EXPLANATORY MEMORANDUM TO

THE NATIONAL HEALTH SERVICE (PHARMACEUTICAL AND LOCAL PHARMACEUTICAL SERVICES) (AMENDMENT) (NO. 2) REGULATIONS 2024

2024 No. 894

1. Introduction

1.1 This explanatory memorandum has been prepared by Department of Health and Social Care "DHSC" and is laid before Parliament by Command of His Majesty.

2. Declaration

2.1 Stephen Kinnock, Minister of State for Care at the Department of Health and Social Care confirms that this Explanatory Memorandum meets the required standard.

2.2 Alette Addison, Deputy Director for Pharmacy, Eye Care and Controlled drugs at the Department of Health and Social Care confirms that this Explanatory Memorandum meets the required standard.

3. Contact

3.1 Inna Kochetkova at the Department of Health and Social Care Email: communitypharmacyteam@dhsc.gov.uk can be contacted with any queries regarding the instrument.

Part One: Explanation, and context, of the Instrument

4. Overview of the Instrument

What does the legislation do?

4.1 These Regulations amend the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (S.I. 2013/349, as amended) ("the PLPS Regulations"). The principal purposes of this instrument are: to introduce new regulatory flexibilities regarding the dispensing requirements for NHS community pharmacies; to remove a barrier to the timely approval of new pharmacy contractors wanting to provide NHS services; and to enable NHS community pharmacies to use centrally purchased pertussis (whooping cough) vaccines when providing NHS pharmaceutical services.

4.2 The amendments to the PLPS Regulations in essence are:

- To enable NHS community pharmacies in England from 1 January 2025 to adopt the flexibilities enabled by the amendments to the Human Medicines Regulations 2012 (S.I. 2012/1916) ("HMR") made by the Human Medicines (Amendment Relating to Original Pack Dispensing) (England and Wales and Scotland) Regulations 2023 S.I. 2023/1015)[1] ("OPD Regulations"). The HMR amendments expanded the use of original pack dispensing ("OPD") to allow pharmacists (including pharmacy staff under the supervision of a pharmacist) the flexibility to dispense up to 10% more or 10% less of a prescription only medicine compared to the quantity prescribed, if it means pharmacists can dispense the medicine in its

1 The Human Medicines (Amendment Relating to Original Pack Dispensing) (England and Wales and Scotland) Regulations 2023 (legislation.gov.uk) https://www.legislation.gov.uk/ukdsi/2023/9780348249446

original manufacturer's packaging. The same flexibility has also been extended to the dispensing by community pharmacies of most other prescription items that are treated as "drugs". However, the new NHS flexibilities will not apply to controlled drugs listed in Schedules 1 to 4 of the Misuse of Drugs Regulations 2001 (S.I. 2001/3998, as amended) ("MDR") or unlicensed medicines that are on the market via a route to the market in regulation 167 of the HMR. These are commonly known as "specials".

- To remove an information obligation from applicants seeking entry onto pharmaceutical lists (see below). Up until now, the fitness information that applicants have had to provide has included referees' details for the applicant (in the case of an individual application made by a pharmacist) or for pharmacists who are partners in, or directors or superintendents of, the applicant (in the case of business applicants). This requirement is removed, as are the obligations on NHS England ("NHSE") – or integrated care boards ("ICBs") acting on their behalf – to take up and check the references.
- To provide that, where the Government has centrally purchased pertussis vaccines that are made available to community pharmacies at no cost for supply or administration to NHS patients, the Secretary of State or in some instances NHSE may determine that the amount to be paid by way of NHS reimbursement for product costs to community pharmacies for supplying or administering those vaccines may be set at zero or a nominal amount, if certain conditions are met. This only affects the reimbursement for the product costs. It does not affect the amount that the community pharmacy will be paid for the service cost of supplying or administering the vaccine as part of NHS pharmaceutical services.

Where does the legislation extend to, and apply?

4.3 The extent of this instrument (that is, the jurisdiction(s) which the instrument forms part of the law of) is England and Wales.

4.4 The territorial application of this instrument (that is, where the instrument produces a practical effect) is England.

5. Policy Context

What is being done and why?

Regarding a change to market entry fitness information requirement

5.1 Most NHS pharmaceutical services provision in England is by community pharmacies that are on lists, known as pharmaceutical lists. Applications for entry onto those lists are determined by NHSE, who delegate this type of function to ICBs. Arrangements with retail pharmacy businesses are made on the basis of either entry on these pharmaceutical lists or, much less often, on the basis of a contract for local pharmaceutical services (LPS).

5.2 Businesses that are party to these arrangements are known as, respectively, "pharmacy contractors" and "LPS contractors". Arrangements with dispensing appliance contractors (DACs) are made on the basis of separate pharmaceutical lists especially for them, but they share with pharmacy contractors common arrangements for market entry and market exit.

5.3 The PLPS Regulations specify what information prospective applicants should provide as part of their application. This includes fitness information requirements for individual applicants who are pharmacists, and for pharmacists who are partners in

partnerships or pharmacists who are directors or superintendents of retail pharmacy businesses. Up until now, this has included a requirement to provide names and addresses of 2 referees who are willing to provide references in respect of 2 recent posts (which may include any current post) as a pharmacist which lasted at least 3 months without a significant break, or where this is not possible, details of why and the names and addresses of alternative referees who are acceptable to the ICB. The ICB then has to take up and check references from these referees, and compliance with this requirement often causes delays to processing applications, so removing this requirement was identified as a measure that will help expedite approval process without undermining the importance of scrutiny of the applicants' fitness.

5.4 A new transitional provision was added to cover applications that were submitted before the changes come in force. ICBs will not be required to ensure references are provided in the case of applications already in the system. However, they will be able to act on information that is or has been provided – it is possible that some information will come in from applicants or referees after the requirement to provide referees details simply because the provision of it is already in train. The ICB may need to act on it in one of two ways. Firstly, they may need simply to take it into account of information already received in a decision on fitness. But secondly, it may precipitate a desire for more information. For example, something a referee says may mean there is a discrepancy in the information that is before the ICB. That may prompt the ICB to request further information. The new provision would mean that ICBs are not barred from doing that simply because there will no longer be an obligation on the applicant to provide details of referee or on the ICB to take up and consider the references.

Regarding Original pack dispensing

5.5 Regulation 217A(4) of the HMR delayed the application in England and Wales of the provisions introduced by the OPD Regulations, preventing them applying to prescriptions dispensed as part of NHS pharmaceutical services by community pharmacies on pharmaceutical lists or, in England, with LPS contracts until the new arrangements were expressly applied by the PLPS Regulations and the equivalent Regulations in force in Wales. This was to allow the Department and the Welsh Government the opportunity to arrange how the OPD provisions would apply in their respective NHS services.

5.6 This Statutory Instrument contains that express application for England. Accordingly, in line with the HMR changes made by the OPD Regulations, it will enable community pharmacies in England to dispense prescription only medicines in the original manufacturers pack where the quantity in the pack is up to 10% more or less than what is ordered on NHS prescription. At the same time, the same 10% flexibility is being extended to all prescription items that are treated as "drugs" (in practice, medicines that are not prescription only medicines and foods and cosmetics treated as drugs because of their medical benefits), subject to some exceptions as explained in paragraphs 5.21 and 5.22.

5.7 Alongside these 10% flexibilities, there will be a requirement for community pharmacists to exercise their professional skill and judgement and consider whether it is reasonable and appropriate to use these flexibilities to supply a different quantity to that ordered on a prescription, having regard to the benefits to patients, whenever it may be possible to make such supplies. However, that obligation to consider only arises where the pharmacist is not already obliged to supply medicines in an original manufacturer's pack in any event. Under the PLPS Regulations, they are currently

obliged to do so in two situations. Firstly, if the exact quantity ordered on the prescription is readily available in an original manufacturer's pack (or packs) and it is possible to obtain that pack (or packs) with reasonable promptness in the normal course of business – unless it is not practicable to provide such a pack (or packs) in response to the prescription (for example, because of patient needs or the method of administration of the drug). Secondly, there are some types of products that need necessarily to be supplied in their original packs, for example if they are in special containers or are sterile products. If neither of these current obligations applies and the new duty to consider using the 10% flexibility does apply (there are four exceptions noted below), the pharmacist may still choose to split the original pack and provide the exact quantity ordered in a plain box or a monitored dosage system. Indeed, they must do so if there are concerns that the patient will otherwise not be able to follow the medicine regimen. The new 10% flexibilities, where they may apply, aim to support increased patient safety by improving patient access to safety information that is included in a medicine's original packaging.

Regarding Zero or nominal reimbursement of pertussis vaccines

5.8 The policy context is a desire to enable community pharmacies to use centrally procured pertussis vaccines in specially commissioned services (known as enhanced services) to support NHSE's immunisation programmes.

5.9 Pertussis (whooping cough) is a respiratory disease that is vaccine preventable. Pertussis can cause serious and life-threatening complications. Immunisation is the most effective way to protect against pertussis.

5.10 NHSE has proposed to commission community pharmacies to provide additional capacity and increased access to pertussis vaccines. This is in response to increasing pertussis cases and declining vaccine uptake. NHSE are looking to provide the vaccine in community pharmacies near hospitals where there is low uptake or where the overseeing Trust does not administer the pertussis vaccine in maternity units. This will increase patient access to vaccines, therefore improving patient health and reducing the pressure on health services in responding to the increasing outbreaks of whooping cough before the Winter months.

What was the previous policy, how is this different?

Regarding a change to market entry fitness information requirement

5.11 The obligations on applicants for inclusion in pharmaceutical lists to provide the names of referees, and on ICBs to take up and check the references, are explained in paragraph 5.3 above. These obligations have simply been removed, subject to the transitional arrangements explained in paragraph 5.4 above.

5.12 As is mentioned above, the previous system often caused delays to processing applications. This potentially delayed the opening a new pharmacy and therefore the meeting the needs of patients for pharmaceutical services in the local area, in particular if referees did not meet the requirements specified in the PLPS Regulations or took a long time to respond to the ICB's request for references. As the referees are selected by the applicants, the information provided in the references did not add sufficient value to the appraisal of applicants' fitness to offset these drawbacks.

Regarding original pack dispensing

5.13 Part 12 of the HMR contain a number of detailed requirements around the sale or supply of prescription only medicines. These have been understood as requiring, with

limited exceptions, sales or supplies in pursuance of a prescription to be exactly in accordance with that prescription. This approach was reflected in the PLPS Regulations, which also set out what has been a common position in England on what those exceptions were. They provide a list of types of products that need necessarily to be supplied in their original packs, for example special containers and sterile products ("the special container rule"). The full list is in paragraph 8(8) of Schedule 4 to the PLPS Regulations.

5.14 OPD Regulations amended the HMR so as to enable pharmacists to supply a different quantity of a prescription only medicine to that ordered on the prescription, enabling the medicine to be dispensed in its original outer packaging. Such different quantities may be sold or supplied where:

- The quantity is no more than 10%, and no less than 10% of the prescribed quantity; and
- The sale or supply is otherwise in accordance with the prescription.

5.15 For this change to be introduced successfully, a number of operational changes need to be made alongside the HMR regulatory change, for example in relation to NHS reimbursement. Therefore, as explained in paragraphs 5.5 and 5.6 above, a transitional provision was included in the HMR changes to allow the Department and the Government of Wales the opportunity to arrange how the OPD provision is applied in their respective NHS services. Importantly, the Department has, as part of that process, decided to apply that 10% flexibility not just to prescriptions for prescription only medicines, but also to prescriptions for all prescription items treated as "drugs", with some exceptions.

5.16 The approach that pharmacists will have to take to NHS dispensing in community pharmacies, going forward, is reflected in the following example.

5.17 If a NHS pharmacist receives a prescription for 28 doses of a medicine potentially available in packs of 28, 30 and 84, if that medicine is readily available in the 28 pack size from a holder of a UK marketing authorisation for the medicine, the pharmacist must, under the rules already in place, supply that pack of 28 ("the readily available rule"). They are however released from that obligation if they cannot obtain that 28 pack with reasonable promptness or there is a patient need reason, for example the patient is supplied with medicines as part of a monitored dosage system. These are methods of combining medicines in new packs to support patient adherence to a medication regime, such as a tray with different indents containing all the medicines that a patient needs to take at a particular time. In this type of case, the box will need to be broken open anyway.

5.18 If the pharmacist cannot obtain the pack of 28 with reasonable promptness or the medicine is not readily available in a pack of 28, the pharmacist must next consider whether the special container rule mentioned in paragraph 5.13 applies – for example, the medicines are only available in sterile packs that cannot be opened without adversely affecting the medicine. If this is the case, an original pack must be supplied in the nearest possible quantity to the prescribed quantity that is actually available, even if that means providing the patient with a pack of a significantly greater quantity than the amount prescribed. If it was the case that only a box of 84 was actually available on the UK market and the patient had been prescribed 28, the pharmacist would need to exercise their professional judgement in deciding whether it really was appropriate to give out the 84. That professional judgement in that highly unusual situation is unaffected by these legislative changes.

5.19 If neither the readily available rule nor the special container rule applies, up until now the pharmacist has been expected to break open a box of 30 or 84 and then supply 28 doses in a plain box (so-called "white box dispensing") or a monitored dosage system.

5.20 Going forward, the pharmacist will also have the option, subject to four exceptions noted below, of supplying the box of 30, with everything still in its original packaging, even though only 28 are needed. That option only falls away if the pharmacist thinks the patient may have difficulty following the medication regimen if they are given 30 instead of 28 – for example, if the patient might be confused by being given the wrong amount. If the pharmacist does have those concerns, they must still provide the 28, and do so in a plain box or a monitored dosage system. When considering whether or not to use the 10% flexibility, they are obliged to have regard to the benefits to patients of receiving their medicines in the manufacturer's original outer packaging. However, apart from the need at least to consider supplying the box of 30, their obligations are otherwise unchanged. If what they have in stock is the box of 84, they can still simply split open the box of 84 and supply 28 doses in a plain box or a monitored dosage system. And similarly, they can still split open a box of 30 that they have in stock or can order in, and supply 28.

5.21 The four exceptions mentioned in the previous paragraph are, firstly and secondly, the new 10% flexibility does not apply in the case of controlled drugs in Schedules 1 to 4 of the MDR (although community pharmacies will not be supplying Schedule 1 drugs anyway) – and, as noted above, in the case of "specials". These will still need to be supplied in the exact quantity ordered as are the medicines supplied under Patient Group Directions and Serious Shortage Protocols. The "special container rule" also does not apply to Schedules 1 to 4 controlled drugs, although it does apply to "specials".

5.22 Thirdly and fourthly, there are also special rules for sodium valproate and methadone supply. Broadly, the former must generally be supplied in their original pack, and the most appropriate approach to supply of the latter has to be determined on a case by case basis.

Regarding Zero or nominal reimbursement of pertussis vaccines

5.23 The expectation under the ordinary reimbursement arrangements for NHS pharmaceutical services is that pharmacy contractors are reimbursed an amount which is in respect of (but ordinarily slightly more than) the price that they paid when they purchased a prescription item that they go on to supply or administer. However, there are powers in Part 7 of the 2006 Act to make regulations to enable alternatives to these ordinary remuneration arrangements in some circumstances. That option is being exercised here.

6. Legislative and Legal Context

How has the law changed?

Regarding market entry information

6.1 As is explained paragraph 5.3 above, the requirements on applicants to provide information about referees, and on ICBs take up and check the references, has simply been removed, subject to the transitional provision explained in paragraph 5.4 above.

Regarding original pack dispensing

6.2 The new system is explained in detail paragraphs 5.12 to 5.22 above. It will apply both to community pharmacies on NHS pharmaceutical lists and to community pharmacies with LPS contracts – and so to all community pharmacies dispensing NHS prescriptions as part of NHS primary care.

6.3 The terms of service for dispensing doctors (who provide NHS pharmaceutical services in some rural areas) and DACs are unaffected by these changes.

Regarding Zero or nominal reimbursement of pertussis vaccines

6.4 As is noted above in paragraph 5.22, the scheme for payment for pharmaceutical and local pharmaceutical services in Part 7 of the NHS Act is predicated on the basis that the determining authorities for pharmaceutical remuneration (that is, the Secretary of State and, for some purposes, NHSE) will ordinarily include, in the payments for those services, an amount which is in respect of (but ordinarily slightly more than) the price paid by service providers when they purchased the prescription items that they supply or administer to NHS patients.

6.5 However, section 164 of the 2006 allows for the creation, by regulations, of some statutory exceptions to this principle. The exceptions are to allow for the use of some centrally purchased medicines in the NHS services provided by community pharmacies – and where the medicines are supplied free of charge to the pharmacies, the remuneration for the pharmacies then does not need to include anything for those medicines when the pharmacies go on to supply or administer those medicines for NHS patients. The powers have previously been exercised to support the supply of coronavirus, MMR and RSV vaccines and antivirals, and now a new statutory exception is being created for pertussis vaccines in the same terms as the existing vaccines exceptions.

Why was this approach taken to change the law?

6.6 This is the only possible approach to make the necessary changes.

7. Consultation

Summary of consultation outcome and methodology

7.1 The Government engaged widely with stakeholders on the introduction of OPD and whole-pack dispensing of medicines containing valproate, including extensive pre-consultation engagement. In general, there was very strong support from respondents for the proposals and the HMRs 2012 were amended and the provisions came into force on 11 October 2023. The consultation response document can be found on the following webpage: Original pack dispensing and supply of medicines containing sodium valproate - GOV.UK (www.gov.uk**2**)

7.2 Customarily, the Department seeks the views of the Community Pharmacy England (CPE), the representative body for community pharmacies, on changes to PLPS Regulations relating to the market entry process and changes to community pharmacies' NHS terms of service. The Department has been able to discuss the policy changes in these areas with CPE and responded to their comments, making changes to the Regulations where appropriate.

2 https://www.gov.uk/government/consultations/original-pack-dispensing-and-supply-of-medicines-containing-sodium-valproate/outcome/original-pack-dispensing-and-medicines-containing-sodium-valproate-consultation-response#:~:text=A%20large%20majority%20of%20respondents,%25%20%E2%80%93%20disagreed%20or%20strongly%20disagreed.

7.3 CPE has also been consulted on the amendment to the PLPS Regulations with regards to the addition of pertussis. CPE have agreed to the proposed amendment.

8. Applicable Guidance

8.1 No Guidance will be provided by the Department following this legislative change. Community pharmacy trade bodies may choose to provide guidance for their members.

Part Two: Impact and the Better Regulation Framework

9. Impact Assessment

9.1 An Impact Assessment **3**was submitted with The Human Medicines (Amendment Relating to Original Pack Dispensing) (England and Wales and Scotland) Regulations 2023 (S.I. 2023/1015) and published alongside the Explanatory Memorandum on the legislation.gov.uk website.

9.2 A full Impact Assessment has not been prepared for this instrument because these Regulations are not expected to have a significant impact on the public and voluntary sectors, and only a limited impact on the private sector, below the threshold for undertaking a full impact assessment.

Impact on businesses, charities and voluntary bodies

9.3 There is no impact on charities or voluntary bodies because the changes only impact pharmacies supplying patients with medicines and other "drugs" ordered on prescription.

9.4 The legislation may impact businesses, including small or micro businesses, to the following effects:

- pharmacies may incur losses for dispensing fewer items for repeat prescriptions because of some patients requiring fewer repeat prescriptions if receiving up to 10% more medicine than ordered on a prescription,
- familiarisation costs may be incurred – as it may take time for pharmacies and patients to understand the changes.

9.5 No specific action is proposed to minimise regulatory burdens on small businesses. The Government foresees that the introduction of OPD may create a small burden for pharmacies taking the time to familiarise themselves with the changes and communicate the changes to patients and carers, however, this burden will be outweighed by the increased patient safety and efficiencies gained by pharmacy businesses.

9.6 The impact on the public sector includes increase or decrease in GPs needing to reissue repeat prescriptions, which are expected to balance out.

10. Monitoring and review

What is the approach to monitoring and reviewing this legislation?

10.1 DHSC will keep the impact of the policy under review. This will be completed via discussions with CPE.

3 The Human Medicines (Amendment Relating to Original Pack Dispensing) (England and Wales and Scotland) Regulations 2023 - Impact Assessment (legislation.gov.uk) https://www.legislation.gov.uk/uksi/2023/1015/impacts

10.2 The instrument does not include a statutory review clause and, in line with the requirements of the Small Business, Enterprise and Employment Act 2015 Stephen Kinnock, the Minister of State for Care has made the following statement:

"It is not appropriate in the circumstances to make provision for review in this instrument. This is because there is already a requirement under section 28 of The Small Business, Enterprise and Employment Act 2015, the Secretary of State is legally required to undertake a review of the 2013 Regulations to review the operation of these Regulations every 5 years".

Part Three: Statements and Matters of Particular Interest to Parliament

11. Matters of special interest to Parliament

11.1 None.

12. European Convention on Human Rights

12.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

13. The Relevant European Union Acts

13.1 This instrument is not made under the European Union (Withdrawal) Act 2018, the European Union (Future Relationship) Act 2020 or the Retained EU Law (Revocation and Reform) Act 2023 (''relevant European Union Acts'').