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COMMISSION STAFF WORKING DOCUMENT

Commission report on the phasing out of derogations for certain medicinal products in Cyprus, Ireland, and Malta

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Contents

INTRODUCTION

The withdrawal of the United Kingdom (UK) from the European Union (EU) has presented significant challenges for Cyprus, Ireland, and Malta, which historically relied on the UK for the supply of medicines.

To prevent shortages of medicinal products and ultimately to ensure a high level of public health protection, on 12 April 2022, temporary derogations were granted to these countries, allowing them to continue sourcing medicines for human use from the UK, if necessary, until 31 December 2024. These derogations have been introduced by Regulation (EU) 2022/641[1] and Directive (EU) 2022/642[2] and provided for in Regulation (EU) 536/2014 [3] and Directive 2001/83/EC[4]. For example, during this period in these three countries, importers of medicines from the UK will not need to hold manufacturing authorisations, nor will these medicines need to be batch tested again if they have already been tested in the UK. In addition, Cyprus and Malta will be able, under certain conditions, and for justified public health reasons, to authorise the placing on their national market of a medicine authorised in the UK.

The purpose of this report is to provide information on the progress made by Cyprus, Ireland, and Malta in the phasing out of these derogations.

The Commission has engaged with the relevant authorities in the three Member States at issue, through regular information sharing and situation review meetings. This report is based on the information provided by these Member States to the Commission, in September and October 2023.

It is important to note that the situation may evolve and that the Commission services intend to further accompany the three Member States at issue in phasing out their reliance on the derogations allowing temporarily to supply medicinal products from or through parts of the United Kingdom other than Northern Ireland.

Section 1 of this report offers an overview of each of the three Member States' progress on phasing out the derogations and transition towards sourcing medicines for human use from the EU market. It examines the challenges faced, regulatory initiatives implemented, and alternative routes explored (or being considered) to ensure a consistent supply of medicines for human use.

Section 2 outlines the Commission's actions taken to accompany the competent authorities of Cyprus, Ireland, and Malta in their endeavours.

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[1] Regulation (EU) 2022/641 of the European Parliament and of the Council of 12 April 2022 amending Regulation (EU) No 536/2014 as regards a derogation from certain obligations concerning investigational medicinal products made available in the United Kingdom in respect of Northern Ireland and in Cyprus, Ireland and Malta (Text with EEA relevance). *OJ L 118, 20.4.2022, p. 1–3*

[2] Directive (EU) 2022/642 of the European Parliament and of the Council of 12 April 2022 amending Directives 2001/20/EC and 2001/83/EC as regards derogations from certain obligations concerning certain medicinal products for human use made available in the United Kingdom in respect of Northern Ireland and in Cyprus, Ireland and Malta (Text with EEA relevance). *OJ L 118, 20.4.2022, p. 4–13*

[3] Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1).

[4] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

Annex contains a compilation of data provided by these Member States, showing how they have used the derogations specified in Regulation (EU) 2022/641 and Directive (EU) 2022/642.

I GENERAL OVERVIEW

1. Challenges

a. Cyprus

Cyprus has highlighted the persistent challenges related to accessibility and availability of medicinal products, which were present even before the UK's withdrawal. Cyprus mentioned that the small market size has been a historical deterrent for commercial viability of marketing products in Cyprus, resulting in a continuous lack of several medicinal products in the market. However, Cyprus reported that these challenges were further intensified by the UK's withdrawal.

Based on the information provided by Cyprus until Q3 2023, after the UK's withdrawal, Cyprus is currently facing the following challenges:

- the marketing authorisation granted in Cyprus pursuant to Article 126a of Directive 2001/83/EC of the medicinal products affected by the UK's withdrawal have been withdrawn, and no derogations introduced by Regulation (EU) 2022/641 and Directive (EU) 2022/642 have been sought by the MAH for these products.
- there is a significant number of products that are needed in Cyprus but are either not authorised or not readily accessible:
    - products are imported under Article 5 of Directive 2001/83/EC [5]. The percentage of these imported products in relation to the total number of products on the market in Cyprus is quite significant, reaching almost 20%.
    - the proportion of products actually available in the Cyprus market compared to the products authorised in Cyprus is relatively low, at around 40%.

b. Ireland

Ireland has emphasised the historic close links between the Irish and UK medicinal product supply chains, highlighting its unique position to be impacted by the UK's withdrawal due to geographic proximity and shared language with the UK market for medicines.

Out of an estimated 4000 authorised medicines marketed in Ireland, currently, less than 350[6] medicines are availing of the derogations established by Regulation (EU) 2022/641 and Directive (EU) 2022/642. Based on the information provided by Ireland until Q3 2023, Ireland expects that suppliers of many of these medicinal products will seek to continue to apply the derogations until the last possible opportunity to delay incurring the additional costs associated with making the required changes. In cases where such changes are not

[5] Import of non-authorised medicinal products for compassionate use on a named patient basis.

[6] These products can be broken down into two main categories: medicinal products which are supplied by large multinational companies with an established presence in multiple EU markets and medicinal products supplied by small companies, who historically have only supplied the UK and Irish markets and who do not have a presence in other EU countries.

commercially feasible, there is a risk of the marketing authorisation being withdrawn, eventually leading to the loss of some products to the Irish market.

In addition, Ireland has reported that the adoption of Regulation (EU) 2023/1182 [7], to become applicable on 1 January 2025, if certain conditions are met, significantly changed the landscape in which future planning was based upon, particularly regarding the use of joint IE/UK packs for centralised products. Work is still ongoing to assess the additional impact of this change.

c. Malta

The UK market for medicines was the natural purchase market for Malta, primarily due to the labelling requirements under the pharmaceutical legislations.

Based on the information provided by Malta until Q3 2023, after the UK's withdrawal, Malta is currently facing the following challenges:

- Lack of interest from suppliers within the EU to supply Malta. Many public tenders have no bidders with EU compliant products.
- Additional repackaging and relabelling requirements;
- Complex procurement processes and consequences to the out-of-pocket private market complementing the public health system;
- Industry's overall refusal to apply for authorisations through decentralised procedure (DCP) and/or the mutual recognition procedure (MRP);
- Low volumes in demand linked to treatments approved on a named patient basis (Article 5 of Directive 2001/83/EC), treatment reserved on a stand-by stock basis and effect of long-standing product recalls;
- Clinicians who have acquired prescribing habits from the UK;
- Malta has emphasised the importance of the private market complementing the public health system and expressed concerns about the impact of global shortages on both sectors. It explained that if the private sector alternative fails, supplies procured by the Maltese authority in charge of procurement for the public health systems also have to be diverted to the out-of-pocket private market in order to ensure continuity of care for the relevant patients.

2. *Regulatory efforts and alternative routes to address these challenges*

a. Cyprus

Cyprus reported that the derogations were not really used for concerned products because the particular MAHs did not have any intention of moving their batch release/testing facilities within the EU or registering the MAH company in the EU. As such, Cyprus mentioned that no extension of the derogation period (i.e., beyond 31 December 2024) is deemed necessary.

Cyprus reported that it is actively implementing measures and exploring regulatory flexibilities and alternatives to address its challenges. Some of the measures reported by Cyprus include:

[7] Regulation (EU) 2023/1182 of the European Parliament and of the Council of 14 June 2023 on specific rules relating to medicinal products for human use intended to be placed on the market in Northern Ireland and amending Directive 2001/83/EC (Text with EEA relevance)

- The use to the "*zero-day procedure",* i.e. the MRP, as provided for by Article 28 of Directive 2001/83/EC, with a shortened timetable in view of mitigating the effects of shortages or other issues relating to access to critical medicines. In this procedure, the concerned Member State recognises the marketing authorisation at stake on the basis of the application approved by other Member States, reducing the timeline from 90 days to basically zero. This procedure can be used when a Member State has not been included in the original or subsequent wave(s) of a DCP or MRP.
- Cyprus reported that while the "*zero-day procedure*" has been successful for products already undergoing a MRP, its use has been limited due to too high reference Member State (RMS) fees.
- Measures to encourage the use of common packaging with other Member States and other flexibilities related to stock exhaustion.
- Low fees for most procedures to ensure that fees do not discourage industry participation in applying for a marketing authorisation in Cyprus.
- More targeted effort to address the accessibility and availability challenge was made prior to the UK's withdrawal by publishing a list of needed products, not authorised in Cyprus or for which Cyprus often experiences availability issues, and which are imported via Article 5 of Directive 2001/83/EC. Cyprus confirmed that such list has been shared with the industry but that the response has been limited.

Given the current challenges, Cyprus has also called for further modifications of the EU pharmaceutical general legislation in the framework of the currently on-going reform, including measures (more language flexibilities, stronger obligations for MAHs to market their products, fee waivers) aiming to improve the situation in small markets such as the Cyprus market. Cyprus reported that the current legislative reform proposals will be of great benefit with regards to access of Cypriot patients to innovative products. Taking note of the changes proposed in the reform to national procedures, MRP and DCP, Cyprus highlighted the importance of these parts for the national market.

b. Ireland

Since the UK confirmed its intention to leave the EU in 2017, Ireland has been working intensively to retain the supply of authorised medicines on the market and has been preparing for the ending of the derogations on 31 December 2024.

Ireland has reported that the number of medicinal products still availing of (at least one of) the time-limited derogations granted in 2022 is continuing to decline. Through intensive engagement with MAHs, Ireland is hopeful that the number of products on the market availing of at least one derogation will soon reduce to approximately 280. Ireland also reported that it is expected that suitable alternative medicinal products will be available for some of these products to ensure continuity of treatment for patients. Finally, Ireland mentioned a significant reduction compared to the pre-UK's withdrawal situation regarding the nationally authorised 'marketed/unknown' medicines still using either joint IE/NI or IE/UK packs - (relatively low) percentage - 9.1% (167 out of 1842 (who responded to inquiries) still using either joint IE/NI or IE/UK packs).

In order to address the remaining challenges, Ireland reported that it has implemented several measures:

- It has communicated to companies that no further extension of the duration of the derogations will occur;
- The Irish Department of Health, the Irish Health Products Regulatory Authority (HPRA) and the Health Service Executive (HSE) have been consistently monitoring and reviewing the situation. The HPRA is actively contacting all companies availing of the exemptions to understand their long-term plans for their products.
- In a certain of cases, where clinically necessary, Ireland acknowledges that some medicinal products may need to be sourced as unauthorised medicinal products under Article 5 of Directive 2001/83/EC. However, Ireland views this as a sub-optimal outcome and not a viable long-term solution, as medicinal products would no longer be covered by marketing authorisations.
- Regarding the challenges posed by the Windsor Framework, Ireland has intensified engagement with MAHs since the adoption of Regulation (EU) 2023/1182.

Ireland reported that it is considering further alternatives to address its remaining challenges. In particular, Ireland is keen to facilitate joint packs (including multilingual packs) with other Member States and is open to working towards facilitating electronic leaflets. However, Ireland cannot yet assess the impact of the challenge posed by the ending of joint packs with the UK. Previous efforts made by the HPRA to encourage joint packs with other EU countries has not led to increased uptake of this option by MAHs.

c. Malta

To address its challenges, Malta is taking various measures:

- Malta confirmed that it is working on a pilot project to electronically label products dispensed within the Maltese public health system, which tests exemptions from the inclusion of a paper leaflet in medicinal products, derogating from requirements of Article 61(1) of Directive 2001/83/EC, pursuant to Article 63(3) of Directive 2001/83/EC, to improve availability. Malta reported that it is currently developing a software to link the medicinal product to the ePIL in English, without tampering with the packaging of the product.
- Malta confirmed that it signed a Memorandum of Understanding (MoU) with one Member State to facilitate competition in Maltese tenders for the supply of the Maltese public health system. Malta is having similar discussions with other Member States, however no other MoU was signed yet at this date.
- Malta reported that it established an emergency route to supply medicines when the tendering process is not completed for reasons beyond the control of the Maltese authority in charge of procurement (such as withdrawal of offers, appeals and non-compliant specifications), although this emergency route involved time-consuming and costly procedures. In particular, Malta reported that through this emergency route it has managed to get competitive sources from different EU Member States since they bid for short term orders. For such items, the Maltese authority in charge of procurement seeks an urgent distribution of non-authorised medicinal products through Article 5 of Directive 2001/83/EC. Even though the order covers a two-month-stock based on annual consumption, such import of non-authorised medicinal product is conditional on the Government to register the product in Malta. This also requires that the Maltese authority in charge of procurement caters for the translations

of the patient information leaflet and of the summary of the products characteristics in the English or Maltese language.

- Malta is urging companies to apply for marketing authorisation of medicines for the Maltese market through the MRP and DCP routes, including Malta as concerned Member State (CMS). Whilst there has been a measure of success as some companies have resorted to this type of procedures, Malta reported that companies continue to resort to the route provided by Article 126a of Directive 2001/83/EC, rather than adding Malta as CMS (fee for Malta is €250) and that, so far this year, 453 marketing authorisations have been granted on the basis of Article 126a for products originating from the EU/EEA. According to the analysis of the Maltese authority, the companies claim either the high fees of the RMS to include Malta as CMS, or the refusal of some Member States to act as RMS, or the fact that adding Malta as CMS may create additional regulatory burden in view of economies of scale. It is important to note that these considerations on the MR and DC procedures were raised by Malta in numerous fora, including the Heads of Medicines Agencies network (HMA), the Co-ordination Group for Mutual Recognition and Decentralised procedures - Human (CMDh) and one-to-one meetings with some competent authorities, with however limited progress, if any.

In conclusion, Malta reported that it decreased its dependency on supply from the UK from 85% in 2019 to 65% in 2023 and that efforts towards further reducing that dependency are ongoing and new options being explored.

Malta highlighted that the dependency on the UK market is still significant and that *de facto* the COVID-19 pandemic and the global challenges to the supply chains have made the phasing out process more difficult than expected. In particular, it is important to note that Malta indicated that it believes it difficult to foresee that the total dependency on the supply from the UK market will be ever eliminated through its ongoing efforts within the deadline indicated in the legislation[8] (31 December 2024). Malta is however confident that it could improve the sourcing from the EU market as long as the companies support the authorities' efforts in supplying the Maltese market. Finally, as potential new solutions from the revision of the EU pharmaceutical general legislation would only come after the end of the derogations, Malta expressed concerns about the gap time between the end of the derogations and the application of these new proposed solutions.

Given the current challenges, Malta has also called for further modifications of the EU pharmaceutical general legislation in the framework of the currently on-going reform, including measures (incentives or stronger obligations on MAHs) aiming to improve the situation in small markets such as the Maltese market (so that MAHs include small Member States in their market access commercial strategies and also to periodically repeat MRP, in particular for those products which are already on the market). Malta finally pointed out that it is to be ensured that products are authorised and actually placed on the market at a reasonable price.

[8] see Introduction and footnotes 1 and 2.

II COMMISSION'S ACTIONS OF THE COMMISSION TO ACCOMPANY THE COMPETENT AUTHORITIES OF CYPRUS, IRELAND, AND MALTA.

The Commission has collaborated with the competent authorities of Cyprus, Ireland, and Malta, through regular information sharing and review meetings.

The Commission has reminded industrial operators, which still need to make changes to their supply chains, of the urgent need to adapt in order to ensure access to medicines in smaller markets.

Furthermore, and beyond these immediate and necessary steps, in April 2023, the Commission presented its proposals to reform the EU pharmaceutical general legislation. These proposals aim to ensure access to medicines for all patients across Europe, including those in smaller Member States that are often overlooked by companies due to their small, commercially less attractive market or language barriers. The reform proposals include several measures:

- Facilitating the use of electronic product information and multi-country packages to overcome language barriers.
- Enhancing security of supply, addressing risks of shortages, and simplifying the authorisation procedures to reduce bureaucratic hurdles and improve access to medicines for all Europeans.
- Transitioning from a one size fits all incentives system to a system that rewards the launch of medicines in all Member States simultaneously, enabling all citizens to benefit.

FINAL REMARKS

This report is based on the information provided by the Member States concerned as of Q3 2023.

It is important to acknowledge that the situation is dynamic, and the Commission services intend to further monitor developments in these Member States in accordance with Union law and the distribution of competences between the Union and Member States in the field of medicines for human use.

The Commission services intend to continue to accompany the competent authorities of Cyprus, Ireland, and Malta in their endeavours to reduce their domestic market's reliance on the supply of medicinal products from or through parts of the United Kingdom, excluding Northern Ireland, by the legal deadline of 31 December 2024.

The Commission services note the significant efforts made by Cyprus, Ireland, and Malta to phase out the derogations introduced by Regulation (EU) 2022/641 and Directive (EU) 2022/642. However, achieving this objective remains challenging. Therefore, the Commission service intends to work closely with the concerned Member States encouraging them to intensify their efforts in reducing their domestic market's reliance on the supply of medicinal products from or through parts of the United Kingdom, and it also encourages other Member States to demonstrate greater solidarity.

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ANNEX DATA PROVIDED BY MEMBER STATES RELATING TO THE USE OF THE DEROGATIONS SPECIFIED IN REGULATION (EU) 2022/641 AND DIRECTIVE (EU) 2022/642

CYPRUS

	October 2022	April 2023	October 2023
(Number of) Investigational medicinal products allowed to be imported from parts of the United Kingdom other than Northern Ireland without a manufacturing and import authorisation, provided that the conditions of Article 1 of the Directive (EU) 2022/642 and of Article 1 of the Regulation (EU) 2022/641 are fulfilled. - **please list the investigational medicinal product(s) concerned**	0	0	0
(Number of) Marketing authorisations granted in accordance with the mutual recognition or the decentralised procedures to marketing autorisation holders established in parts of the United Kingdom other than Northern Ireland, in accordance with Article 2(2) of the Directive. - **please list the marketing authorisation holder(s) concerned** **please list the medicinal product(s) concerned**	0	0	0
Number of "justifiable case" within the meaning of Article 2(4) of the Directive allowing quality control testing in parts of the United Kingdom other than Northern Ireland, provided that the conditions of Article 2(4) of the Directive are fulfilled. - **please list the medical product(s) concerned**	4 Products: 1) D-Gam Solution for Injection 50mg/ml 2) Zenalb 20 solution for Infusion 3) Optivate Powder and Solvents for Solution for Injection 4) Replenine VF Powder for	3 Products: 1) HEPARIN SODIUM 10 I.U./ML FLUSHING SOLUTION FOR MAINTENANCE OF PATENCY OF INTRAVENOUS DEVICES FLUSHING SOLUTION 10IU/ML 2) CODEINE PHOSPHATE TABLET 30MG 3) DISPERSIBLE	2 Products 1) Histergan Cream (derogation only for a specific quantity of the product) 2) Protamine sulphate Solution for Injection 10mg/ml

	October 2022	April 2023	October 2023
	reconstitution 500IU	ASPIRIN TABLET 75MG	
(Number of) Medicinal products imported from parts of the United Kingdom other than Northern Ireland by holders of a wholesale distribution autorisation who are not in possession of a relevant manufacturing autorisation, provided that the conditions of Article 2(5) of the Directive are fulfilled. - **please list the medicinal product(s) concerned**	0	0	0
(Number of) Applications made by holders of a wholesale distribution autorisation to obtain the manufacturing autorisation to end the derogatory regime and measure progress toward compliance with EU law. - **please indicate the holder(s) of such wholesale distribution authorisation in possession of a relevant manufacturing authorisation** - **please indicate whether the manufacturing authorisation is time limited and for how long any contractual relationships are granted**	0	0	0
(Number of) Batches of medicinal products exported to parts of the United Kingdom other than Northern Ireland from a Member State and subsequently into Cyprus, Ireland or Malta - **please indicate the medicinal product(s) concerned**; - **please provide proof that they have undergone batch testing in a Member State prior to being exported to Great Britain; and that they are accompanied by the control reports**, as referred to in Article 2(6) of the Directive.	0	0	0
(Number of) Medicinal products which are authorised in parts of the United Kingdom other than Northern Ireland, that Cyprus and Malta decided to authorise in the absence of a marketing authorisation or of a pending application for a marketing authorisation and the justified public health reasons in accordance with Article 2(10) of the Directive. - **please indicate the medicinal product(s) concerned and the marketing authorisation holder(s)**	0	1 Product: HEPARIN SODIUM 10 I.U./ML FLUSHING SOLUTION FOR MAINTENANCE OF PATENCY OF INTRAVENOUS DEVICES FLUSHING SOLUTION 10IU/ML	1 Product: Protamine Sulphate Solution for Injection 10mg/ml

	October 2022	April 2023	October 2023
		MAH: WOCKHARDT UK LTD, UK	
(Number of) Marketing authorisations granted, extended or maintained in force, in accordance with Article 2(10) of the Directive. - **please indicate the medicinal product(s) concerned and the marketing authorisation holder(s)**	4 1) D-Gam Solution for Injection 50mg/ml 2) Zenalb 20 solution for Infusion 3) Optivate Powder and Solvents for Solution for Injection 4) Replenine VF Powder for reconstitution 500IU	3 Number of products: 3 1) Product: PHENYLEPHRINE SOLUTION FOR INJECTION OR INFUSION 10MG/ML MAH: BEACON PHARMACEUTICALS LIMITED, UK 2) Product: CODEINE PHOSPHATE TABLET 30MG MAH: BRISTOL LABORATORIES LTD, UK 3) Product: DISPERSIBLE ASPIRIN TABLET 75MG MAH: MEDILINK PHARMACEUTICALS LTD, CY	1 Product: Protamine Sulphate Solution for Injection 10mg/ml

IRELAND

	October 2022	April 2023	October 2023
(Number of) Investigational medicinal products allowed to be imported from parts of the United Kingdom other than Northern Ireland without a manufacturing and import authorisation, provided that the conditions of Article 1 of the Directive and of Article 1 of the Regulation are fulfilled. - **please list the investigational medicinal product(s) concerned**	0	0	0
(Number of) Marketing authorisations granted in accordance with the mutual recognition or the decentralised procedures to marketing autorisation holders established in parts of the United Kingdom other than Northern Ireland, in accordance with Article 2(2) of the Directive. - **please list the marketing authorisation holder(s) concerned** **please list the medicinal product(s) concerned**	0	0	0
Number of "justifiable case" within the meaning of Article 2(4) of the Directive allowing quality control testing in parts of the United Kingdom other than Northern Ireland, provided that the conditions of Article 2(4) of the Directive are fulfilled. - **please list the medical product(s) concerned**	298 1st reporting period under Directive 2022/642	294 - 1.3% reduction in the number of derogations from 1st reporting period.	179 40% reduction since April 2023 reporting period.
(Number of) Medicinal products imported from parts of the United Kingdom other than Northern Ireland by holders of a wholesale distribution autorisation who are not in possession of a relevant manufacturing autorisation, provided that the conditions of Article 2(5) of the Directive are fulfilled. - **please list the medicinal product(s) concerned**	367 1st reporting period under Directive 2022/642 See Excel document entitled 'Nov 2022 Import under a WDA'	304 - 17% reduction in the number of derogations since 1st reporting period. See Excel document entitled 'April 2023 Import under a WDA'	205 32.5% reduction since April 2023 reporting period.
(Number of) Applications made by holders of a wholesale distribution autorisation to obtain the manufacturing autorisation to end the derogatory regime and measure progress toward compliance with EU law. - **please indicate the holder(s) of such wholesale distribution authorisation in possession of a relevant**	0	0	0

	October 2022	April 2023	October 2023
manufacturing authorisation - **please indicate whether the manufacturing authorisation is time limited and for how long any contractual relationships are granted**			
(Number of) Batches of medicinal products exported to parts of the United Kingdom other than Northern Ireland from a Member State and subsequently into Cyprus, Ireland or Malta - **please indicate the medicinal product(s) concerned**; - **please provide proof that they have undergone batch testing in a Member State prior to being exported to Great Britain; and that they are accompanied by the control reports**, as referred to in Article 2(6) of the Directive.	38 number of products not batches. HPRA required and received a declaration from each MAH that the batches of medicinal product have undergone the controls upon importation referred to Article 51(1) of Directive 2001/83/EC, first and second paragraphs, in a MS prior to being exported to Great Britain and are accompanied by the control reports referred to in article 51(1) third subparagraph of Directive 2001/83/EC. These products are compliant with EU regulatory requirements, other than being imported from Great Britain. 1st reporting period under Directive 2022/642	42 refers to the number of products not batches. HPRA required and received a declaration from each MAH that the batches of medicinal product have undergone the controls upon importation referred to Article 51(1) of Directive 2001/83/EC, first and second paragraphs, in a MS prior to being exported to Great Britain and are accompanied by the control reports referred to in article 51(1) third subparagraph of Directive 2001/83/EC. These products are compliant with EU regulatory requirements, other than being imported from Great Britain. + 10.5% increase in the number of derogations since 1st reporting period. See Excel document entitled 'April 2023 BR and QC testing in EU'	48 refers to the number of products not batches. HPRA required and received a declaration from each MAH that the batches of medicinal product have undergone the controls upon importation referred to Article 51(1) of Directive 2001/83/EC, first and second paragraphs, in a MS prior to being exported to Great Britain and are accompanied by the control reports referred to in article 51(1) third subparagraph of Directive 2001/83/EC. These products are compliant with EU regulatory requirements, other than being imported from Great Britain. 14% increase in the number of derogations since April 2023 reporting period.

MALTA

	June 2022	October 2022	April 2023	October 2023
(Number of) Investigational medicinal products allowed to be imported from parts of the United Kingdom other than Northern Ireland without a manufacturing and import authorisation, provided that the conditions of Article 1 of the Directive and of Article 1 of the Regulation are fulfilled. - **please list the investigational medicinal product(s) concerned**	0	0	0	0
(Number of) Marketing authorisations granted in accordance with the mutual recognition or the decentralised procedures to marketing authorisation holders established in parts of the United Kingdom other than Northern Ireland, in accordance with Article 2(2) of the Directive. - **please list the marketing authorisation holder(s) concerned** **please list the medicinal product(s) concerned**	0	0	0	0
Number of "justifiable case" within the meaning of Article 2(4) of the Directive allowing quality control testing in parts of the United Kingdom other than Northern Ireland, provided that the conditions of Article 2(4) of the Directive are fulfilled. - **please list the medical product(s) concerned**		69 +15% from June 2022	70 +1.5% from last update	78 +11.45% from last update
(Number of) Medicinal products imported from parts of the United Kingdom other than Northern Ireland by holders of a wholesale distribution authorisation who are not in possession of a relevant manufacturing authorisation, provided that the conditions of Article 2(5) of the Directive are fulfilled. - **please list the medicinal product(s) concerned**		157 +23.6% from June 2022	165 +5.1% from last update	176 +6.6% from last update
(Number of) Applications made by holders of a wholesale distribution authorisation to obtain the		4	4	4

	June 2022	October 2022	April 2023	October 2023
manufacturing authorisation to end the derogatory regime and measure progress toward compliance with EU law. - **please indicate the holder(s) of such wholesale distribution authorisation in possession of a relevant manufacturing authorisation** - **please indicate whether the manufacturing authorisation is time limited and for how long any contractual relationships are granted**		The wholesale dealers below (in Malta) have been granted an importer's authorisation: Charles de Giorgio Limited Mint Health Limited Pharmabart Limited Cherubino Limited An importer's authorisation is granted for 3 years. A re-inspection would be required to extend the validity.	The wholesale dealers below (in Malta) have been granted an importer's authorisation: Charles de Giorgio Limited Mint Health Limited Pharmabart Limited Cherubino Limited An importer's authorisation is granted for 3 years. A re-inspection would be required to extend the validity.	The wholesale dealers below (in Malta) have been granted an importer's authorisation: Charles de Giorgio Limited Mint Health Limited Pharmabart Limited Cherubino Limited An importer's authorisation is granted for 3 years. A re-inspection would be required to extend the validity.
(Number of) Batches of medicinal products exported to parts of the United Kingdom other than Northern Ireland from a Member State and subsequently into Cyprus, Ireland or Malta - **please indicate the medicinal product(s) concerned**; - **please provide proof that they have undergone batch testing in a Member State prior to being exported to Great Britain; and that they are accompanied by the control reports**, as referred to in Article 2(6) of the Directive.		This information (by batch) is not available. Products are not exported to the United Kingdom from the EU and imported back into Malta. The medicinal products are arriving directly from UK.	This information (by batch) is not available. Products are not exported to the United Kingdom from the EU and imported back into Malta. The medicinal products are arriving directly from UK.	This information (by batch) is not available. Products are not exported to the United Kingdom from the EU and imported back into Malta. The medicinal products are arriving directly from UK.
(Number of) Medicinal products which are authorised in parts of the United Kingdom other than Northern Ireland, that Cyprus and Malta decided to authorise in the absence of a marketing authorisation or of a pending application for a marketing authorisation and the justified public health reasons in accordance with Article 2(10) of the Directive. - **please indicate the medicinal product(s) concerned and the marketing authorisation holder(s)**	37	93 +151% from June 2022	179 +92% from last reported in October 2022 *This number does not include authorisations granted on the basis of article 126a before end of 2020 to the public health service	263 +46.93% from last reporting in April 2023

	June 2022	October 2022	April 2023	October 2023
			and maintained into force after the publication of Directive 642/2022 (551 products)	
(Number of) Marketing authorisations granted, extended or maintained in force, in accordance with Article 2(10) of the Directive. - **please indicate the medicinal product(s) concerned and the marketing authorisation holder(s)**	46	68 +47.8% from last reported in June 2022 *This number does not include authorisations granted on the basis of article 126a before end of 2020 to the public health service and maintained into force after the publication of Directive 642/2022 (551 products).	77 +13.24% from last reported in October 2022 *This number does not include authorisations granted on the basis of article 126a before end of 2020 to the public health service and maintained into force after the publication of Directive 642/2022 (551 products).	80 +3.9% from last reporting in April 2023 *This number does not include authorisations granted on the basis of article 126a before end of 2020 to the public health service and maintained into force after the publication of Directive 642/2022 (551 products).