PSNC response to the Department of Health and Social Care’s consultation on -Original pack dispensing and supply of medicines containing sodium valproate

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Introduction

The Pharmaceutical Services Negotiating Committee (PSNC) promotes and supports the interests of all NHS community pharmacies in England. We are recognised by the Secretary of State for Health and Social Care as the body that represents NHS pharmacy contractors. We work closely with Local Pharmaceutical Committees (LPCs) to support their role as the local NHS representative organisations.

Our goal is to develop the NHS community pharmacy service, and to enable community pharmacies to offer an increased range of high quality and fully funded services; services that meet the needs of local communities, provide good value for the NHS and deliver excellent health outcomes for patients.

We welcome the opportunity to be able to provide our response to the proposals set out in the Department of Health and Social Care’s (DHSC’s) consultation on ***Original pack dispensing and supply of medicines containing sodium valproate***.

We ask that our response as a national organisation for all community pharmacies in negotiations with the DHSC and others, is given appropriate consideration against other representations from, for example, individuals.

Response

Background

In 2019, PSNC agreed *the Community Pharmacy Contractual Framework for 2019/20 to 2023/24: supporting delivery for the NHS Long Term Plan[[1]](#footnote-2)* (the 5-year deal) with DHSC and NHS England and NHS Improvement (NHSE&I).

One aspect of the 5-year deal was that:

1. *This agreement between the Government, the NHS and the Pharmaceutical Services Negotiating Committee (PSNC) describes our joint vision for how community pharmacy will support delivery of the NHS Long Term Plan. The deal:*

* *… Recognises that an expanded service role* ***is dependent on action to release pharmacist capacity*** *from existing work. The deal rationalises existing services and commits all parties to action which will maximise the opportunities of automation and developments in information technology and skill mix, to deliver efficiencies in dispensing and services that release pharmacist time …*

And

*31. A new and expanded role for community pharmacy will require the sector to adopt new and different ways of working. In particular, we need dispensing to become more efficient to free pharmacists up to provide new services, working at the top of their clinical licence in a way that is both more rewarding professionally but also adds maximum benefit for patients.*

*32. To help achieve this, we have agreed that with the support of PSNC, the Government will …* ***explore and implement*** *greater use of original pack dispensing to support efficient automation [as well as other potential efficiencies – financial and/or activity saving]*

The Proposal

The proposal is: *…. to introduce amendments to Part 12 of the Human Medicine Regulations 2012, so that when dispensing medicines, pharmacists may utilise manufacturer’s original packs … [such] that:*

* *pharmacists have flexibility to dispense more or less than the prescribed quantity (up to 10% more or less) if that means they can dispense in the manufacturer’s original packs, except where this would negatively affect the patient’s clinical treatment regimen – so they have to make a judgement that this is appropriate. This would not apply to controlled drugs*
* *however, the amendments will include a transitional provision, so the flexibility does not automatically apply in NHS pharmaceutical services in England, Northern Ireland and Wales, to enable these administrations to decide how they want these to apply in their respective NHS services. In Scotland, the Scottish government is not seeking such a transitional provision because of arrangements already made so pharmacists will be able to utilise the original pack dispensing (OPD) flexibility within their NHS service provision straight away*
* *the supply of sodium valproate must always be in original packaging regardless of the conditions we set around OPD*
* *we propose to use the enabling powers in Part 2 of the [Medicines and Medical Devices Act] MMDA. Currently, we are only proposing a flexibility around quantity, not around formulation or strength.*

Summary

In principle, PSNC supports appropriate changes to the Human Medicines Regulations 2012 (HMRs) to provide Original Pack Dispensing (OPD) as anticipated in the 5-year deal.

We have the following key comments and observations in response to the consultation. They recognise that the consultation relates to proposed changes to UK legislation and looks towards (but do not cover fully) changes to the NHS dispensing arrangements in England (regulations and funding), and are as follows:

**Patient safety**

* Patient considerations are more nuanced than described and include reference to patient preference and payment of the NHS charge;
* The proposed 10% discretion may be insufficient to allow community pharmacy to make full use of OPD;
* There is no evidence of patient safety concerns in the consultation so PSNC cannot assess whether the proposed measures are appropriate to address the risk (Safety concerns around sodium valproate are evidenced in earlier studies);
* The Medicines and Medical Devices Impact Assessment in 2020[[2]](#footnote-3) suggested that any such patient safety concerns could be met ‘*in relation to a specific medicine only, [or] a class of medicines ...’*;
* The Medicines and Medical Devices Impact Assessment contained a proposal that Manufacturers provide up to date, digital Patient Information Leaflets (PILs) to address any patient safety considerations;
* OPD should not apply to controlled drugs, given the significant control of supply of such products;

**Efficiencies**

* OPD provides efficiencies for certain community pharmacies, particularly those with large-scale automated dispensing, or remote hub assembly units, but is unlikely to provide efficiencies for all community pharmacies;
* There may be an adverse financial effect of the proposal for some NHS community pharmacy contractors, particularly for contractors with only one to five pharmacies who have no legal, or financially viable access, to local or remote automated dispensing, and this should be explored when NHS funding arrangements are considered;

**Legislation and the NHS**

* NHS considerations (regulatory and funding) around OPD should dovetail with the HMR changes to ensure that the HMR changes provide the basis for all options required for NHS OPD;
* Community pharmacy issues are referenced in relation to patient safety, efficiencies, business impact and legislation;
* Community pharmacy regulatory and funding considerations are not the subject of this consultation;
* Community pharmacies will be concerned about the reimbursement mechanism around OPD within NHS dispensing;
* Community pharmacies and GP practices are likely to have a higher level of initial patient queries around OPD and a continued residual level of query, resulting in additional patient consultation time;

**Alternatives**

* The alternatives to OPD should be considered more fully, including consistency of approach by manufacturers and prescribers; they should also be approached as additional measures to support OPD; and

**Sodium valproate**

* Changes around sodium valproate are agreed on an exceptional basis; however, it is considered that the general OPD proposals would achieve the desired patient safety aim for the product (with suitable professional advice).

Patient Safety

**Patient considerations are more nuanced than described and include reference to patient preference and payment of the NHS charge.**

Currently, patients receive the exact quantity of medicine prescribed and this is their expectation, subject to certain exceptions. Not all patients will accept differing amounts provided, particularly if they perceive they are somehow losing out, or the community pharmacy is somehow gaining. Those patients who pay an NHS prescription charge for each prescription are particularly likely to question the practice. Accepting that whether a prescriber prescribes 28, 56 or 84 doses may also have an impact on the annual cost of prescriptions for a patient who pays for each one. The pharmacist and pharmacy team can manage this, but it is likely to take more of their time.

Management of repeats from a patient’s GP may also be an issue because the GP practice will be unaware of the exact quantity of medicine supplied. The GP practice will only be aware of the quantity of medicine prescribed. This may not be an immediate issue, but over time may lead to re-ordering issues. A GP practice may delay issuing a repeat prescription if the patient is thought to have a stock of medicine to use up before a prescription is required. This in turn may lead to more emergency supplies by community pharmacy; and more conversations between pharmacists, patients and GPs.

Appropriate messaging and communication for patients will help them to embrace the changes and thus reduce the time community pharmacy and general practice are likely to spend explaining the changes.

Pharmacies’ differing practices may also affect patients. One may supply twenty-eight, another thirty tablets for the same prescription. This would mean that the time at which the medicine runs out varies for different months and with the natural lag time ordering a prescription, could increase the likelihood that on occasions patients will run out of medicine and need to obtain more as an emergency supply from a community pharmacy. Where one pharmacy regularly supplies a patient’s medicine this is less likely to occur.

The professional judgement of the pharmacist supervising the supply is important, to ensure that any general OPD discretion is appropriate to apply to the individual patient. For certain medicines, such as antibiotics, the community pharmacy should supply the full course of treatment to the patient and not supply less than the treatment prescribed. Equally, there are medicines, where it may be inappropriate to give a patient more medicine than prescribed. The recommended dose in the PIL and British National Formulary and any unlicensed use are also relevant considerations. While the consultation document states that 77% of all prescriptions are repeat prescriptions, this means 23% of prescriptions are not. With approximately 1 billion prescription items dispensed annually in England, this is a significant number of prescription items and associated patients for whom the judgement of the supervising pharmacist is particularly important.

It is not clear why the consultation document references the professional judgment of the responsible pharmacist, who is in charge of the business at the premises, rather than the supervising pharmacist who supervises individual transactions involving the preparation, dispensing and sale or supply of medicines. Anything other than supervision by the supervising pharmacist, supervision on an individual patient basis, would be a patient safety issue.

**The proposed 10% discretion may be insufficient to allow community pharmacy to make full use of OPD.**

It is questionable whether the proposed 10% discretion will be enough to allow community pharmacy to make full use of OPD. The 10% works for prescriptions for 28 and 30 doses. This enables a pharmacy to provide 28 doses for a prescription for 30 and 30 doses for a prescription for 29 for example, tablets or capsules). But if the quantity prescribed varies by more than 10% from the pack size a community pharmacy will still have to split the pack. For example, if 84 is prescribed, a 100 pack cannot be given; and if for example 42 are prescribed (for a medicine presented in packs of 28), neither 28 nor 56 may be supplied. Therefore, PSNC encourages DHSC to consider whether the legislation fully supports an OPD model such as the OPD model used in Scotland.

In addition, the consultation document states that e*nabling OPD would also make it more likely that patients will get complete packs where the days of the week are marked.* This will only be the case if the community pharmacy can supply the full or half pack to the patient.

The status of special containers may need to be considered as part of this consultation. The consultation documents states that the exceptions to supply of the exact quantity of medicine prescribed are *where it is practically impossible or very difficult to split the original pack.* However, determination of special container status sometimes appears to be influenced by other considerations, such as funding considerations, as well as the medicinal product itself. It is suggested that provision for special containers could be included in the current proposals.

**There is no evidence of patient safety concerns in the consultation so PSNC cannot assess whether the proposed measures are appropriate to address the risk (Safety concerns around sodium valproate are evidenced in earlier studies).**

**The Medicines and Medical Devices Impact Assessment in 2020 suggested that any such patient safety concerns could be met ‘*in relation to a specific medicine only, [or] a class of medicines ...’*.**

**The Medicines and Medical Devices Impact Assessment contained a proposal that Manufacturers provide up to date, digital Patient Information Leaflets (PILs) to address any patient safety considerations.**

These observations are primarily based on the DHSC’s own assessment in the Medicines and Medical Devices Impact Assessment in 2020. This stated that:

*Human Medicines Regulations illustrative example ii – leafletting and labelling*

*133. The current regulation around leafletting and labelling requires a hard-copy patient information leaflet to be included with every original box of relevant medicine supplied by manufacturers. Given the increasing appetite for digital information access, we could consider whether hard copy leaflets continue to be the most appropriate vehicle for delivering this information to patients.*

*134. An example of where we could legislate in this area is an information provision for “whitebox” medicines. If a pharmacist is filling a prescription for 6 tablets, but the manufacturer sold the product in boxes of 10 tablets, the pharmacist will split the contents of the pack to dispense 6 of the 10 tablets in a plain white box. The original 10 tablet box is required under legislation to contain a patient information leaflet, but the repackaged 6 tablets dispensed to the patient is not. Therefore, patients receiving repackaged prescriptions will not receive a patient information leaflet under current regulations.*

*135. The Bill would allow us to propose a requirement for manufacturers to provide and maintain up-to-date statutory information about certain medicines on a variety of digital platforms and for all packs dispensed to signpost these resources. This might mean the regulations provide these changes in relation to a specific medicine only, a class of medicines or (at least theoretically) all medicines. This is necessary as we cannot foresee what medicines will be available in the future, nor whether information requirements might change for existing treatments if side-effects arise.*

*….*

*139. Electronic delivery of the statutory information could ensure patient access to the latest safety information about their medicines. It could also empower patients with diverse abilities to access information about their medicines directly with the support of digital technology.*

*…*

*141. Ultimately, we anticipate patients will benefit from improved access to timely information about their medication and potentially avoiding adverse health outcomes if the current information gaps persisted. There may also be savings to manufacturers if there is a possibility of reducing the provision of hard-copy leaflets. These benefits will be balanced against the cost to manufacturers of providing the information digitally and to pharmacies of sign-posting these resources where they split packs.*

**OPD should not apply to controlled drugs, given the significant control of supply of such products.**

We agree with the proposal that OPD will not apply to controlled drugs (Schedules 1 – 4). These medicines are subject to significant additional controls varying with their schedule and it would not be appropriate to vary the prescribed quantity, particularly to avoid additional supply and ensure that records of prescribed and dispensed medicines are clear in community pharmacy and correspond with GP prescription records.

Efficiencies

**OPD provides efficiencies for certain community pharmacies, particularly those with large-scale automated dispensing units, or remote hub assembly units, but is unlikely to provide efficiencies for all community pharmacies.**

**There may be an adverse financial effect of the proposal for some NHS community pharmacy contractors, particularly for contractors with only one to five pharmacies who have no legal, or financially viable access, to local or remote automated dispensing, and this should be explored when NHS funding arrangements are considered.**

**Snipping**

Community pharmacies with large-scale automated dispensing units and remote hub assembly units employ numbers of staff to snip blister packs. This is time consuming, costly and removes the medicine from the automated process. There are therefore benefits or efficiencies from increased use of OPD.

However, snipping will continue following the introduction of any OPD proposals because they will not apply to all prescriptions. In addition, the consultation document indicates that 77% of all prescription items are already repeat medicines and many of these are provided in the manufacturer’s original container. Where they are, community pharmacies will have no efficiency from the introduction of any OPD discretion.

Pharmacies with one to five pharmacies are less likely to gain any efficiency from the OPD proposals. While there may be streamlining of activity, it is unlikely to mean a reduction in staff costs and the time saved is unlikely to be significant for the pharmacy staff. In terms of a manual dispensing process the saving in time between OP and split pack dispensing is likely to be minimal. In addition, as the container allowance of 10p for each split pack is not payable with OPD, they could neither gain nor lose, or alternatively could be worse off.

**Hub and spoke**

There is reference to hub and spoke dispensing in the consultation document. Community pharmacy contractors with such arrangements already have realised any efficiencies, generally after making significant upfront capital investment. Therefore, those community pharmacy contractors will not achieve further efficiencies from such arrangements.

Those community pharmacy contractors with businesses that are not sufficiently large to support hub and spoke dispensing may be able to use such arrangements when permitted, if DHSC introduces changes to legislation following consultation. However, DHSC has indicated in its Medicines and Medical Devices impact assessment (paragraphs 169 – 177) the benefits of hub and spoke dispensing between different legal entities are uncertain, it will not be for all community pharmacy contractors, and nobody will have to do it.

The National Pharmacy Association, which represents independent community pharmacy contractors has indicated that *there is currently no basis for claims that Hub & Spoke will allow pharmacies to reduce their operating costs[[3]](#footnote-4).*

**Container allowance**

As indicated, currently community pharmacies are paid a container allowance of 10p for each split pack. PSNC estimates that approximately 24% of all items dispensed (1 billion annually) attract a container allowance and, therefore, overall, the sector is paid approximately £24 million annually for this work.

Where a prescribed medicine is dispensed in the manufacturer’s original container, clearly no container allowance is paid. Accordingly, as OPD use increases payments of this allowance decrease for community pharmacies. Therefore, increased use of OPD leads to a decrease in income for individual community pharmacies.

Furthermore, this is a decrease in income for the community pharmacy sector because the funding for the container allowance is outside the global sum paid. So, income ‘lost’ due to increased OPD is not paid to the sector in other fees or allowances.

Therefore, community pharmacies must offset this loss in income before any other efficiencies can be achieved in accordance with the 5-year deal – such as the release of staff time in pharmacies.

**Carbon footprint**

While we accept that reducing the use of cardboard boxes for split pack dispensing gives the greatest reduction in carbon footprint, recycling these boxes can reduce the carbon footprint. Community pharmacy could play a part in this for the NHS, for example, recommending such recycling, as it already plays a part in seeking to reduce the carbon footprint around the supply of medicines as shown below:

**Medicines** account for **25% of emissions within the NHS**. A small number of medicines account for a significant proportion of the emissions with **inhalers making up 3%** of them. In England, more than **65 million inhalers are prescribed every year**, with the most frequently prescribed being pressurised Metered Dose Inhalers (pMDIs) and Dry Powder Inhalers. pMDIs currently use **hydrofluorocarbon gases** (HFCs or ‘F-gases’) as propellants.

A typical pMDI with 10g of propellant can have a carbon footprint of 13-33kg depending on the type of propellant. This is **equivalent to driving an average car 45-115 miles**. Used inhalers typically have **30% of the original propellant remaining** in the canister. Inhalers returned to pharmacies for safe disposal will be **incinerated at high temperature** by NHS England and NHS Improvement’s waste contractor.

Pharmacy teams can **take a lead in educating patients** who use inhalers **about the environmental benefits of returning their inhalers** to the pharmacy for disposal, rather than putting them in their domestic refuse; and the 2021/22 Pharmacy Quality Scheme includes a relevant requirement.[[4]](#footnote-5)

Legislation and the NHS

**NHS considerations (regulatory and funding) around OPD should dovetail with the HMR changes to ensure that the HMR changes provide the basis for all options required for NHS OPD.**

**Community pharmacy issues are referenced in relation to patient safety, efficiencies, business impact and legislation.**

**Community pharmacy regulatory and funding considerations are not the subject of this consultation.**

**Community pharmacies will be concerned about the reimbursement mechanism around OPD within NHS dispensing;**

We agree with the proposed introduction of transitional provisions so that community pharmacy contractors may not use the flexibility of any changes to the HMRs until appropriate arrangements are in place for OPD use within NHS dispensing in England.

We look forward to negotiating with DHSC changes to the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 and changes to the Drug Tariff to support OPD in England.

We are keen to explore the OPD model currently used in Scotland, to assess its suitability for OPD in England.

As indicated earlier, we are concerned that the current proposed OPD changes may not go far enough to support fully an OPD model for England based on the model used in Scotland, or the use of the special container category for original pack dispensing in England.

Accordingly, we consider changes to the HMRs should be greater than proposed changes.

Changes will also be required to the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 to provide for OPD for GSL and P medicines prescribed on NHS prescriptions and dispensed by community pharmacies, if the amendments to the HMRs cover only POMs.

Finally, we consider that OPD within the NHS should not be overly complicated for the benefit of patients, community pharmacy teams and contractors and commissioners and their representatives.

**Community pharmacies and GP practices are likely to have a higher level of initial patient queries around OPD and a continued residual level of query, resulting in additional patient consultation time.**

As stated earlier, we consider that community pharmacy and general practice will spend some additional time discussing relevant issues with patients.

Alternatives

**DHSC should consider fully alternatives to OPD, including consistency of approach by manufacturers and prescribers.**

We consider that the answers in relation to OPD primarily lie with the NHS as the ultimate purchaser of the medicines, the manufacturer of the medicines and the prescribers, recognising the importance of the prescriber’s professional judgement.

We consider that the use of OPD by community pharmacy while important and welcomed is seeking to minimise the effect of the problem – there is no consistency in the quantity used for monthly dispensing, 28 or 30 - rather than seeking to influence manufacturers and, to an appropriate extent, prescribers, to produce and thus prescribe pack sizes for a month that are routinely either 28 or 30.

Sodium Valproate

**Changes around sodium valproate are agreed on an exceptional basis; however, it is considered that the general OPD proposals would achieve the desired patient safety aim for the product (with suitable professional recommendation).**

In 2018, MHRA introduced guidance for pharmacists supplying sodium valproate[[5]](#footnote-6). This followed EU guidance. The Royal Pharmaceutical Society and others support the pregnancy prevention programme with guidance and materials for community pharmacy.

NHSE&I has shared data from the Pharmacy Quality Scheme (PQS) 2018/2019 valproate audit — which was conducted by just over 90% of community pharmacies in England (10,293) and completed by 94.3% of women taking the epilepsy drug (12,068) — showing that 88.9% were given the card by their pharmacist, which is a requirement under Medicines and Healthcare Regulatory Agency (MHRA) guidance introduced in 2018. Of the women surveyed, just 5.6% (675) said they had not been provided with advice and information in line with the [MHRA’s 2018 Drug Safety Update](https://www.gov.uk/drug-safety-update/valproate-medicines-epilim-depakote-contraindicated-in-women-and-girls-of-childbearing-potential-unless-conditions-of-pregnancy-prevention-programme-are-met), which said that valproate medicines must no longer be used in women or girls of childbearing potential unless a pregnancy prevention programme was in place.

The Community Pharmacy Patient Safety Group’s website states that in relation to the audit, Janice Perkins, former Chair of the Patient Safety Group said**“**the audit’s findings demonstrate the significant role that pharmacy teams play in raising awareness and understanding about high-risk medicines among patients and their families and carers. Supporting women and girls prescribed valproate is a key priority across the whole health sector.”[[6]](#footnote-7)

We considered that there are other products where provision of the PIL is very important and our view is that the proposed OPD discretion for community pharmacy together with the current MHRA and professional guidance ought to be sufficient, particularly if combined with appropriate NHS funding provisions to ensure that the original pack is supplied, for example, as a special container.

Consultation questions

**Original pack dispensing**

To what extent do you agree or disagree that we should remove current restrictions preventing original pack dispensing?

* strongly agree
* agree
* neither agree nor disagree
* disagree
* strongly disagree

The consultation considers consequences such as patients receiving too much or too little medication and changes in pack size purchasing patterns. Do you think there are other consequences that need to be considered?

**Patient considerations are more nuanced than described and include reference to patient preference and payment of the NHS charge.**

Currently, patients receive the exact quantity of medicine prescribed and this is their expectation, subject to certain exceptions. Not all patients will accept differing amounts provided, particularly if they perceive they are somehow losing out, or the community pharmacy is somehow gaining. Those patients who pay for each prescription are particularly likely to question the practice, if they pay a charge for each prescription dispensed. Accepting that whether a prescriber prescribes 28, 56 or 84 doses may also have an impact on the cost of prescriptions for a patient who pays for each one. The pharmacist and pharmacy team can manage this, but it is likely to take more of their time.

Management of repeats from a patients GP may also be an issue because the GP practice will be unaware of the exact quantity of medicine supplied. The GP practice will only be aware of the quantity of medicine prescribed. This may not be an immediate issue, but over time may lead to re-ordering issues. A GP practice may delay issuing a repeat prescription if the patient is thought to have a stock of medicine to use up before a prescription is required. This in turn may lead to more emergency supplies by community pharmacy; and more conversations between pharmacists, patients and GPs.

Appropriate messaging and communication for patients will help patients to embrace the changes and thus reduce the time community pharmacy and general practice are likely to spend explaining the changes.

Pharmacies’ differing practices may also affect patients. One may supply twenty-eight, another thirty tablets for the same prescription. This would mean that the time at which the medicine runs out varies for different months and with the natural lag time ordering a prescription, could increase the likelihood that occasions patients will run out of medicine and need to obtain more as an emergency supply from a community pharmacy. Where one pharmacy regularly supplies a patient’s medicine this is less likely to occur.

The professional judgement of the pharmacist supervising the supply is important, to ensure that any general OPD discretion is appropriate to apply to the individual patient. For certain medicines, such as antibiotics, the community pharmacy should supply the full course of treatment to the patient and not supply less than the treatment prescribed. Equally, there are medicines, where it may be inappropriate to give a patient more medicine than prescribed. The recommended dose in the PIL and British National Formulary and any unlicensed use are also relevant considerations. While the consultation document states that 77% of all prescriptions are repeat prescriptions, this means 23% of prescriptions are not. With approximately 1 billion prescription items dispensed annually in England, this is a significant number of prescription items and associated patients for whom the judgement of the supervising pharmacist is particularly important.

It is not clear why the consultation document references the professional judgment of the responsible pharmacist, who is in charge of the business at the premises, rather than the supervising pharmacist who supervises individual transactions involving the preparation, dispensing and sale or supply of medicines. Anything other than supervision by the supervising pharmacist, supervision on an individual patient basis, would be a patient safety issue.

The consultation considers and dismisses other options such as making all manufacturers supply in the same pack size or asking all prescribers to prescribe consistent quantities.

We consider that the answers in relation to OPD primarily lie with the NHS as the ultimate purchaser of the medicines, the manufacturer of the medicines and the prescribers, recognising the importance of the prescriber’s professional judgement.

We consider that the use of OPD by community pharmacy while important and welcomed is seeking to minimise the effect of the problem – there is no consistency in the quantity used for monthly dispensing, 28 or 30 - rather than seeking to influence manufacturers and, to an appropriate extent, prescribers, to produce and thus prescribe pack sizes for a month that are routinely either 28 or 30.

To what extent do you agree or disagree that these other options suggested are not viable?

* strongly agree
* agree
* neither agree nor disagree
* disagree
* strongly disagree

Do you believe there are alternative options that you feel should be considered?

Nothing to add.

To what extent do you agree or disagree with the proposed deviation of a different quantity that is not greater or smaller than 10%?

* strongly agree
* agree
* neither agree nor disagree
* disagree
* strongly disagree

Do you have any comments on the proposed deviation limit of 10%?

**The proposed 10% discretion may be insufficient to allow community pharmacy to make full use of OPD.**

It is questionable whether the proposed 10% discretion will be enough to allow community pharmacy to make full use of OPD. The 10% works for prescriptions for 28 and 30 doses. This enables a pharmacy to provide 28 doses for a prescription for 30 and 30 doses for a prescription for 29 for example, tablets or capsules). But if the quantity prescribed varies by more than 10% from the pack size a community pharmacy will still have to split the pack. For example, if 84 is prescribed, a 100 pack cannot be given; and if for example 42 are prescribed (for a medicine presented in packs of 28), neither 28 nor 56 may be supplied. Therefore, PSNC encourages DHSC to consider whether the legislation fully supports a OPD model such as the OPD model used in Scotland.

In addition, the consultation document states that e*nabling OPD would also make it more likely that patients will get complete packs where the days of the week are marked.* This will only be the case if the community pharmacy can supply the full or half pack to the patient.

The status of special containers may need to be considered as part of this consultation. The consultation documents states that the exceptions to supply of the exact quantity of medicine prescribed are *where it is practically impossible or very difficult to split the original pack.* However, determination of special container status sometimes appears to be influenced by other considerations, such as funding considerations, as well as the medical product itself. It is suggested that provision for special containers could be included in the current proposals.

To what extent do you agree or disagree that OPD should not apply to controlled drugs?

* strongly agree
* agree
* neither agree nor disagree
* disagree
* strongly disagree

**OPD should not apply to controlled drugs, given the significant control of supply of such products.**

We agree with the proposal that OPD will not apply to controlled drugs (schedules 1 – 4). These medicines are subject to significant additional controls varying with their schedule and it would not be appropriate to vary the prescribed quantity, particularly to avoid additional supply and ensure that records of prescribed and dispensed medicines are clear in community pharmacy and correspond with GP prescription records.

To what extent do you agree or disagree that OPD and the supply of complete packs of sodium valproate should apply to dispensing doctors?

* strongly agree
* agree
* neither agree nor disagree
* disagree
* strongly disagree

This is appropriate in terms of consistency for the provision of NHS pharmaceutical services.

**Supply of medicines containing sodium valproate in original packs**

To what extent do you agree or disagree that requiring the dispensing of medicines containing sodium valproate in the manufacturer’s original pack will ensure patients are always provided with the safety information supplied on the label and in the PIL?

* strongly agree
* agree
* neither agree nor disagree
* disagree
* strongly disagree

Please provide a reason for your answer and any evidence to support it, including any experiences you or your organisations have had trying to provide patients with important risk minimisation measures.

**Changes around sodium valproate are agreed on an exceptional basis; however, it is considered that the general OPD proposals would achieve the desired patient safety aim for the product (with suitable professional recommendation).**

In 2018, MHRA introduced guidance for pharmacists supplying sodium valproate[[7]](#footnote-8). This followed EU guidance. The Royal Pharmaceutical Society and others support the pregnancy prevention programme with guidance and materials for community pharmacy.

NHSE&I has shared data from the Pharmacy Quality Scheme (PQS) 2018/2019 valproate audit — which was conducted by just over 90% of community pharmacies in England (10,293) and completed by 94.3% of women taking the epilepsy drug (12,068) — showing that 88.9% were given the card by their pharmacist, which is a requirement under Medicines and Healthcare Regulatory Agency (MHRA) guidance introduced in 2018. Of the women surveyed, just 5.6% (675) said they had not been provided with advice and information in line with the [MHRA’s 2018 Drug Safety Update](https://www.gov.uk/drug-safety-update/valproate-medicines-epilim-depakote-contraindicated-in-women-and-girls-of-childbearing-potential-unless-conditions-of-pregnancy-prevention-programme-are-met), which said that valproate medicines must no longer be used in women or girls of childbearing potential unless a pregnancy prevention programme was in place.

The Community Pharmacy Patient Safety Group’s website states that in relation to the audit, Janice Perkins, former Chair of the Patient Safety Group said**“**the audit’s findings demonstrate the significant role that pharmacy teams play in raising awareness and understanding about high-risk medicines among patients and their families and carers. Supporting women and girls prescribed valproate is a key priority across the whole health sector.”[[8]](#footnote-9)

**Impact assessment**

Can you provide any evidence or comments that would help us to develop the cost benefit analysis on these proposed changes?

**OPD provides efficiencies for certain community pharmacies, particularly those with large-scale automated dispensing units, or remote hub assembly units, but is unlikely to provide efficiencies for all community pharmacies.**

**There may be an adverse financial effect of the proposal for some NHS community pharmacy contractors, particularly for contractors with one to five pharmacies who have no legal, or financially viable access, to local or remote automated dispensing, and this should be explored when NHS funding arrangements are considered.**

**Snipping**

Community pharmacies with large-scale automated dispensing units and remote hub assembly units employ numbers of staff to snip blister packs. This is time consuming, costly and removes the medicine from the automated process. There are therefore benefits or efficiencies from increased use of OPD.

However, snipping will continue following the introduction of any OPD proposals because they will not apply to all prescriptions. In addition, the consultation document indicates that 77% of all prescription items are already repeat medicines and many of these are provided in the manufacturer’s original container. Where they are, community pharmacies will have no efficiency from the introduction of any OPD discretion.

Pharmacies with one to five pharmacies are less likely to gain any efficiency from the OPD proposals. While there may be streamlining of activity, it is unlikely to mean a reduction in staff costs and the time saved is unlikely to be significant for the pharmacy staff. In terms of a manual dispensing process the saving in time between OP and split pack dispensing is likely to be minimal. In addition, as the container allowance of 10p for each split pack is not payable with OPD, they could neither gain nor lose, or alternatively could be worse off.

To what extent do you agree or disagree that OPD will result in time savings on dispensing?

See above.

If you agree, are you able to provide any evidence on the time savings, including anything around how long it takes to split a pack? If you don’t think there will be time savings, why not?

See above.

Do you believe that OPD will have positive patient safety impacts? Are you able to provide specific evidence about the size of these impacts?

**There is no evidence of patient safety concerns in the consultation so PSNC cannot assess whether the proposed measures are appropriate to address the risk (Safety concerns around sodium valproate are evidenced in earlier studies).**

**The Medicines and Medical Devices Impact Assessment in 2020 suggested that any such patient safety concerns could be met ‘*in relation to a specific medicine only, [or] a class of medicines ...’*.**

**The Medicines and Medical Devices Impact Assessment contained a proposal that Manufacturers provide up to date, digital Patient Information Leaflets (PILs) to address any patient safety considerations.**

These observations are primarily based on the DHSC’s own assessment in the Medicines and Medical Devices Impact Assessment in 2020. This stated that:

*Human Medicines Regulations illustrative example ii – leafletting and labelling*

*133. The current regulation around leafletting and labelling requires a hard-copy patient information leaflet to be included with every original box of relevant medicine supplied by manufacturers. Given the increasing appetite for digital information access, we could consider whether hard copy leaflets continue to be the most appropriate vehicle for delivering this information to patients.*

*134. An example of where we could legislate in this area is an information provision for “whitebox” medicines. If a pharmacist is filling a prescription for 6 tablets, but the manufacturer sold the product in boxes of 10 tablets, the pharmacist will split the contents of the pack to dispense 6 of the 10 tablets in a plain white box. The original 10 tablet box is required under legislation to contain a patient information leaflet, but the repackaged 6 tablets dispensed to the patient is not. Therefore, patients receiving repackaged prescriptions will not receive a patient information leaflet under current regulations.*

*135. The Bill would allow us to propose a requirement for manufacturers to provide and maintain up-to-date statutory information about certain medicines on a variety of digital platforms and for all packs dispensed to signpost these resources. This might mean the regulations provide these changes in relation to a specific medicine only, a class of medicines or (at least theoretically) all medicines. This is necessary as we cannot foresee what medicines will be available in the future, nor whether information requirements might change for existing treatments if side-effects arise.*

*….*

*139. Electronic delivery of the statutory information could ensure patient access to the latest safety information about their medicines. It could also empower patients with diverse abilities to access information about their medicines directly with the support of digital technology.*

*…*

*141. Ultimately, we anticipate patients will benefit from improved access to timely information about their medication and potentially avoiding adverse health outcomes if the current information gaps persisted. There may also be savings to manufacturers if there is a possibility of reducing the provision of hard-copy leaflets. These benefits will be balanced against the cost to manufacturers of providing the information digitally and to pharmacies of sign-posting these resources where they split packs.*

Do you believe there will be impacts to areas in addition to those on patients and pharmacies?

Yes. See the response as a whole.

Is there any further evidence we should take into account?

**Container allowance**

As indicated, currently community pharmacies are paid a container allowance of 10p for each split pack. PSNC estimates that approximately 24% of all items dispensed (1 billion annually) attract a container allowance and, therefore, overall, the sector is paid approximately £24 million annually for this work.

Where a prescribed medicine is dispensed in the manufacturer’s original container, clearly no container allowance is paid. Accordingly, as OPD use increases payments of this allowance decrease for community pharmacies. Therefore, increased use of OPD leads to a decrease in income for individual community pharmacies.

Furthermore, this is a decrease in income for the community pharmacy sector because the funding for the container allowance is outside the global sum paid. So, income ‘lost’ due to increased OPD is not paid to the sector in other fees or allowances.

Therefore, community pharmacies must offset this loss in income before any other efficiencies can be achieved in accordance with the 5-year deal – such as the release of staff time in pharmacies.

Do you think that the OPD flexibility will create a cost burden for manufacturers if the demand for certain pack sizes changes?

No comment.

Do you think there are any other impacts for the supply chain that we have not considered?

None identified.

Do you believe the reduction in the use of boxes will result in a minimal cost saving? And a positive impact on carbon footprint? Are you able to provide any evidence?

**Carbon footprint**

While we accept that reducing the use of cardboard boxes for split pack dispensing gives the greatest reduction in carbon footprint, recycling these boxes can reduce the carbon footprint. Community pharmacy could play a part in this for the NHS, for example, recommending such recycling, as it already plays a part in seeking to reduce the carbon footprint around the supply of medicines as shown below:

**Medicines** account for **25% of emissions within the NHS**. A small number of medicines account for a significant proportion of the emissions with **inhalers making up 3%** of them. In England, more than **65 million inhalers are prescribed every year**, with the most frequently prescribed being pressurised Metered Dose Inhalers (pMDIs) and Dry Powder Inhalers. pMDIs currently use **hydrofluorocarbon gases** (HFCs or ‘F-gases’) as propellants.

A typical pMDI with 10g of propellant can have a carbon footprint of 13-33kg depending on the type of propellant. This is **equivalent to driving an average car 45-115 miles**. Used inhalers typically have **30% of the original propellant remaining** in the canister. Inhalers returned to pharmacies for safe disposal will be **incinerated at high temperature** by NHS England and NHS Improvement’s waste contractor.

Pharmacy teams can **take a lead in educating patients** who use inhalers **about the environmental benefits of returning their inhalers** to the pharmacy for disposal, rather than putting them in their domestic refuse; and the 2021/22 Pharmacy Quality Scheme includes a relevant requirement.[[9]](#footnote-10)

To what extent do you agree or disagree with our assessment that the OPD flexibility regarding patients access to medicines and hence needing to see their GP will either balance out or be marginal?

As stated earlier, we consider that community pharmacy and general practice will spend some additional time discussing relevant issues with patients.

Without knowing the detail of each administrations’ approach to reimbursement of the OPD flexibility, do you agree or disagree with our assessment that the impact on NHS medicine costs will either be cost neutral or marginal?

**NHS considerations (regulatory and funding) around OPD should dovetail with the HMR changes to ensure that the HMR changes provide the basis for all options required for NHS OPD.**

**Community pharmacy issues are referenced in relation to patient safety, efficiencies, business impact and legislation.**

**Community pharmacy regulatory and funding considerations are not the subject of this consultation.**

**Community pharmacies will be concerned about the reimbursement mechanism around OPD within NHS dispensing;**

We agree with the proposed introduction of transitional provisions so that community pharmacy contractors may not use the flexibility of any changes to the HMRs until appropriate arrangements are in place for OPD use within NHS dispensing in England.

We look forward to negotiating with DHSC changes to the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 and changes to the Drug Tariff to support OPD in England.

We are keen to explore the OPD model currently used in Scotland, to assess its suitability for OPD in England.

As indicated earlier, we are concerned that the current proposed OPD changes may not go far enough to support fully an OPD model for England based on the model used in Scotland, or the use of the special container category for original pack dispensing in England.

Accordingly, we consider changes to the HMRs should be greater than proposed changes.

Changes will also be required to the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 to provide for OPD for GSL and P medicines prescribed on NHS prescriptions and dispensed by community pharmacies, if the amendments to the HMRs cover only POMs.

Finally, we consider that OPD within the NHS should not be overly complicated for the benefit of patients, community pharmacy teams and contractors and commissioners and their representatives.

**Community pharmacies and GP practices are likely to have a higher level of initial patient queries around OPD and a continued residual level of query, resulting in additional patient consultation time.**

As stated earlier, we consider that community pharmacy and general practice will spend some additional time discussing relevant issues with patients.

**Are there any potential costs or financial implications of the proposals that you do not think we have considered?**

**Hub and spoke**

There is reference to hub and spoke dispensing in the consultation document. Community pharmacy contractors with such arrangements already have realised any efficiencies, generally after making significant upfront capital investment. Therefore, those community pharmacy contractors will not achieve further efficiencies from such arrangements.

Those community pharmacy contractors with businesses that are not sufficiently large to support hub and spoke dispensing may be able to use such arrangements when permitted, if DHSC introduces changes to legislation following consultation. However, DHSC has indicated in its Medicines and Medical Devices impact assessment (paragraphs 169 – 177) the benefits of hub and spoke dispensing between different legal entities are uncertain, it will not be for all community pharmacy contractors, and nobody will have to do it.

The National Pharmacy Association, which represents independent community pharmacy contractors has indicated that *there is currently no basis for claims that Hub & Spoke will allow pharmacies to reduce their operating costs[[10]](#footnote-11).*

**DHSC Consultation Document**

**Background**

Regulation 214(1) contained in part 12 of the Human Medicines Regulation 2012 requires that a pharmacist may not sell or supply a prescription only medicine ‘except in accordance with a prescription given by an appropriate practitioner’.

Currently we interpret dispensing ‘in accordance with a prescription’ to mean pharmacists must supply the exact quantity prescribed Health and Social Care Act 2008 with a few exceptions, where it is practically impossible or very difficult to split the original pack. This means where the quantity prescribed on a prescription is not equal to (or multiple of) a pack size, pharmacy staff need to split a manufacturer’s original pack in order to dispense the prescribed quantity. In many circumstances this will require splitting the manufacturer’s original pack and either providing the manufacturer’s pack but with a quantity taken out or providing the amount prescribed in a dispensing box or bottle.

This has many consequences, for example:

1. If a patient receives the manufacturer’s original pack but with some dosage units missing, the tamper evident seal will be broken. The patient might be concerned either that someone has interfered with the medicine or that the pharmacist has accidentally underfilled their prescription.
2. If a patient receives their medicine in a dispensing box, they may get lots of small ‘snips’ from a blister strip making it difficult to manage their supply, ensure compliance and identify whether they have taken their tablet that day.
3. If a patient receives their medicine in a dispensing box or bottle, they may not get all the patient information such as the manufacturer’s patient information leaflet (PIL).
4. Pharmacy staff spend considerable time splitting boxes, snipping blisters and repackaging medicines.
5. It reduces the cost effectiveness of automated dispensing – as, in the main, automation cannot ‘split and snip’ – so any prescription where this is required, it must be done outside of the automated process.

**Proposals**

Our intention is to introduce amendments to Part 12 of the Human Medicine Regulations 2012, so that when dispensing medicines, pharmacists may utilise manufacturer’s original packs. Our proposal is that:

* pharmacists have flexibility to dispense more or less than the prescribed quantity (up to 10% more or less) if that means they can dispense in the manufacturer’s original packs, except where this would negatively affect the patient’s clinical treatment regimen – so they have to make a judgement that this is appropriate. This would not apply to controlled drugs
* however, the amendments will include a transitional provision, so the flexibility does not automatically apply in NHS pharmaceutical services in England, Northern Ireland and Wales, to enable these administrations to decide how they want these to apply in their respective NHS services. In Scotland, the Scottish government is not seeking such a transitional provision because of arrangements already made so pharmacists will be able to utilise the original pack dispensing (OPD) flexibility within their NHS service provision straight away
* the supply of sodium valproate must always be in original packaging regardless of the conditions we set around OPD
* we propose to use the enabling powers in Part 2 of the MMDA. Currently, we are only proposing a flexibility around quantity, not around formulation or strength

**Impacts**

As part of this consultation we are asking responders to let us know of any measurable impacts or impacts we have not considered. An impact assessment will then be completed following this consultation considering information we gather through responses.

**Efficiency of OPD**

By allowing community pharmacies to dispense medicines in their original packs, we believe OPD will help them to become more efficient and to free up their time for other tasks such as providing clinical services to patients.

A further way in which we committed to supporting efficiencies in the sector is through pursuing legislative change to enable all pharmacies to use “hub and spoke” dispensing models. Hub and spoke dispensing is where parts of the dispensing process are undertaken on a separate pharmacy premises, a “hub”. The assembly of prescriptions takes place on a large scale in a hub and therefore is much more likely to be able to make the use of automated processes viable. OPD will mean more prescriptions can be assembled using an automated process and so there will be synergistic efficiencies gained by use of hub and spoke dispensing and automation.

Further to an initial consultation in 2016 on hub and spoke dispensing, in January 2021 we began pre-consultation engagement with stakeholders to enable hub and spoke dispensing across legal entities, with the view to launching a full public consultation in due course. Previously, stakeholders have pointed to OPD as a main factor in determining whether hub and spoke dispensing will create efficiencies. If OPD is not enabled, the potential efficiencies of hub and spoke dispensing will be curtailed, as automated processes rely on being able to dispense full packs.

**Patient safety considerations for OPD**

Safeguarding public health was one of the critical considerations of the Medicines and Medical Devices Act 2021 (the MMDA) and was central to the development of these proposals. We think that as well as increasing efficiency, OPD would lead to clear patient safety benefits. By dispensing medicines in their original packs, it will be easier for pharmacies to ensure that patients will receive the PIL, which provides detailed information on the safe and effective use of the product.

Enabling OPD would also make it more likely that patients will get complete packs where the days of the week are marked. In turn making it easier for patients to see whether they have taken their medicine that day and how many they have left.

We are proposing a 10% flexibility to deviate from the prescribed amount. A deviation of 10% provides sufficient flexibility to cover the majority of the mismatches in pack sizing due to the quantity prescribed, for example a 28 pack (or multiple) when 30 is prescribed, or a 30 pack when 28 is prescribed.

We have considered the risk of giving too much medicine and alongside that the risk of not giving patients enough. In giving a patient too much medicine there is a potential increased risk of either accidental or intentional overdose, or patients taking medicines longer than they medically need to (for example unnecessary extended use of antibiotics or steroids). The other aspect is the risk of not giving patients enough medication, which could mean they receive a suboptimal dose. We have considered this against the evidence that repeat prescriptions make up around 77% of all prescription items ([NHS England and Improvement, June 2020 – letter template](https://www.england.nhs.uk/coronavirus/wp-content/uploads/sites/52/2020/03/C0546-electronic-repeat-dispensing-letter-4-june-2020.pdf)). Given this high percentage, an increase or decrease would most likely mean that the patient would access their next repeat prescription either a few days earlier or later than they would have done.

However, judgement by the responsible pharmacist will remain an important part of the dispensing process; for instance there are some prescriptions such as a course of steroids or antibiotics where a decision may need to be made not to give people less, so they have enough to finish their treatment. Alternatively, a decision may need to be made not to give people more, so they do not take medication for longer than the course of treatment such as steroids or strong pain relievers. Furthermore, we are not at this point proposing any flexibility on the quantity of controlled drugs supplied compared to dispensed.

**Business impact of OPD**

It is our expectation that in enabling original pack dispensing additional costs would not fall on businesses. We anticipate that these changes could release staff time in pharmacies as they utilise OPD to maximise efficiency.

However, by allowing community pharmacies to dispense medicines in their original packs this could lead to changes that could impact manufacturers. For example, it may lead to changes in pack size purchasing patterns that would then have a knock-on effect in terms of demand for particular pack sizes from manufacturers.

We anticipate that OPD will also mean a reduction in the use of boxes currently required. While a minimal cost reduction as there is a small price per unit, this could be positive in reducing the carbon footprint of the medicines supply process.

**NHS impact of OPD**

The proposed amendments would be enabling and not mandatory. The policy intention is for the proposals to cover NHS and private prescriptions. However, we propose to place a transitional provision in the Human Medicines Regulations 2012 so that the flexibility does not automatically apply in pharmaceutical services in England, Northern Ireland and Wales. This will enable these administrations to consider how they want to implement this enabling flexibility within their respective NHS services. The Scottish Government is not seeking such a transitional provision because of arrangements it has already made, so pharmacists will be able to utilise the OPD flexibility within their NHS service provision straight away.

It is not clear whether these changes will result in a significant increase or decrease in total medicines dispensed, nor a significant increase or decrease in the quantity of medicines that patients can access compared to what has been prescribed for them.

From our internal analysis, we estimate that approximately 75% of prescription items are already prescribed in quantities that align with available pack sizes (DHSC, April 2021). Therefore, as the flexibility is capped at 10%, the majority will not need a change to the quantity supplied. Of the remaining 25%, not all will be suitable for the flexibility to be applied. As a result, the number of prescription items that are affected is likely to be small, and it may be the case that any impact will either balance out or be marginal.

For example, a patient who receives a 10% decrease in supply compared to a prescribed quantity may access their next repeat prescription a few days earlier and may in turn need to see their GP earlier. However, a patient who receives a 10% increase in supply compared to a prescribed quantity may access their next repeat prescription a few days later and may in turn need to see their GP later. Under this scenario the knock-on impact on GP appointments, will therefore balance out. If, however, more patients get less medicine than those patients who get more, the increase in access to repeat prescriptions earlier, and in turn need to see their GP earlier, will be more than those who need to see their GP later and therefore may marginally increase the number of GP appointments needed. If, however, more patients get more medicine than those patients who get less, the increase in access to repeat prescriptions later, and in turn need to see their GP later, will be more than those who need to see their GP earlier and therefore may marginally decrease the number of GP appointments needed.

We welcome any views from stakeholders on the likely balance of patients receiving more or less medicine so that this can be factored into our impact assessment.

Alongside how the flexibility is implemented as part of NHS services, each administration will need to consider the consequences for NHS reimbursement. It is therefore difficult at this point to consider the impact on NHS medicine spend; however, again similar to patients’ earlier or later access to GPs, it may be cost neutral or, any change in costs will be marginal.

**Alternative options to OPD**

In proposing OPD as our preferred approach we have considered alternative options that would provide commonality in packs, for instance, if all manufacturers supply in the same pack size. However, we do not have the power to enable this and, critically, it would also have adverse impact around multi-market packs and could lead to unnecessary shortages where a manufacturer could not supply in a pack of that size. Another alternative option could involve asking all prescribers to prescribe consistent quantities, for example, if all prescribers prescribed 28 days’ supply for a monthly supply. However, this could reduce clinical freedom, and add an extra burden on GPs in terms of aligning pack sizes. GPs also would not know what pack sizes pharmacies had available.

The proposal being put forward through this consultation allows for flexibility, with their judgement, by the pharmacist.

**Particular safety concerns with medicine containing sodium valproate**

Sodium valproate is an effective treatment for epilepsy and bipolar disorder. It is a commonly used anti-epileptic and it may be the only effective treatment for some patients. However, the use of sodium valproate was, however, already known to be associated with birth defects when it was first licensed in the 1970s and further evidence has emerged since then about other adverse effects, in particular neurodevelopmental disorders in children where sodium valproate is taken used during pregnancy. The risk of such neurodevelopmental disorders is estimated at 30 to 40%, which is in addition to an 11% risk of a congenital abnormality.

In order to try to minimise the risk of unborn babies being exposed to the effects of this medication, any woman who could become pregnant must be enrolled in a Pregnancy Prevention Programme (PPP) if they are prescribed a product containing sodium valproate, which involves an annual specialist review, coupled with an acknowledgement of risk form, and supported by clear sodium valproate product information and labelling.

To support the implementation of the sodium valproate PPP, pharmacists received a written notification from the MHRA Chief Executive and the UK’s four Chief Pharmaceutical Officers which, among other things, stressed the need to provide a PIL with every valproate prescription even when sodium valproate is dispensed in dispensing boxes or bottles and not in its original packaging.

However, despite these initiatives, sodium valproate patient groups have continued to raise concerns that PILs are not always being provided by pharmacists where sodium valproate medicines are dispensed in dispensing boxes or bottles rather than the manufacturer’s original packs, and evidence continues to emerge suggesting many women remain unaware of the significant risks posed to their unborn baby should they fall pregnant while taking sodium valproate.

Therefore, the proposal is that where a prescription is not for a quantity in an original pack size, the requirement will be that the nearest number of whole packs will be supplied (either up or down) so that the patient receives only complete packs. These must not subsequently be re-packaged into dispensing boxes.

The impacts on patient safety, efficiency, business and the NHS, will be similar to those outlined above for OPD. Other than the difference between the quantity prescribed and the quantity dispensed could be more than 10% and the pharmacist does not have the ability to make a professional judgment as to whether to supply the quantity prescribed or an original pack. However, we have assessed that the ability to always dispense sodium valproate (which can pose risks to unborn children) in its original pack to ensure that all of the necessary safety information will be provided to the patient is of particular importance to outweigh any potential downsides to this. We welcome views from stakeholders around further impacts of whole pack dispensing of sodium valproate.

We have considered alternative policy options to ensure women are aware of the risks where sodium valproate medicines are dispensed. For example, as highlighted above for OPD, introducing other mandatory measures, such as manufacturers or prescribers to always supply or prescribe in set quantities but for the same reasons set out under OPD, we do not consider these appropriate. Furthermore, manufacturers have been required to supply sodium valproate only in small pack-sizes for some time but this has not always resulted in patients receiving original packs and the associated risk minimisation measures as pharmacy professionals continue to supply multiple packs in single dispensing boxes without the additional information resources.

**Dispensing doctors**

The policy intention is for both OPD and supply of complete packs of sodium valproate to apply to dispensing doctors. This does not need additional amendments to the Human Medicine Regulations 2012. However, as with community pharmacies, to enable OPD will require an amendment to their NHS pharmaceutical terms of service.

**Equality assessment**

In considering the amendments to the Human Medicines Regulations 2012, ministers must comply with the Public Sector Equality Duty (PSED). We will develop an equality assessment based on the following proposals:

* enabling the use of original pack dispensing
* requiring the dispensing of sodium valproate in the manufacturer’s original pack

**Questions**

**Original pack dispensing**

To what extent do you agree or disagree that we should remove current restrictions preventing original pack dispensing?

* strongly agree
* agree
* neither agree nor disagree
* disagree
* strongly disagree

The consultation considers consequences such as patients receiving too much or too little medication and changes in pack size purchasing patterns. Do you think there are other consequences that need to be considered?

The consultation considers and dismisses other options such as making all manufacturers supply in the same pack size or asking all prescribers to prescribe consistent quantities .

To what extent do you agree or disagree that these other options suggested are not viable?

* strongly agree
* agree
* neither agree nor disagree
* disagree
* strongly disagree

Do you believe there are alternative options that you feel should be considered?

To what extent do you agree or disagree with the proposed deviation of a different quantity that is not greater or smaller than 10%?

* strongly agree
* agree
* neither agree nor disagree
* disagree
* strongly disagree

Do you have any comments on the proposed deviation limit of 10%?

To what extent do you agree or disagree that OPD should not apply to controlled drugs?

* strongly agree
* agree
* neither agree nor disagree
* disagree
* strongly disagree

To what extent do you agree or disagree that OPD and the supply of complete packs of sodium valproate should apply to dispensing doctors?

* strongly agree
* agree
* neither agree nor disagree
* disagree
* strongly disagree

**Supply of medicines containing sodium valproate in original packs**

To what extent do you agree or disagree that requiring the dispensing of medicines containing sodium valproate in the manufacturer’s original pack will ensure patients are always provided with the safety information supplied on the label and in the PIL?

* strongly agree
* agree
* neither agree nor disagree
* disagree
* strongly disagree

Please provide a reason for your answer and any evidence to support it, including any experiences you or your organisations have had trying to provide patients with important risk minimisation measures.

**Impact assessment**

Can you provide any evidence or comments that would help us to develop the cost benefit analysis on these proposed changes?

To what extent do you agree or disagree that OPD will result in time savings on dispensing?

If you agree, are you able to provide any evidence on the time savings, including anything around how long it takes to split a pack? If you don’t think there will be time savings, why not?

Do you believe that OPD will have positive patient safety impacts? Are you able to provide specific evidence about the size of these impacts?

Do you believe there will be impacts to areas in addition to those on patients and pharmacies? Is there any further evidence we should take into account?

Do you think that the OPD flexibility will create a cost burden for manufacturers if the demand for certain pack sizes changes?

Do you think there are any other impacts for the supply chain that we have not considered?

Do you believe the reduction in the use of boxes will result in a minimal cost saving? And a positive impact on carbon footprint? Are you able to provide any evidence?

To what extent do you agree or disagree with our assessment that the OPD flexibility regarding patients access to medicines and hence needing to see their GP will either balance out or be marginal?

Without knowing the detail of each administrations’ approach to reimbursement of the OPD flexibility, do you agree or disagree with our assessment that the impact on NHS medicine costs will either be cost neutral or marginal?

Are there any potential costs or financial implications of the proposals that you do not think we have considered?

**NI respondents**

In Northern Ireland new policies must be screened under Section 75 of the [Northern Ireland Act 1998](https://www.legislation.gov.uk/ukpga/1998/47/section/75) which places a statutory duty on public authorities, to mainstream equality in all its functions – so that equality of opportunity and good relations are central to policy making and service delivery. In addition new or revised policies must be rural proofed in line with the [Rural Needs Act (NI) 2016](https://www.legislation.gov.uk/nia/2016/19/contents) which requires public authorities to have due regard to rural needs.

The Department of Health in NI do not consider that our proposals risk impacting different people differently with reference to their protected characteristics or where they live in NI. We welcome views on this point.

Do you think the proposals risk impacting people differently with reference to their (or could impact adversely on any of the) protected characteristics covered by the Public Sector Equality Duty set out in section 149 of the Equality Act 2010 or by section 75 of the Northern Ireland Act 1998? If so, please provide details.

**Equality assessment**

Do you have any evidence that we should consider in the development of an equality assessment?

**Demographic information**

Have you been prescribed sodium valproate in the past?

* yes
* no

Do you have professional experience of sodium valproate use?

* yes
* no

**Confidentiality of information**

We manage the information you provide in response to this consultation in accordance with the Department of Health and Social Care’s [Personal Information Charter](https://www.gov.uk/government/organisations/department-of-health-and-social-care/about/personal-information-charter).

Any information received, including personal information, may be published or disclosed in accordance with the access to information regimes (primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 2018 (DPA 2018) and the Environmental Information Regulations 2004).

If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory code of practice with which public authorities must comply and which deals, among other things, with obligations of confidence. In view of this it would be helpful if you would explain to us why you regard the information that you have provided as confidential. If we receive a request for disclosure of the information you have provided, we will take full account of your explanation, but we cannot give an assurance that confidentiality will be maintained in all circumstances.

An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the department.

The department will process your personal data in accordance with the DPA 2018 and, in most circumstances, this will mean that your personal data will not be disclosed to third parties.

**Legislative background and basis**

Section 45(1) of the MMDA includes a statutory requirement for the appropriate authority (here the Secretary of State for Health and Social Care and Northern Ireland Department of Health) to carry out a public consultation on proposed amendments to the Human Medicines Regulations 2012. This consultation is conducted in line with that requirement.

Section 2(1) of the MMDA requires that, in making regulations about human medicines, the appropriate authority’s overarching objective must be ‘safeguarding public health’. In considering whether the proposed changes would contribute to this objective, section 2(3) states that the appropriate authority must have regard to:

a) the safety of human medicines

b) the availability of human medicines

c) the likelihood of the relevant part of the United Kingdom being seen as a favourable place in which to:

* carry out research relating to human medicines
* conduct clinical trials
* manufacture or supply human medicines

Section 2(4) of the MMDA specifies that where the regulations may have an impact upon the safety of human medicines, the appropriate authority may only make the regulations if the benefits outweigh the risks. In conjunction, section 45(3) requires that the consultation carried out by the appropriate authority must include a summary assessment of how proposed changes contribute to the overarching objective of safeguarding public health, including whether there is an impact on the safety of medicines.

Patient safety is at the heart of these proposals. We consider the proposals to directly contribute to the overarching objective of safeguarding public health and the aim is to improve patient safety. In enabling pharmacists to supply in original packs there will be greater opportunity to provide additional clinical interventions within the pharmacy as time will be freed up from the dispensing process. The proposals also aim to ensure that every patient who is prescribed sodium valproate is provided with the important safety messages contained both on the label of the manufacturer’s original packs and in the accompanying patient information leaflet.

Having regard to section 2(1)(b), the proposed amendments may influence the quantities of medicines dispensed to an individual. However, the proposal includes a provision for pharmacists to use their judgement as to whether it is appropriate to deviate from the quantity prescribed by plus or minus 10% – to supply an original pack. Where it is critical that the patient receives the exact quantity prescribed, the pharmacist should ensure the patient receives the exact quantity and therefore the impact on availability should be neutral. Further, as the provision is enabling where pharmacists cannot access a pack that enables them to use the flexibility to supply an original pack, they can continue to supply the patient with the exact quantity by snipping and splitting other pack sizes as now, so again the impact on availability should be neutral. These 2 elements of the proposal contribute to it being a better option to other alternatives, such as making all manufacturers supply in the same pack size or asking all prescribers to prescribe consistent quantities which could lead to shortages of certain pack sizes and so impacts on availability of medicines. Furthermore, we have had regard to section 2(1)(c). While we recognise that enabling pharmacists to dispense original packs may influence manufacturers’ decision-making around packaging, we do not believe these changes will impact on any part of the United Kingdom being seen as a favourable place to carry out research, conduct clinical trials or manufacture or supply medicines.

1. The Community Pharmacy Contractual Framework for 2019/20 to 2023/24: supporting delivery for the NHS Long Term Plan <https://www.gov.uk/government/publications/community-pharmacy-contractual-framework-2019-to-2024> [↑](#footnote-ref-2)
2. Medicines and Medical Devices Bill Impact Assessment <https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/865994/Medicines_and_Medical_Devices_Bill_impact_assessment.pdf> [↑](#footnote-ref-3)
3. PSNC Briefing 017/21: Hub and spoke dispensing+ June 2021 <https://psnc.org.uk/wp-content/uploads/2021/06/PSNC-Briefing-010.21-Hub-and-spoke-dispensing-changed-tracked-draft-final-not-tracked.pdf> [↑](#footnote-ref-4)
4. PSNC Briefing 024/21 **Reducing the climate change impact of inhalers: environmentally safe disposal** [**https://psnc.org.uk/our-news/reducing-the-climate-change-impact-of-inhalers-environmentally-safe-disposal/**](https://psnc.org.uk/our-news/reducing-the-climate-change-impact-of-inhalers-environmentally-safe-disposal/) [↑](#footnote-ref-5)
5. DHSC: Valproate medicines: are you acting in compliance with the pregnancy prevention measures?

   <https://www.gov.uk/drug-safety-update/valproate-medicines-are-you-in-acting-in-compliance-with-the-pregnancy-prevention-measures#reports-of-instances-of-non-adherence-to-new-regulatory-measures-and-reminder-to-pharmacists> [↑](#footnote-ref-6)
6. The Community Pharmacy Patient Safety Group’s website <https://pharmacysafety.org/2018/06/25/valproate-safety/> [↑](#footnote-ref-7)
7. DHSC: Valproate medicines: are you acting in compliance with the pregnancy prevention measures?

   <https://www.gov.uk/drug-safety-update/valproate-medicines-are-you-in-acting-in-compliance-with-the-pregnancy-prevention-measures#reports-of-instances-of-non-adherence-to-new-regulatory-measures-and-reminder-to-pharmacists> [↑](#footnote-ref-8)
8. The Community Pharmacy Patient Safety Group’s website <https://pharmacysafety.org/2018/06/25/valproate-safety/> [↑](#footnote-ref-9)
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