

# WELSH HEALTH CIRCULAR



Llywodraeth Cymru  
Welsh Government

**Issue Date:** 22 December 2020

## STATUS: INFORMATION

### CATEGORY: HEALTH PROFESSIONAL LETTER

**Title:** EU Exit – Continuity of Medicine Supply at the End of the Transition Period

**Date of Expiry / Review:** This Welsh Health Circular remains in force until such time as it is replaced.

**For Action by:**

Chief Pharmacists; Community Pharmacists; General Practitioners; and Dispensing Doctor Practices.

**Action required by:** 31 December 2020

**Sender:** Pharmacy and Prescribing Branch, Health and Social Services Group

**HSSG Welsh Government Contact(s):**

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**Enclosure(s):** Chief Pharmaceutical Officer Letter

## EU Exit – Medicines supply continuity

### **Purpose**

To provide NHS bodies in Wales with detail of measures being taken to ensure the continuity of supply of medicines as part of the UK Government's contingency preparations for leaving the European Union (EU).

This WHC updates and replaces WHC/2019/005.

<https://gov.wales/brexit-and-medicines-supply-whc2019005>

The UK exited the EU on 31 January 2020 and is now in a transition period until 31 December 2020, at which point the UK will leave the EU Single Market and Customs Union.

### **Background**

The Welsh Government has continued to work with the UK Government and the pharmaceutical industry to understand and mitigate the risks to the medicine supply chain at the end of the transition period on 31 December 2020.

The Welsh Government's preparations have been developed to compliment those of the Department of Health and Social Care (DHSC), which maintains overall responsibility for medicines supply to the UK, and has taken action to help ensure medicines continue to be available to all parts of the UK, and that any supply disruptions are minimised.

This letter describes UK and Wales level preparations for the end of transition period and sets out actions for suppliers of medicines in Wales.

The key message remains that it is neither necessary nor appropriate for health boards, NHS Trusts, community pharmacies or dispensing doctors to stockpile medicines. Neither is it necessary or appropriate for prescribers to issue additional or to extend the duration of, prescriptions for patients.

Unnecessary stockpiling puts pressure on supply chains and risks adversely affecting the availability of medicines in Wales and other parts of the UK. Prescribers and pharmacists should explain to patients that they should continue to order their prescriptions as they would normally.

### **UK and Welsh Government Preparations**

#### Utilising alternative transport routes

The DHSC has worked with suppliers to help ensure they transport medicines to the UK through alternative routes away from the Channel short straits crossings to mitigate against any risk of bottlenecks at the busiest ports. The UK Government has secured additional freight capacity on ferry routes for all health supplies. This includes additional

express freight capacity. The NHS will have access to next day delivery on small consignments, including temperature-controlled or hazardous products, 48-hour delivery for larger loads, and access to specialist services, including hand-delivered courier services if needed.

### Supporting trader readiness for the new customs and border processes

The UK Government is also supporting suppliers' preparation to ensure they are ready for new customs and border arrangements that will be in place from 1 January 2021.

If you or your organisation directly imports any medicines, clinical trial supplies or other products from the EU, this letter serves as a reminder that from 1 January 2021 you will need an Economic Operators Registration Identification (EORI) number to track and register customs data, as you would do when already importing from the rest of the world. If you or your organisation exports to the EU – for example to clinical trial sites – a UK EORI number must be used by the business making the export declaration and an EU EORI number must be used by the business making the import declaration on the EU side.

Guidance on exporting and importing can be found at:

- [The Border Operating Model - GOV.UK \(www.gov.uk\)](https://www.gov.uk/guidance/the-border-operating-model)
- [Get an EORI number - GOV.UK \(www.gov.uk\)](https://www.gov.uk/guidance/get-an-eori-number)

### Retaining buffer stocks of medical supplies wherever possible

The DHSC has asked suppliers of medicines from or through the EU to retain at least six weeks' total stock in the UK wherever possible. This includes unlicensed medicines and specials. For medicines that cannot be stockpiled because they have short shelf-lives, such as medical radioisotopes, suppliers are ensuring they arrange alternative routes such as using air freight.

### Regulatory changes

The UK Government is making sure that medicines, medical devices and clinical trials licensed or tested in the EU can continue to be imported and used in the UK by amending regulations. The Medicines and Healthcare products Regulatory Agency (MHRA) has published guidance for the end of the transition period and will continue to publish guidance post transition: [MHRA post-transition period information - GOV.UK \(www.gov.uk\)](https://www.gov.uk/guidance/mhra-post-transition-period-information)

### Falsified Medicines Directive (FMD)

The EU Falsified Medicines Directive 2011/62/EU (FMD) was published to prevent the increasing risk that falsified medicines would enter the legal supply chain and reach

patients. As of 1 January 2021, pharmacies in Great Britain (as well as wholesalers, hospitals and others handling or supplying medicines) will no longer be able to access the EU-based systems necessary to verify and decommission medicines.

An update and guidance including next steps that you may need to take regarding local pharmacy systems and disconnecting them from the FMD systems can be found at: <https://fmdsource.co.uk/2020/11/16/future-of-the-safety-features-measures-under-fmd-in-great-britain-and-northern-ireland/>

### Supplier and product level risk assessments

The DHSC has undertaken supplier and product level risk assessments for all medicines used in the UK that have a touchpoint in the EU. In addition, in response to the DHSC risk assessments, the Wales Medicines Shortages Advisory Group considered the risk of supply disruption to and whether further mitigating actions were required across a range of medicines. The Group considered prescribing data, clinical indications and the availability of clinically suitable alternatives, as well as obtaining specific assurances from suppliers to NHS Wales. The actions implemented and future mitigations proposed by the DHSC to secure medicines supply, along with the already well established processes for managing acute medicines shortages in the UK, were considered adequate and will form the basis of managing any shortages which may occur after the end of the transition period.

### Shortage management response

As noted, the UK Government is responsible for maintaining continuity of supply of medicines. The NHS regularly experiences temporary shortages of medicines and a number of established measures are in place to manage shortages and minimise the risks to patients.

The Serious Shortage Protocol arrangement provides an extra tool to manage and mitigate primary care medicine shortages in the exceptional and rare situation that other measures have been exhausted or are likely to be ineffective.

If a specific medicine shortage emerges at national level, prescribers and pharmacies will be quickly alerted and advised of the appropriate management plan for patients who may be affected.

In preparation for the end of the transition period, the Wales Medicines Shortage Advisory Group has been meeting fortnightly to consider current medicines shortages, mitigations and whether further action is required. The Group will continue to meet fortnightly in the period immediately following 31 December.

Please continue to report medicine shortages through the usual routes and ensure that your organisation shares Welsh Government Medicines Shortage Letters and Public Health Wales Link alerts with fellow healthcare professionals.

## Information on shortages

Summary information about current medicines shortages is published in the Medicines Shortage Log which is updated weekly and available via the NHS intranet at:

<http://howis.wales.nhs.uk/sites3/page.cfm?orgid=428&pid=77202>

Welsh Government Medicines Shortage Letters are published on the Public Health Wales Link system:

<https://www2.nphs.wales.nhs.uk/contacts.nsf>

The Welsh Government mailbox for queries about shortages is:

[Medicinesshortages@gov.wales](mailto:Medicinesshortages@gov.wales)

Yours sincerely



**Andrew Evans**

Prif Swyddog Fferyllol / Chief Pharmaceutical Officer  
Llywodraeth Cymru / Welsh Government

This letter has been distributed to those listed in Annex 1.

**Distribution**

Chief Executives of Health Boards and Trusts  
Medical Directors of Health Boards and Trusts  
Nurse Directors of Health Boards and Trusts  
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Chief Pharmacists of Health Boards and Trusts  
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Royal Pharmaceutical Society (Wales)  
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**Onward circulation by NHS Shared Services Partnership to:**

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