

**Original pack dispensing and supply of medicines containing sodium valproate**

**Royal Pharmaceutical Society response (submitted online)**

We ask certain questions to help make sure that our policy making is representative and to understand how it may affect certain groups.

Is it OK for the Department of Health and Social Care to contact you about your response? [\*](https://consultations.dhsc.gov.uk/6154795607ffe964ee47a737/3889f676-903a-4acf-ba62-1d6e182c0e3d/9152f925-9672-4aee-95e9-6f7d5403c19d)

Yes

No

Would you like to receive information about other DHSC consultations? [\*](https://consultations.dhsc.gov.uk/6154795607ffe964ee47a737/3889f676-903a-4acf-ba62-1d6e182c0e3d/9152f925-9672-4aee-95e9-6f7d5403c19d)

Yes

No

What is your email address? \*heidi.wright@rpharms.com

Your contact details will not be shared with anyone outside the consultation team

To evaluate responses fully we need to ensure we reach a wide number of people from diverse backgrounds and experiences.

The following set of questions will help us better understand who is responding to this consultation and in what capacity.

Are you responding as an individual or an organisation?

an individual

an organisation

**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? (maximum 500 words)**

We particularly welcome this proposal in regard to the dispensing of Valproate. Enabling the dispensing of the original valproate pack is an important way of ensuring that patients get the safety information within and on the original container at all times. This equally applies to other medicines and we believe that the measures suggested in this consultation will improve patient safety overall.

Consideration needs to be given to community pharmacies that currently have opened packs of medicines due to the fact that they have supplied the exact amounts as requested on prescriptions. These opened packs will no longer be able to be used so a phased approach to implementation of any changes needs to be taken.

**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? (maximum 500 words)**

We believe that giving pharmacists the ability to supply up to 10% more or 10% less than the amount prescribed is the best option as suggested in this consultation document. This has been in place in Scotland for some time and works well.

We believe that these changes could go further and provide a solution which uses the clinical expertise and professionalism of pharmacists to help manage the continuity of care for people prescribed medicines that are in short supply. This solution will also minimise the burden across the healthcare system and provide parity across the UK. To improve patient access to medicines and mitigate the negative effects of medicines shortages, legislation should be amended to allow pharmacists to make minor amendments without a protocol. Amendments would include changes to enable different quantity, different strength, different formulation and generic versions of the same medicines (generic substitution) to be supplied.

**To what extent do you agree or disagree with the proposed deviation of a different quantity is not greater or smaller than that ordered by no greater than 10%?**

Strongly agree

Agree

Neither agree nor disagree

Disagree

Strongly disagree

**Do you have any comments on the proposed deviation limit of 10%? (maximum 500 words)**

We believe that this will cover the majority of cases where currently quantities prescribed do not match the pack size in which the medicine is supplied. However, pharmacies must be reimbursed against what is actually supplied which will be known via their endorsements on the prescription. We support monthly pack sizes of 28 tablets as this is generally the amount prescribers prescribe for a month’s supply.

Consideration also needs to be given to when some medicines, such as antibiotics, need to be supplied as the exact amount prescribed to enable people to take a set course.

**To what extent do you agree or disagree that original pack dispensing (OPD) should not apply to controlled drugs?**

Strongly agree

Agree

Neither agree nor disagree

Disagree

Strongly disagree

**Please provide a reason for your answer and any evidence to support it. (maximum 500 words)**

 A proportion of CDs are supplied for end-of-life care. If quantities had to be supplied in OPD this could lead to more medicines being wasted. There is also the potential for large quantities of controlled drugs ending up in the community when they are not required, and this has a potentially negative impact on patient safety. We believe that exact quantities should be given for all Schedule 2 controlled drugs

**To what extent go you agree or disagree that original pack dispensing (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

**Please provide a reason for your answer and any evidence to support it. (maximum 500 words)**

It is essential that all those dispensing medicines to patients have the same requirements.

**Supply of sodium valproate in original packs**

**To what extent do you agree or disagree that requiring the dispensing of 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. (maximum 500 words)**

It is critically important that those patients receiving sodium valproate have access to the information, both the on-pack warnings and the patient information leaflets. We would also support having this information available in other formats such as via barcodes and other electronic means.

**Impact Assessment**

**Can you provide any evidence or comments that would help us to develop the cost benefit analysis on these proposed changes (maximum 500 words)**

**To what extent do you agree or disagree that original pack dispensing (OPD) will result in time savings on dispensing?**

Strongly agree

Agree

Neither agree nor disagree

Disagree

Strongly disagree

**Do you believe that original pack dispensing (OPD) will have positive patient safety impacts?**

Yes

No

**Are you able to provide specific evidence about the size of these impacts? (maximum 500 words)**

We do not have any specific evidence, but it seems logical that time will be saved by pharmacists and their teams if they do not have to open packages and divide amounts. However, we expect these time savings to be minimal

We do believe this will have an impact on patient safety as it will prevent some patients being dispensed a pack that contains tablets from different manufacturers, with batch numbers and expiry dates missing etc which will ultimately improve patient safety. It will also reduce the risk of the wrong medicine being given or mixed with other medicines from two split packs.

In order for the time to be saved on dispensing it is important that the process for NHS reimbursement is not too burdensome and, where possible, done electronically, and that pharmacies are reimbursed for the amount they supply as demonstrated by their endorsement of the prescription. It will also potentially make the use of new accuracy checking technology and any bar code scanning easier in the future.

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

Yes

No

**Is there any further evidence we should take into account? (maximum 500 words)**

There is likely to be some impact on the pharmaceutical industry

**Do you think that the OPD flexibility will create a cost burden for manufacturers if the demand for certain pack size changes (maximum 500 words)**

**Do you think there are any other impacts for the supply chain that we have not considered? (maximum 500 words)**

**Do you believe the reduction in the use of boxes will result in a minimal cost saving and a positive impact on carbon footprint?**

Yes

No

**Are you able to provide any evidence? (maximum 500 words)**

Whilst we do not have any direct evidence of this, we believe that enabling pharmacists to supply original packs will reduce the carbon footprint as they will not have to dispense medicines in other boxes or print out additional PILs.

In the future we would also like to see:

* The environmental risk of medicines to be readily available from manufacturers to allow it to be included in NHS prescribing guidance and formularies
* Improved management and recycling of medicines packaging and pharmaceutical waste
* Review of legislation to further utilise advances in technology, while maintaining access for patients who may not be digitally connected, to be explored e.g. the use of QR codes on medicines packaging to reduce paper patient information leaflets

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

Strongly agree

Agree

Neither agree nor disagree

Disagree

Strongly disagree

**Please explain your answer (maximum 500 words)**

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

Strongly agree

Agree

Neither agree nor disagree

Disagree

Strongly disagree

**Please explain your answer (maximum 500 words)**

However, consideration needs to be given to reimbursement of medicines where packs have already been split or a transitional period introduced

**Are there any potential costs or financial implications of the proposals that you do not think we have considered (maximum 500 words)**

# **Equality assessment**

**Do you have any evidence that we should consider in the development of an equality assessment? (maximum 500 words)**