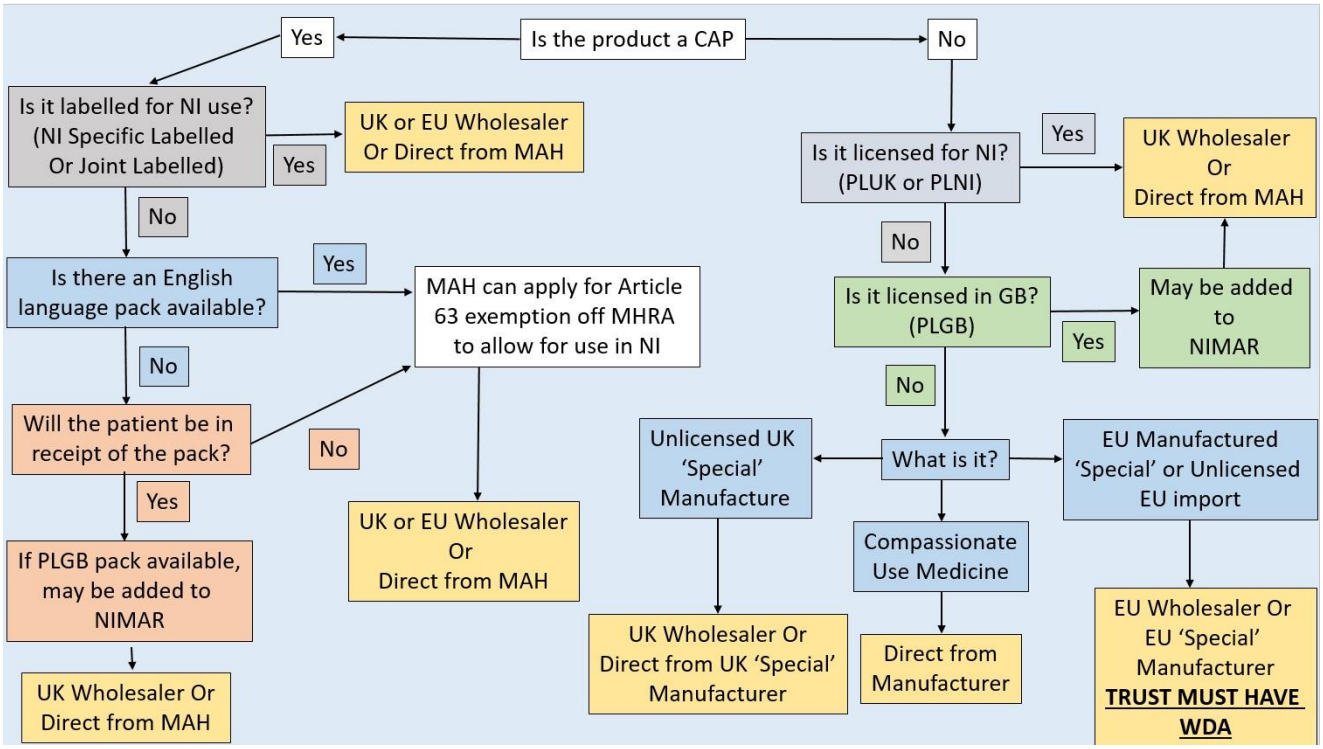
Medical Devices

- **Medical devices in NI must follow EU acquis and bear CE or CE and UKNI markings.**
- **GB are continuing to recognise medical devices bearing CE marking until July 2023. After July 2023 GB products must bear UKCA marking and conform to UK regulations.**

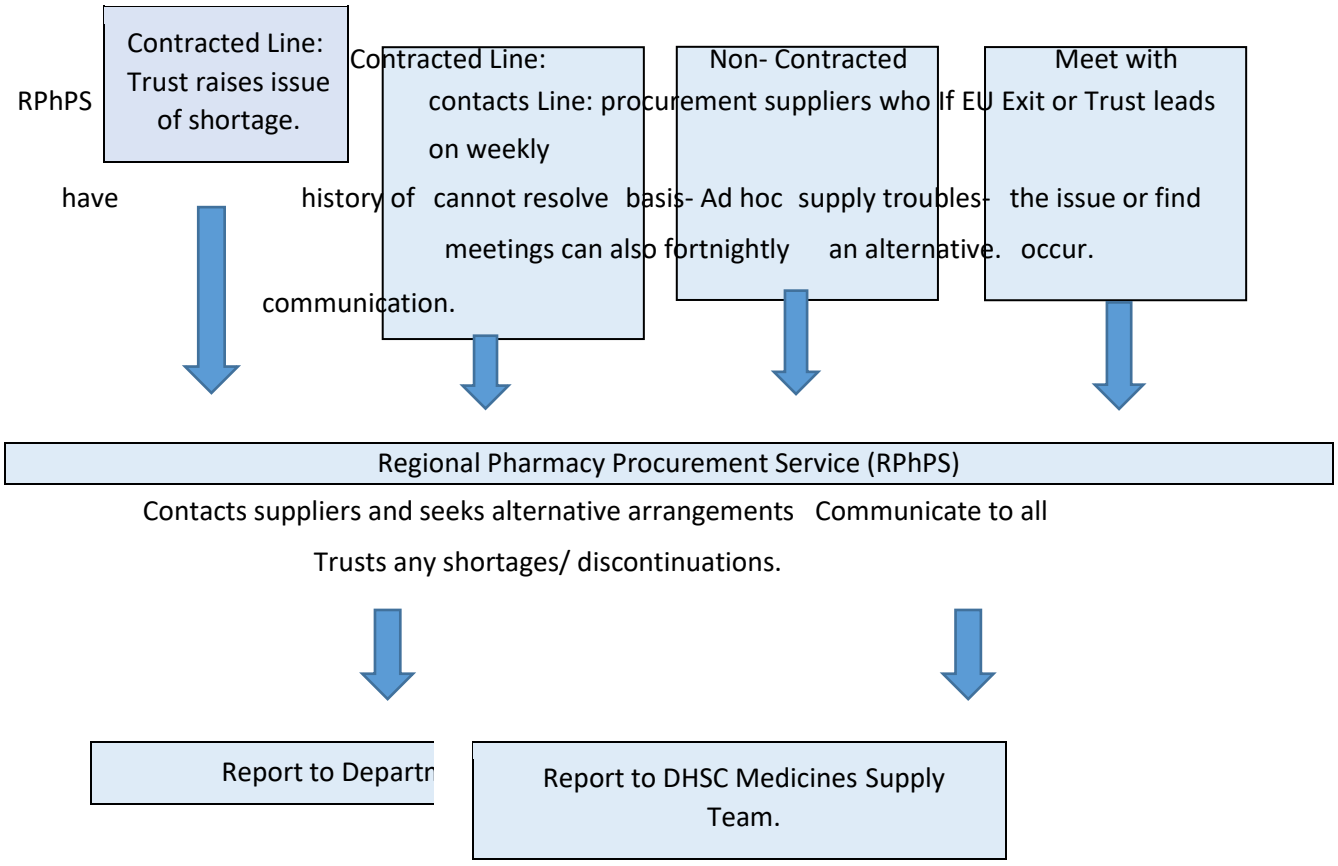
Shortages and discontinuations

- **National and local arrangements in place to mitigate risks associated with shortages and discontinuations.**
- **Medicines and medical devices shortages or discontinuations to be reported via normal business arrangements.**

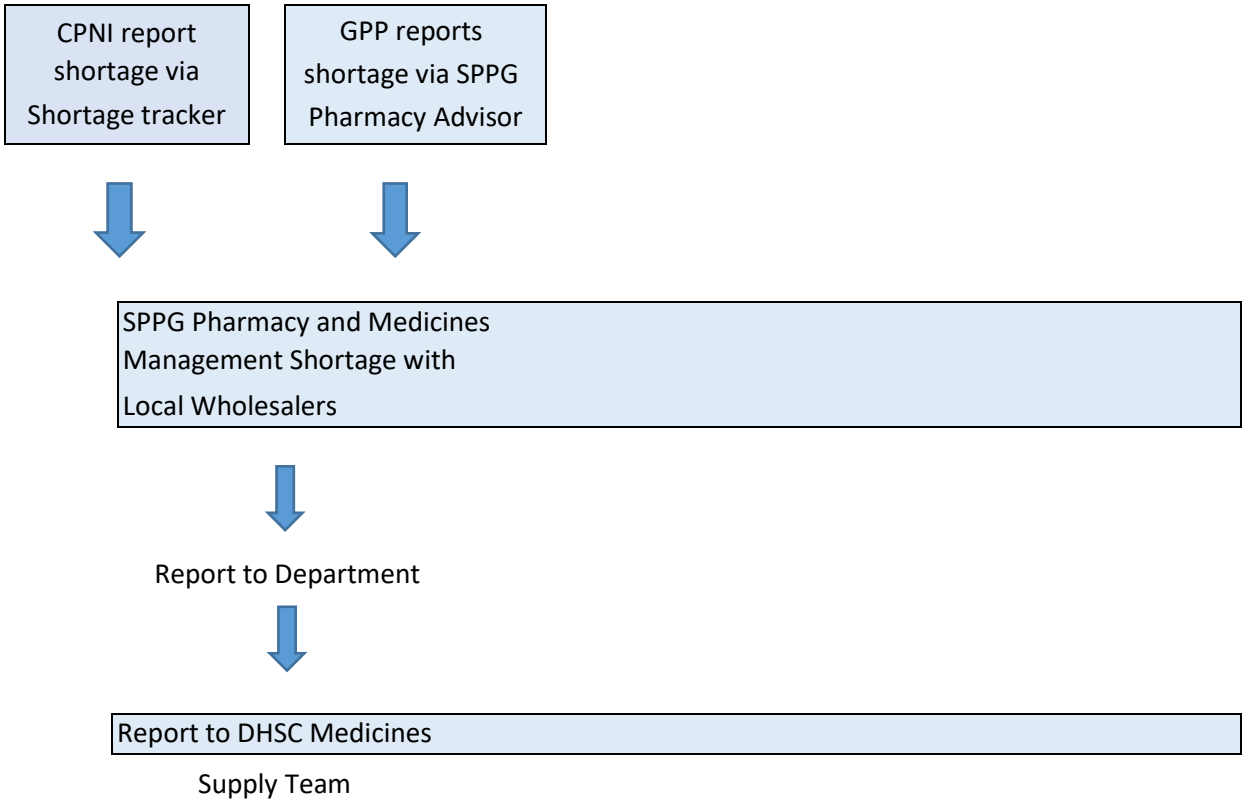
Annex A Possible medicines supply routes for NI



Annex B Reporting shortages or discontinuations within the Trusts



Reporting shortages or discontinuations within Primary Care



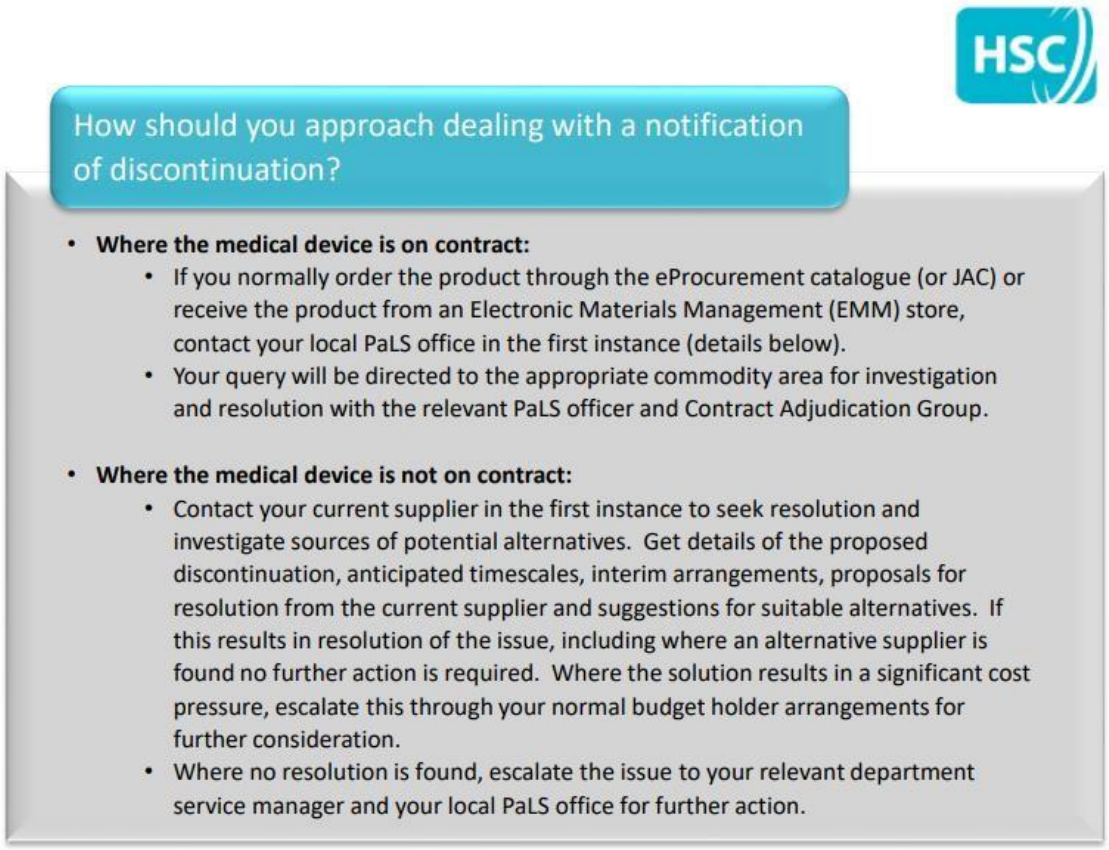
Community Pharmacy NI (CPNI)

General Practice Pharmacists (GPP)

Strategic Planning and Performance Group (SPPG)

Annex C Reporting of medical/In vitro medical device discontinuations- Taken from previous communication from BSO PaLS

The following applies for both medical and in vitro medical devices



Local PaLS Contact Details		
BHSCT, NIAS, NIBTS Gail.watts@hscni.net	**NHSCT** Sandra.armstrong@hscni.net	**SEHSCT** Andrew.carmichael@hscni.net
SHSCT Esther.gracey@hscni.net	**WHSCT** Roisin.mcdonald@hscni.net	