Medicines & Healthcare products Regulatory Agency

Post-Implementation Review of the Human Medicines Regulations 2012: Questionnaire

We are writing to invite you to participate in a Post Implementation Review of the Human Medicines Regulations 2012 (HMRs), conducted by the Medicines & Healthcare Products Regulatory Agency (MHRA) with the Department of Health and Social Care (DHSC).

It is a statutory obligation to carry out this Review and regulation 346 of the HMRs sets out the requirement. This includes which regulations from the HMRs are to be assessed and their key areas, which are as follows:

- Pharmacovigilance
- Cross border prescriptions
- Sales and supply:
    - Exemptions for certain collection and delivery arrangements
    - The repeal of Section 10(7) of the Medicines Act 1968 on Pharmacy wholesale dealing
- Falsified medicines

As part of the review, we are keen to gain views and experiences on the extent to which the objectives for the above areas have been achieved, whether they remain appropriate and, if so, the extent to which they could be achieved with a system that imposes less regulation.

A copy of the most recent version of the HMRs can be accessed at: The Human Medicines Regulations 2012 (legislation.gov.uk). Details of the requirements of this review can be found in regulation 346.

This is the second Review since the implementation of the HMRs, with the first taking place in 2017[1].

[1] PIR_HMRs_Final_Report_publication.pdf (publishing.service.gov.uk)

Our request

This is a targeted Review and you have been identified as a key stakeholder to help inform it. We would be grateful for your views and experiences on those sections of the questionnaire which are relevant to you or your organisation. In addition, we encourage all respondents to answer the general questions in Section 6.

All of the questions are aligned to the statutory requirements. Please provide us with objective responses and where possible, specific examples.

Since the 2017 Review, the context of the HMR regulatory framework has changed as the MHRA became the UK's sovereign medicines and medical devices regulator, when the UK left the EU. This resulted in amendments to the HMRs to implement the EU Exit agreement, including provisions for Northern Ireland. These changes do not affect the underlying policy intent of the regulations which are being considered in this questionnaire.

The findings from the completed questionnaire will inform the Review and the outcome will be submitted to the Regulatory Policy Committee and outlined in a report published by the Secretary of State for Health and Social Care.

The online version of the questionnaire can be accessed here. Alternatively, you can complete this MS Word version of the questionnaire. Please send your completed MS Word form to: Partnerships@mhra.gov.uk.

The deadline for completing the questionnaire is by 9am on Monday, 13 May 2024.

If you have any questions relating to this review and the completion of the questionnaire, please email: Partnerships@mhra.gov.uk.

Questionnaire

Contents

Please answer all sections that are of relevance to you or your organisation.

Section 1: Pharmacovigilance

Implementation of the Pharmacovigilance (PV) Directive

Provisions - Part 11 and Regulations – 59; 60(3)(b), (9) and (10); 61; 63; 64(4)(b), (d) and (e), (5)(a) and (6); 65(2); 66(5) and (6); 68(2)(a) and (b) and (5); 69(2)(a) and (b), (5) and (10); 73(5A) to (5C); 75(2)(b) and (c); 76; 79; 82(1)(c); 85; 86; 97; 105(3)(b); 107(2), 108(5), 113(3A), 115(2)(b) and (C);, 132(2), 133(5) and (6), 142(5A) to (5C); 266(4) and (5); 327(2)(g) and insofar as the provision relates to active substances paragraphs (1)(c)(iii), (iv) and (viii), (2)(a) to (f), (3), (4) and (6); 331; Schedule - 8 paragraphs 9A, 12, 13, 19 and 23; 12 paragraph 21; 27 paragraphs 14 and 15; 27 paragraphs 14 and 15 where they apply to PV.

The HMRs implemented national requirements of EU PV legislation, Directive 2010/84/EU, key objectives of which included:

- Rationalising EU decision-making on drug safety to deliver measures that are equally implemented across the community.
- Strengthened PV systems, allowing continuous improvement while reducing administrative burden.
- Greater communication to increase understanding and trust of patients and health professionals.

Since the last Review, regulations have been amended to reflect the UK's Exit from the EU and the requirements with regards to the supply of human medicines to Northern Ireland. Amendments include changes that apply to UK marketing authorisation holders regarding PV practices.

1. Overall, do you believe the objectives outlined above for implementing the PV Directive have been met? [please select as appropriate]

   Completely met ☒

   Partially met ☐

   Not met ☐

   Unsure ☐

   Please provide us with any further details you may have.

   The HMR has been updated to ensure that EU requirements are transposed into UK legislation. The accompanying guidance is particularly useful for Risk Management Plans (RMPs) and Periodic Safety Update Reports (PSURs).

2. What effect has the implementation of the PV Directive had on patient safety? [please select as appropriate]

Vastly improved	☐
Improved	☐
No change	☒
Decreased	☐
Vastly decreased	☐
Unsure	☐

Please provide us with any further details you may have.

We anticipate that these positive steps in pharmacovigilance have improved patient safety. Through our engagement exercise we have not been made aware of any specific examples to illustrate this.

3. What best describes the impact the PV Directive has had on industry? [please select as appropriate]

Vastly reduced burden	☐
Somewhat reduced burden	☐
No impact	☐
Somewhat increased burden	☒
Vastly increased burden	☐
Unsure	☐

Please provide us with any further details you may have.

Additional annexes may be required for RMPs and PSURs, which can increase the burden slightly. However, this increase is minimal, and since the differences apply primarily to regions outside the EEA, the impact is not significant.

4. Please provide us with suggestions for improvements if you have seen a decrease in patient safety and/or an increased burden on industry:

n/a

5. Are you aware of any unintended or unforeseen consequences as a result of the implementation of the PV Directive? [please select as appropriate]

Yes ☐

No ☐

Unsure ☒

Please provide us with any further details you may have.

6. Have there been any benefits or costs arising from the implementation of the PV Directive? [please select as appropriate]

Yes ☐

No ☐

Unsure ☒

Please provide us with any further details you may have, including any estimates of costs or benefits or other evidence to support your answer.

7. How does the way in which the PV Directive has been implemented in the UK compare to implementation in EU Member States? [please select as appropriate]

More burdensome ☐

Burdensome ☐

In line with other Member States ☒

Less burdensome ☐

Significantly less burdensome ☐

Unsure ☐

Please provide us with any further details you may have.

The implementation in the UK has remained essentially unchanged compared to the EU.

8. Taking into account your feedback for this section, do you think the policy objectives for PV remain appropriate?

Yes ☒

No ☐

Unsure ☐

Please provide us with any further details you may have.

Our member feedback suggests that the output from the Baroness Cumberlege report should be taken into account in this review. The Baroness Cumberlege Report – First do no harm (Published 8th July 2020) – HQIP

9. Do you think the policy objectives for PV could be achieved with less regulation? [please select as appropriate]

Yes ☐

No ☒

Unsure ☐

If yes, please give specific feedback including which regulations you think could be amended.

Maintaining robust reporting and communication mechanisms are crucial, and regulation is the vehicle for assuring processes.

Section 2: Cross Border Prescriptions.

Implementation of cross border prescriptions Regulations: 213(3); 217A; 218(2)(b), (3) and (5); 219 and 219A
Objective: The HMRs, as amended in 2019, have enabled dispensing healthcare professionals to dispense certain prescriptions written outside the UK if it was written by a member of a listed profession and written in a listed country, and otherwise meets the requirements in the HMRs.

1. What effect has cross border recognition of prescriptions had on patients?

   [please select as appropriate]

   Very beneficial ☐

   Beneficial ☒

   No change ☐

   Detrimental ☐

   Very Detrimental ☐

   Unsure ☐

   Please provide us with any further details you may have.

Our feedback from members highlights the importance of alternative routes for accessing medicines which has benefits for those visitors travelling to the UK and widens access to medicines for them. In addition, for those UK residents who access care abroad, they can then secure a supply of medicines through this route, ensuring timely access to medicines.

2. What effect have cross border prescriptions had on pharmacists? [please select as appropriate]

   Very beneficial ☐

   Beneficial ☒

   No change ☐

   Detrimental ☒

   Very Detrimental ☐

Unsure ☐

Please provide us with any further details you may have.

Managing expectations of patients who wish to access medicines supply in this way can be difficult for pharmacy teams who have a number of checks to complete before supplying a medicine.
The benefits to pharmacists are related to the ability to provide care and support for patients who present these prescriptions.
The administrative burden on pharmacists and their teams to complete the checks on cross border prescriptions is considerable. Factors such as prescription legality, prescriber status, licensed indication, prescribing by brand can sometimes lead to a delay in dispensing the medication and the frustration from patients can lead to aggression towards the community pharmacy workforce.
Pharmacists have been placed in positions where they have been presented with legally valid prescriptions but through which it is complicated to complete due diligence to assure the clinical appropriateness of the prescription. For some indications e.g. ADHD, gender incongruence; safety checks may also lead to ethical dilemmas for the pharmacist (especially for prescriptions for children). Any delays due to the safety checks being undertaken may be misinterpreted by the patient as judgement or bias and lead to aggressive interactions with staff.

3. If you think cross border prescriptions have been detrimental, have there been specific difficulties for pharmacists?

Our Professional Support team receives a significant number of queries related to cross border prescriptions and from interaction with members, there is low level awareness of the enabling legislation in this area, furthermore members struggle to understand how to manage electronic prescriptions. It is also challenging to appreciate the differences between electronic signatures (Regulation 219a) and advanced electronic signatures (Regulation 219).

Verifying prescriber identity and/or prescribing intention (when there is ambiguity or error on the prescription) is difficult. On some occasions, the prescribing activity is within a therapeutic area where UK guidance does not support the prescription, therefore increasing the risk for the pharmacist who must make a decision about supply.

4. What effect have cross border prescriptions had on healthcare professionals (other than pharmacists)? [please select as appropriate]

Very beneficial ☐

Beneficial ☐

No change ☐

Detrimental ☐

Very Detrimental ☐

Unsure ☒

Please provide us with any further details you may have.

5. If you think cross border prescriptions have been detrimental, have there been specific difficulties for healthcare professionals (other than pharmacists)? [Please provide any further details below]

6. Overall, in your view, what best describes how the requirements to recognise cross border prescriptions have been implemented in the UK? [please select as appropriate]

Vastly reduced burden ☐

Somewhat reduced burden ☐

No impact ☐

Somewhat increased burden ☒

Vastly increased burden ☐

Unsure ☐

Please provide us with any further details you may have.

7. Please provide us with suggestions for improvements should there be an opportunity to reduce burdens on businesses and/or healthcare professionals as a result of cross border prescriptions.

Putting the requirement for cross border prescriptions to be a physical copy with contact details for the prescriber would mitigate some of the challenges.

8. Have there been any benefits or costs relating to cross border prescriptions (i.e. for patients or pharmacists)? [please select as appropriate]

Yes ☐

No ☐

Unsure ☒

Please provide us with any further details you may have, including any estimates of costs or benefits or other evidence to support your answer.

Patients accessing healthcare in this way can be expected to pay for the medicines supplied in this way.
Anecdotally, it may be comparatively more costly to process a cross border prescription than the equivalent UK private prescriptions. This could be
A result of the due diligence necessary, for example, the staff time required to perform any necessary additional regulatory/legal checks with associated phone calls etc.

9. How does the implementation of cross border prescriptions in the UK compare to their implementation in EU Member States? [please select as appropriate]

More burdensome ☐

Burdensome ☐

In line with other Member States ☐

Less burdensome ☐

Significantly less burdensome ☐

Unsure ☒

Please provide us with any further details you may have.

In other EU member states they have prohibited the use of digital prescriptions from overseas (e.g. Ireland), and therefore not encountered some of the problems seen in the UK to the same extent.

There may be geographical variation in the value placed on cross border prescription availability e.g. Northern Ireland.

10. Taking into account feedback in this section, do you think the policy objectives for cross border prescriptions remain appropriate? [please select as appropriate]

Yes ☒

No ☐

Unsure ☐

Please provide us with any further details you may have.

The objective of allowing prescriptions to be dispensed from other countries was met. However, this has precipitated other issues particularly in relation to online prescribing which has driven prescribing and practice outside of the regulatory framework of the UK. To this end the changes haven't always been beneficial to patients.

11. Do you think the policy objectives for cross border prescriptions could be achieved with less regulation? [please select as appropriate]

Yes ☐

No ☒

Unsure ☐

If yes, please give specific feedback including which regulations you think could be amended.

Section 3 - Sale and Supply: Exemptions for certain collection and delivery arrangements

Exemptions for certain collection and delivery arrangements (regulations 248(1)(a) and (2)(a)
"Collection and delivery arrangement" means an arrangement whereby a retail pharmacy may take or send a medicine to be supplied in accordance with a prescription given by a doctor, dentist, nurse independent prescriber, pharmacist independent prescriber, physiotherapist independent prescriber, podiatrist independent prescriber, therapeutic radiographer independent prescriber, paramedic independent prescriber or optometrist independent prescriber for collection from premises other than a registered pharmacy and which are capable of being closed by the occupier to exclude the public.

1. What impact has regulation 248(1)(a) and (2)(a) had on patient access to medicines? [please select as appropriate]

   Improved ☒

   No change ☐

   Worsened ☐

   Don't know ☐

   Unsure ☐

   Please provide us with any further details you may have.

   These have allowed for the wider use of collection points which can only be a positive and allow patients better access to medicines when needed. However, patients may then be accessing medicines without the opportunity to access medicines advice from a pharmacist at the time of collection. The opportunistic aspect of that is lost.

2. What impact has regulation 248(1)(a) and (2)(a) had on patients' safety? [please select as appropriate]

   Improved ☐

   No change ☐

   Worsened ☐

Don’t know ☐

Unsure ☒

Please provide us with any further details you may have.

3. Are you aware of any unforeseen consequences of this regulation?

Yes ☒

No ☐

Unsure ☐

Please provide us with any further details you may have.

We are aware community pharmacies may deregister part of their premises to install collection points so patients have access to dispensed medicines outside of operating hours at a time convenient to them. These patients will not be able to access medicines advice at the point of collection. Community pharmacy contact details are available on dispensed medicines to allow patients to reach out for advice if necessary.

Section 4 –Sale and Supply: Repeal of Section 10(7)

Repeal of Section 10(7) [regulation 349 in so far as it repeals section 10(7) of the Medicines Act 1968]

Section 10(7) of the Medicines Act 1968 provided an exemption in UK law for the requirement for a pharmacist to hold a Wholesale Dealer's Licence if the wholesale dealing formed only a minor portion of their business at that pharmacy. The repeal of section 10(7) was necessary to comply with EU legislation, in particular articles 77(1) and 77(2) of Directive 2001/83/EC which required anyone undertaking wholesale dealing activities to hold an authorisation.

In doing so, the objective of the HMRs was to:

- Take account of the UK's National Health Service (which is relatively unique among Member States as a health service open to all without the need for private insurance).
- Protect patients by assuring the security of the supply chain.
- Preserve continued supplies of medicines above all other concerns.
- Minimise extra regulatory cost and administrative burden, particularly for the NHS.

To support the above, guidance is available to pharmacists' working in registered pharmacies and in hospitals on how MHRA addresses the implications of the necessary repeal of Section 10(7) for the supply of licensed medicines by pharmacy other than direct to the public.

1. In terms of the repeal of Section 10(7), to what extent have supplies of medicines met the needs of patients? [please select as appropriate]

Completely met	☐
Met	☐
Weakened	☐
Greatly weakened	☒
Unsure	☐

Please provide us with any further details you may have.

This has been detrimental to patients and we believe this should be reinstated. The MHRA guidance document on the conditions where supplies can be made has not proved helpful for pharmacists and uncertainty remains. A pharmacist is more likely not to supply a medicine if there is uncertainty about their situation and interpretation of the regulations, impacting patients.

Previously, pharmacies supplied local health clinics or hospital pharmacies, but now they face additional administrative burdens due to WDL regulations. Challenges include stock sharing during shortages and supporting other pharmacies.

One example to highlight, is a GP practice commissioned to provide a hyperhidrosis clinic, but was unable to be supplied medicines from the hospital pharmacy who did not hold a WDA. Regular supplies meant it did not meet the criteria or occasional supply. Identifying the most appropriate route to access the small supplies required to run the clinic delayed the service and therefore patient access to treatment.

Another example is with the introduction of allowing schools to purchase adrenaline auto-injectors and salbutamol. This puts pharmacies in a complicated position of trying to support schools with their requirements but not being permitted to do so with the removal of this section.

2. How has the repeal of Section 10(7) affected pharmacists? [please select as appropriate]

Very beneficial	☐
Beneficial	☐
No change	☐
Detrimental	☒
Very Detrimental	☐
Unsure	☐

Please provide us with any further details you may have.

Despite the change occurring 12 years ago, we often find members are not aware of the repeal and its impact. The MHRA guidance document on the conditions where supplies can be made has not proved helpful for pharmacists and uncertainty remains. A pharmacist is more likely not to supply a medicine if there is uncertainty about their situation and interpretation of the regulations, impacting patients.

The conditions to be met to allow some wholesale dealer activity is very restrictive, in that it allows activity for one-off events. Even regular frequent supplies of a very small amount of medicines is prohibited and has an impact on service delivery for those services which deliver low volume activity on behalf of an NHS entity.

Previously, pharmacies supplied local health clinics or hospital pharmacies, but now they face additional administrative burdens due to WDL regulations. Challenges include stock sharing during shortages and supporting other pharmacies.

3. How has the repeal of Section 10(7) affected healthcare professionals (other than pharmacists)?

Very beneficial	☐
Beneficial	☐
No change	☐
Detrimental	☐
Very Detrimental	☐
Unsure	☒

Please provide us with any further details you may have.

4. How has the repeal of section 10(7) affected regulatory cost and administrative burden, particularly for the NHS? [please select as appropriate]

Vastly reduced burden ☐

Somewhat reduced burden ☐

No impact ☐

Somewhat increased burden ☒

Vastly increased burden ☐

Unsure ☐

Please provide us with any further details you may have.

For those organisations who do decide to go ahead, there is a cost burden, both in fees for the MHRA but also in the necessary workforce to maintain the conditions of the WDA.

5. Please provide us with suggestions for improvements if you have seen an increase in burden.

The Section 10(7) should be reinstated.

6. Are you aware of any unintended or unforeseen consequences arising from the repeal of Section 10(7)? [please select as appropriate]

Yes ☒

No ☐

Unsure ☐

Please provide us with any further details you may have.

As detailed above. Augmentation of the impact of medicines shortages.

7. In your view, what best describes the way in which articles 77(1) and 77(2) have been implemented in the UK, which require anyone undertaking wholesale dealing activities to hold an authorisation? [Regulation 18 of the HMRs] [please select as appropriate]

Vastly reduced burden	☐
Somewhat reduced burden	☐
No impact	☐
Somewhat increased burden	☒
Vastly increased burden	☐
Unsure	☐

Please provide us with any further details you may have.

8. Taking into account your feedback in this section, do you think the policy objectives remain appropriate? [please select as appropriate]

Yes	☒
No	☐
Unsure	☐

Please provide us with any further details you may have.

9. Do you think the policy objectives could be achieved with less regulation? [please select as appropriate]

Yes	☒
No	☐
Unsure	☐

If yes, please give specific feedback including which regulations you think could be amended.

Section 5: Falsified Medicines

Implementation of the Falsified Medicines Directive (FMD)

Provisions: Chapters 1, 3 and 4 of Part 3; Part 12A; Regulations - 18(6); - 37(4)(b), (5), (6) and (12); 43(5), (6)(a) and (d), 7(c)(iii) and (vii), (8) and (10) to (14); 44(2) to (6), 110(8A); 135(10A); 330(1) and (2); Schedule 5 paragraphs 1(1)(b) to (d), (2)(b) to (d), 3(11)(b)(vi) to (viii), 5(2)(f) to (h) and Schedule 7A

Objective: The EU FMD (2011/62/EU) was adopted in the UK in 2013 with the final part of the Directive, the 'safety features' coming into force in 2019.

It was applied to maximise the protection of the legal supply chain in the EU against infiltration of falsified medicinal products, i.e. to ensure that for all practical purposes the possibility that medicinal products purchased in the legal supply chain in the EU are counterfeit can be practically ruled out. Measures included:

- Tougher rules on import of active pharmaceutical ingredients
- Strengthened record-keeping requirements for wholesale distributors.

Many of the provisions, which relate to FMD, built on existing obligations on those who trade in medicines (manufacturer and wholesale dealers). The legislation also extended to previously unregulated operators such as those engaged in brokering the sale and supply of medicinal products.

Since the UK has exited the EU, the 'safety features' (serialisation) part of the FMD ceased to have effect in Great Britain from 31 December 2020 and will be disapplied in Northern Ireland when the Windsor Framework takes effect on 1 January 2025.

We are therefore not looking for input on the implementation of the 'safety features' and verification provisions, given that these will not apply in any part of the UK from 1 Jan 2025. We are looking for input on the other changes to the HMRs that were originally made as a result of FMD, and remain in place.

1. Overall, do you believe the objectives, outlined above, for implementing the FMD have been met? [please select as appropriate]

Completely met	☐
Partially met	☐
Not met	☒
Unsure	☐

Please provide us with any further details you may have.

Post-EU exit, there is no UK legal requirement for the retention of tamper-evident devices. This is a key element of the Falsified Medicines Directive (FMD) and its absence introduces a risk of counterfeit goods entering the supply chain The UK should consider its track and trace solution going forward.

2. What effect has the implementation of the FMD had on patient safety? [please select as appropriate]

Vastly improved	☐
Improved	☐
No change	☒
Decreased	☐
Vastly decreased	☐
Unsure	☐

Please provide us with any further details you may have.

A key element of the Falsified Medicines Directive (FMD) was the inclusion of safety features. Without the implementation of these features, the impact is minimal.

3. What best describes the impact the FMD Directive has had on industry? [please select as appropriate]

Vastly reduced burden	☐
Somewhat reduced burden	☐
No impact	☐
Somewhat increased burden	☐
Vastly increased burden	☐

Unsure ☒

Please provide us with any further details you may have.

When this was to be introduced and the way it was to be introduced with scanning would have brought positives and negatives with possible increased safety due to barcode scanning. Barcode scanning has now been introduced in a way that has brought added safety benefit but if FMD is to be reintroduced in full then it needs to be done in a better way to reduce cost and administrative burden to community pharmacy. The anti-tamper device has introduced some safety concerns with packs now not being sealed once split. However, if the original pack legislation becomes operational then this will remove some of these safety concerns.
Implementation of delegated regulation (2016/161) had significant impact and therefore vastly increased burden due to additional processes required.

4. Please provide us with suggestions for improvements if you have seen a decrease in patient safety and/or an increased burden on industry.

Any intervention in the process of preventing falsified medicines reaching patients must be much earlier in the supply chain before the products reach the wholesaler network to prevent the burden of checks lying with the pharmacy teams in community and hospital pharmacies.

When requiring safety features via regulation, it is important to consider how any new system can add value. For example, is it less likely that falsified medicines will enter legitimate supply chains compared to patients purchasing medicines online? Additionally, how many interventions were made in the EU with the implementation of serialization?

5. Are you aware of any unintended or unforeseen consequences as a result of the implementation of the FMD?

Yes ☐

No ☐

Unsure ☒

Please provide us with any further details you may have.

6. Have there been any benefits or costs arising from the implementation of the FMD?

Yes ☐

No ☐

Unsure ☒

Please provide us with any further details you may have including any estimates of costs or benefits or other evidence to support your answer.

7. How does the implementation of the FMD, in the UK, compare to implementation in EU Member States? [please delete as appropriate]

More burdensome ☐

Burdensome ☐

In line with other member states ☐

Less burdensome ☐

Significantly less burdensome ☐

Unsure ☒

Please provide us with any further details you may have.

8. Taking into account your comments for this section, do you think the policy objectives for FMD remains appropriate? [please select as appropriate]

Yes ☐

No ☒

Unsure ☐

Please provide any further details you may have.

9. Do you think the policy objectives for FMD could be achieved with less regulation? [please select as appropriate]

Yes ☐

No ☐

Unsure ☒

If yes, please give specific feedback including which regulations you think could be amended.

It should be a legal requirement to include tamper evident devices.

Section 6: General

1. For the sections you have completed, have you seen any unintended equality impacts as a result of implementing the regulations, specifically on groups sharing protected characteristics as defined in the Equality Act 2010?

   Yes ☐

   No ☐

   Unsure ☒

2. If you have seen a negative impact, what do you think could be done to help eliminate unlawful discrimination, advance equality of opportunity and foster good relations?

3. For the sections you have completed, have you seen any effect on the environment as a result of implementing the regulations, for example increased pollution? [please select as appropriate]

   Yes ☐

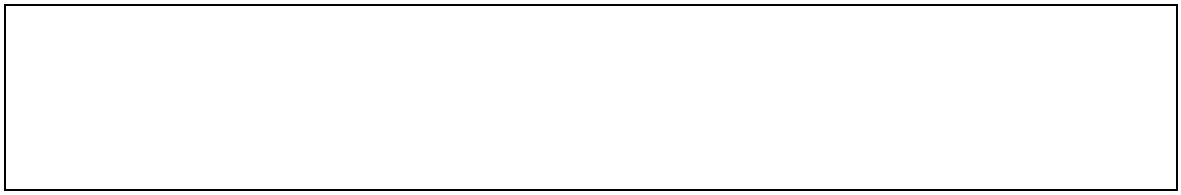
   No ☒

   Unsure ☐

4. If you have seen a negative impact, what do you think could help mitigate this to help protect the environment and prevent environmental harm?

Reinstating Section 10 (7) WDA exemption would support management of waste by supporting separate legal entities to trade in medicines approaching their expiry and optimise the medicines supply chain e.g. cytotoxic chemotherapy.

5. Please provide us with any additional comments you may have with regards to the sections you have completed.



About you

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Please indicate which category (or categories) best describes you:

Marketing Authorisation holder ☐

Manufacturer ☐

Wholesaler ☐

Broker ☐

Pharmacist ☐

Pharmacy business ☐

Pharmacist group ☒

Trade association ☐

Doctor/other healthcare professional ☐

Patient ☐

Patient Group ☐

Other (please specify)

Data privacy

This Review complies with data protection legislation including the Data Protection Act 2018 (DPA) and the UK General Data Protection Regulation (UK GDPR).

The Partnership Division at MHRA will have access to the data. Personal data will be kept for no longer than necessary to fulfil our purpose in processing it. Any personal information will be anonymised.

Information from this review, including personal information, may be disclosed in accordance with the access to information regimes. These are primarily the Freedom of Information Act 2000 (FOIA), the DPA, the UK GDPR and the Environmental Information Regulations 2004.

The MHRA will process your personal data in accordance with the DPA and UK GDPR and in most circumstances, this will mean that your personal data will not be disclosed to third parties. The lawful basis for processing personal data is article 6(1)(e) UK GDPR. Further information on how MHRA handles personal data, including data subject rights, is available in its privacy notice.