Title: Original Pack Dispensing **IA No:** 9599 **RPC Reference No:** **Lead department or agency:** Department of Health and Social Care **Other departments or agencies: Medicines and Healthcare products Regulatory Agency (MHRA)**	**Impact Assessment (IA)** **Date:** 01/07/2021 **Stage:** Final **Source of intervention:** Domestic **Type of measure:** Secondary legislation **Contact for enquiries:** MDAnalysts@dhsc.gov.uk

Summary: Intervention and Options

RPC Opinion: Out of scope

Cost of Preferred (or more likely) Option 2b (in 22/23 prices)			
Total Net Present Social Value	**Business Net Present Value**	**Net cost to business per year**	**Business Impact Target Status**
£270.5m	£m	£m	Non qualifying provision

What is the problem under consideration? Why is government action or intervention necessary?

Currently pharmacists must supply the exact quantity of medicine that is prescribed with a few exceptions. This means pharmacy staff may need to split a manufacturer's original pack to dispense the prescribed quantity. This has many consequences including that pharmacy staff spend considerable time splitting boxes, and repackaging, and there may be implications for patient safety; for example if patients get their medicine put into a dispensing box or bottle they may not get all the patient information such as the patient information leaflet ("PIL"). This is of particular importance for medicines containing all forms of valproate (valproate is an umbrella term which is used to describe all forms of medicines containing valproate including sodium valproate, valproic acid and valproate semisodium products) due to its association with birth defects.

What are the policy objectives of the action or intervention and the intended effects?

- By allowing community pharmacies the flexibility to dispense medicines in their original packs, we believe we can help pharmacists to become more efficient and free up their time for other tasks such as providing clinical services to patients, improving value for money for the NHS.
- Also, the proposal is to support increased patient safety, by ensuring patients receive the necessary information that is included in the original manufacturer's packaging about the safe and effective use of a product.
- There is also a specific policy objective to minimise the risk to unborn babies from medicines containing valproate.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

- Option 1: Do nothing option will mean no change to patient safety or pharmacy efficiency.
- Option 2: We propose to update the requirements in legislation to enable original pack dispensing for pharmacists to within +/- 10% of the quantity prescribed and additionally introduce requirements to ensure medicines containing valproate are always dispensed in whole packs, in the original packaging. For this IA we consider this as option 2a and 2b, where 2a looks at impacts for dispensing whole packs within 10% and option 2b includes the additional impacts around medicines containing valproate.

Option 2b – original pack dispensing within 10% flexibility and for all medicines containing valproate is our preferred option.

Is this measure likely to impact on international trade and investment?		No		
Are any of these organisations in scope?	**Micro** Yes	**Small** Yes	**Medium** Yes	**Large** Yes
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)		**Traded:** n/a	**Non-traded:** n/a	

Will the policy be reviewed? It will not be reviewed. **If applicable, set review date:** n/a

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible Minister: Maria Caulfield Date: 28/06/2023

Summary: Analysis & Evidence Policy Option 1[1]

Description: Do Nothing

FULL ECONOMIC ASSESSMENT

Price Base Year 22/23	PV Base Year 22/23	Time Period Years	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate: £0**

COSTS (£m)	Total Transition (Constant Price) Years		Average Annual £0	Total Cost £0
Best Estimate				

Description and scale of key monetised costs by 'main affected groups'

The "business as usual" option is the counterfactual scenario, against which other options are assessed. The value of costs and benefits are therefore zero, by definition.

Other key non-monetised costs by 'main affected groups'

- N/A

BENEFITS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate				

Description and scale of key monetised benefits by 'main affected groups'

The "business as usual" option is the counterfactual scenario, against which other options are assessed. The value of costs and benefits are therefore zero, by definition.

Other key non-monetised benefits by 'main affected groups'

- N/A

Key assumptions/sensitivities/risks	Discount rate (%)	

- N/A

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:
Costs:	**Benefits:**	**Net:**	

[1] All figures rounded to the nearest one decimal place.

Summary: Analysis & Evidence Policy Option 2a

Description: Enable original pack dispensing for pharmacists to within +/- 10% of the quantity prescribed

FULL ECONOMIC ASSESSMENT

Price Base Year 22/23	**PV Base Year** 22/23	**Time Period Years** 10	**Net Benefit (Present Value (PV)) (£m)**		
			Low: Optional	**High:** Optional	**Best Estimate: £230.4**

COSTS (£m)	**Total Transition** (Constant Price) Years		**Average Annual** (excl. Transition) (Constant Price)	**Total Cost** (Present Value)
Best Estimate			**£15.4m**	**£131.2m**

Description and scale of key monetised costs by 'main affected groups'

- Patients requiring more repeat prescriptions due to receiving less medicine: £1.8m per year.
- Pharmacies' costs for dispensing more items for repeat prescriptions: £0.8m per year.
- GPs will have more appointments due to more frequent repeat prescriptions: £4.3m per year.
- Additional cost of drugs to be dispensed: £9.3m per year.
- Familiarisation costs – time for pharmacies to understand changes: £1m in year 1.

Other key non-monetised costs by 'main affected groups'

BENEFITS (£m)	**Total Transition** (Constant Price) Years		**Average Annual** (excl. Transition) (Constant Price)	**Total Benefit** (Present Value)
Best Estimate			**£42.4m**	**£361.6m**

Description and scale of key monetised benefits by 'main affected groups'

- Patients will need fewer GP appointments and trips to collect their prescription for repeat prescriptions if they receive more medicine: £5.1m per year.
- Pharmacies will save time on not having to split packs: £22.2m and dispensing fewer items: £2.2m per year.
- GPs will have fewer appointments from patients for repeat prescriptions: £12.2m per year.
- Cost of buying fewer drugs: £3.1m per year.

Other key non-monetised benefits by 'main affected groups'

- Increased patient safety (including PIL, tamper seals intact, braille information, clarity of contents).
- The time saving in pharmacies can take pressure off other clinical services in the NHS.
- Private pharmacies will also benefit, as per NHS pharmacies, but represent a very small amount of dispensing.

Key assumptions/sensitivities/risks	**Discount rate (%)**	3.5%

- The latest available evidence has been used throughout the IA with 2022/23 prices as the base year. Wages have been uprated by 6% to reflect the latest NHS pay deal for pharmacists. The cost of branded and Generic drugs has been uprated by 10.1% in line with the latest CPI figure.
- Analysis is based on a representative sample of drugs, and two most common pack sizes per drug.
- A possible knock-on effect based on how pharmacies are reimbursed, not considered here as this is subject to detailed discussion with PSNC and devolved equivalents.
- Small risk of patient safety due to patients receiving more medication than prescribed.

BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:			**Score for Business Impact Target (qualifying provisions only) £m:**
Costs: n/a	**Benefits: n/a**	**Net: n/a**	n/a

Summary: Analysis & Evidence — Policy Option 2b

Description: OPD to within 10% (option 2a) and additionally, introduce requirements to ensure medicines containing valproate are always dispensed in whole packs in the original manufacturer's packaging.

FULL ECONOMIC ASSESSMENT

Price Base Year 22/23	PV Base Year 22/23	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate: £270.5m**

COSTS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Best Estimate		**£16m**	**£136.8m**

Description and scale of key monetised costs by 'main affected groups'

- The same costs as per option 2a.
- Plus, additional cost to patients for additional prescriptions £0.2m, GPs for additional appointments £0.4m, and pharmacies when more medicines containing valproate are dispensed £0.1m per year.

Other key non-monetised costs by 'main affected groups'

- The same non monetised costs as option 2a.

BENEFITS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Best Estimate		£47.7m	**£407.3m**

Description and scale of key monetised benefits by 'main affected groups'

- The same benefits as per option 2a.
- Plus, additional benefits to patients for needing fewer prescription items £1.3m, GPs for fewer appointments £3.1mm and Pharmacies for not having to split packs £0.4m and dispensing fewer items £0.6m per year.

Other key non-monetised benefits by 'main affected groups'

- In addition to option 2 there is a further benefit from providing whole packs for medicines containing valproate which has very specific warning messages around taking this medicine and pregnancy – it is especially important that the PIL is provided, and in addition the original manufacturer packaging will also state this warning and provide information in braille.

Key assumptions/sensitivities/risks	Discount rate (%)	3.5%

- As per option 2a.
- Data on medicines containing valproate was not a sample (as per option 2a), all medicines containing valproate were included in the analysis.
- Analysis for option 2b (all medicines containing valproate) was taken from a complete year (2021). Analysis for option 2a (drug sample) was taken from a 6-month period and doubled (2020/21).

BUSINESS ASSESSMENT (Option 3)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:
Costs:	**Benefits:**	**Net:**	

Evidence Base

Problem under consideration and rationale for intervention

Part 12 of The Human Medicines Regulations 2012 (“HMRs”) in Regulation 214(1) 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 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 a (or multiple of) pack size(s), pharmacy staff need to split a manufacturer's original pack in order to dispense the prescribed quantity. In many circumstances this will requiring 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:

1. If the patient gets the manufacturer's original pack but with some dosage units missing - the tamper evident seal will be broken - they might be concerned either that someone has interfered with the medicine or that the pharmacist has accidentally underfilled their prescription.

2. If the patient gets their medicine put into a dispensing box they may get lots of small 'snips' from a blister strip making it difficult to manage their supply, aid compliance and identify whether they have taken their tablet that day.

3. If the patient gets their medicine put into a dispensing box or bottle, they may not get all the patient information such as the PIL.

4. Pharmacy staff spend considerable time splitting boxes, snipping blisters and repackaging.

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 has to be done outside of the automated process.

One means intended to support the Government’s commitment to efficiencies in the pharmacy sector was through exploring the supply to patients of medicines in a manufacturer's original pack without the need to split packs or repackage. This is termed 'original pack dispensing' (“OPD”).

Particular safety concerns with medicines containing valproate

Medicines containing valproate are 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.

Use of medicines containing valproate were, however, already known to be associated with birth defects when they were first licensed in the 1970s and further evidence has emerged since then about other adverse effects, in particular neurodevelopmental disorders in children exposed if used during pregnancy. The risk of such neurodevelopmental disorders is estimated at 30-40%, which is in addition to an 11% risk of a congenital abnormality[1].

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

To support the implementation of the medicines containing valproate, pharmacists receive a written notification from the MHRA Chief Executive and the UK's four Chief Pharmaceutical Officers which, among other things, stresses the need to provide a PIL with every valproate prescription even when the medicine containing valproate is dispensed in dispensing boxes or bottles.

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

Current evidence on the scope of splitting packs

We conducted interviews with stakeholders who gave us evidence on the frequency to which packs need to be split and the time costs of doing so.

The responses to the consultation agreed that allowing flexibility for pharmacies to dispense whole packs would lead to efficiency and safety benefits. There was evidence provided around the quantity of items that would fall under OPD, which broadly matched our internal analysis. There was little evidence which was able to quantify the health benefits of dispensing original packs compared to the risk of dispensed quantity differing from prescribed quantity.

We conducted our own analysis of dispensing data from the NHS Business Service Authority ("NHS BSA"). By British National Formulary ("BNF")[2] section a DHSC pharmacist excluded sections that would not be appropriate for OPD due to the importance of prescribed dose (i.e. those where we assume pharmacists would use their clinical judgement and dispense the prescribed number). We then scaled up the results for England proportionally to reflect GB results by assuming prescriptions are proportional across and that England accounts for 86.8%

[1] Update on MHRA review into safe use of valproate - GOV.UK (www.gov.uk)

[2] https://bnf.nice.org.uk/

of the population of GB[3]. From this we estimated that 1.081bn items (of 1.312bn total items) would be appropriate for OPD based on clinical reasons. Of these, around 266m items are potentially in scope for whole pack dispensing as they would not be fulfilled with whole packs (or multiples of whole packs).

Description of options considered

Option 1: No change to the HMRs, which means there are no changes to pharmacy efficiency or patient safety due to the need for pharmacies to dispense repacked medicines. Dispensing remains as it currently is in that Part 12 of the HMRs in Regulation 214(1) 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 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 a (or multiple of) pack size(s), pharmacy staff need to split a manufacturer's original pack in order to dispense the prescribed quantity.

Option 2a; Introduce amendments to Part 12 of the HMRs, so that when dispensing medicines, pharmacists may utilise manufacturer's original packs. Our proposal is that:

- For pharmacists to 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 will not apply to controlled drugs.

We propose to use the enabling powers in Part 2 of the Medicines and Medical Devices Act 2021 ("MMD Act"). At this time, we are only proposing a flexibility around quantity, not around formulation or strength.

Option 2b: As per option 2a, but with increased level of whole pack supply of medicines containing valproate.

Introduce amendments to Part 12 of the HMRs, 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.

3 https://www.ons.gov.uk/peoplepopulationandcommunity/populationandmigration/populationestimates/bulletins/annualmidyearpopulationestimates/mid2021#population-change-for-uk-countries

- Dispensing of medicines containing valproate must always be in whole packs, in the original packaging. 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. **However, pharmacists will be able to make an exception to whole pack dispensing of medicines containing valproate on an individual patient basis, where a risk assessment is in place that refers to the need for different packaging such as a Monitored Dosage System ("MDS") and where processes are in place to ensure the supply of PILs.**

We propose to use the enabling powers in Part 2 of the MMD Act. At this time, we are only proposing a flexibility around quantity, not around formulation or strength.

Other options considered:

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 impacts around multi-market packs and could lead to unnecessary shortages where a manufacturer couldn't supply in a pack of that size. An alternative option would involve all prescribers prescribing 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 wouldn't know what pharmacies had available.

The proposal being put forward through this consultation allows for flexibility, with their judgement, by the pharmacist. Many responses to the consultation agreed that a 10% flexibility was appropriate and sensible, while some suggested a 15 or 20% flexibility should be used. While there is evidence that this level of flexibility would allow a greater number of items to be dispensed as original packs, the consultation responses did not quantify the health benefits of original packs compared to the risk of dispensed quantity differing from prescribed quantity.

Policy objective

The policy objective is to allow pharmacists greater flexibility in what they dispense so that they can dispense a manufacturer's original pack where appropriate. The intended outcomes of this are around:

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

Patient Safety - by dispensing medicines in their original packs, it will be easier for pharmacies to ensure that patients will receive the manufacturer's 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.

Interaction with other proposals

A further way in which we committed to supporting efficiencies in the sector was 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 and automation. It has not been possible to determine the proportion of prescriptions that may be able to move to an automated process as a result of the proposed policy. The estimates of efficiency gains (of 90 seconds saving per pack) in this IA relate to original pack dispensing in in-store pharmacies. The gain in automated facilities might be greater than this, but we could not quantify the difference from our stakeholder engagement because it depends how each automated dispensing has been set up.

Further to an initial consultation in 2016, in January 2021 we began pre-consultation engagement with stakeholders to enable hub and spoke dispensing across legal entities, with a full public consultation from 1st November to 13th December 2021. 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 will be curtailed, as automated processes rely on being able to dispense full packs.

Summary and preferred option

Option 2b is our preferred option - to introduce amendments to Part 12 of the HMRs, so that when dispensing medicines, pharmacists may utilise manufacturer's original packs.

Monetised and non-monetised costs and benefits of each option (including administrative burden)

Understanding the scale of OPD:

From our analysis, we estimated that 1.081bn items (of 1.312bn total items) would be appropriate for OPD based on clinical reasons. Of these, we estimate around 266m items are potentially in scope for whole pack dispensing as they would not currently be fulfilled with whole packs (or multiples of whole packs). Of which 49.1m, less than 4% of total prescription items, could be dispensed as a whole pack to within 10% when comparing prescription quantities to the most common pack sizes.

The total number of prescription items per year has been gradually increasing over time but flattened in the last five years. There are ambitions[4] to address the problem of overprescribing, in terms of optimising the use of medicines, developing better systems and listening to the needs and preferences of patients. In addition, based on analysis by NHSE&I there are a number of factors which are expected to impact the number of prescription items going forward, some of which are expected to increase prescription items and others are expected to decrease prescription items, for example reduction in items after the introduction of 90 day prescribing, and increased dispensing due to growth in diabetes prevalence. Based on this and the overall uncertainty in expected number of items over coming years, throughout this analysis we have assumed that dispensing stays constant and does not change.

Summary of analysis for prescription items in scope for OPD in GB:

	Items (million)	Description
Total items	1,312.3	Prescription Cost Analysis - England 2021/2022 totals, NHS BSA data. Scaled up to GB
Items deemed appropriate for OPD	1,080.8	After DHSC pharmacist has assessed BNF sections and excluded those that should always be as prescribed
Items that need splitting	266.3	Matching our sampled drugs to available pack sizes, and scaling up to all items
Items that could be OPD 10%	**49.1**	Those in our sample where a whole pack could be dispensed to within 10% scaled up by BNF section

Patient Impacts:

Under the proposed policy, pharmacists will have flexibility to dispense up to 10% more or less than the prescribed quantity if that means they can dispense in the manufacturer's original packs. This means that, for patients receiving a prescription/course of medication they may receive up to 10% more or less medicine than the amount prescribed by their GP. The impact of this will differ depending on whether the prescription is for a repeat medicine or an acute (i.e. one off) medicine.

There is a risk that this could potentially have health implications for the patient, especially for acute prescriptions, for example if they take too much or not enough of a medicine. However, it is important to note that the proposed policy will still require the pharmacist to use a professional judgement over when it is and is not clinically appropriate to dispense a different quantity to the prescribed amount. Controlled drugs will always be required to be dispensed in exact quantities. There are other areas where we anticipate pharmacists would continue to dispense the prescribed quantity even if that requires splitting packs. These include antibiotics where it is clinically important to complete the full course of medicine as prescribed, and certain pain relief medicines where there is a risk of reliance or addiction.

[4] Department of Health and Social Care, September 2021. Good for you, good for us, good for everybody, https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1019475/good-for-you-good-for-us-good-for-everybody.pdf

There is also a risk that pharmacist judgement may vary between pharmacists, and while it may not be possible to ensure that OPD is fully consistent it should be noted that the proposed policy is only for a 10% difference from the prescribed quantity. This is large enough flexibility to allow whole packs to be dispensed around differences in 28 v 30 prescriptions and pack sizes, but such that the dispensed quantity does not deviate too far from the prescribed quantity. As a result, we would anticipate that any potential health impacts on patients is likely to be minimal.

In the remainder of cases, advice from stakeholders and pharmacists suggests that variation in the quantity of medicine prescribed is largely driven by differences between how a GP prescribes for a set length of time (e.g. a month's supply could be 28 days, 30 days or 31 days), compared to what pack sizes are produced by the manufacturer. Differences of up to 10% are unlikely to be clinically significant in terms of health risks, however allowing a higher percentage of flexibility will increase the risk that too much, or too little medication is dispensed or that GPs are unable to reconcile what has been dispensed, which may lead to health impacts.

As a result, where patients receive less than their acute prescription, this is unlikely to have any significant health implications and we also do not anticipate that patients would need to make another trip to their GP or pharmacist for the remaining amount. Where patients receive more than their prescription, they will either need to dispose of the surplus medicine or they may take a slightly longer course of medicines but with no significant impact on their health.

For patients on repeat prescriptions, any changes in the quantity of medicine that they receive from the pharmacist would not be expected to change the quantity of medicines that they take overall, however it will mean that the patient will require a new prescription more or less often (depending on whether they routinely receive more or less medicine than what is on their prescription). This will result in:

- Time implications for patients needing either fewer or more appointments with their GP and trips to the pharmacy to obtain repeat prescriptions.

- Cost implications for patients if they need to pay a prescription charge either more or less often.

As described in Annex B, we estimate that around 49.1m items (3.7% of prescription items) could be fulfilled with a whole pack to within 10% under OPD. If we then restrict the analysis to only repeat prescriptions (approximately 77% of items[5]), the number of items that could be fulfilled with a whole pack to within 10% is 37.8m items.

From our analysis, looking at the types of medicines where OPD is appropriate, the large majority, around 72% (76% of brands and 71% of Generics), would result in more being dispensed than what is on the prescription and 28% (24% of brands and 29% of generics) where less is dispensed. See Annex B for full details.

[5] Source: Electronic Repeat Dispensing, Annex 1 (england.nhs.uk)

To determine the impact on the number of repeat prescriptions, we examined the most common difference in prescription quantities and pack sizes and found that in general this tended to be a difference of approximately 6.7% (i.e. it tended to be prescriptions of 28 compared to pack sizes of 30 or vice versa). Applying this figure to the number of prescription items above, this would suggest 0.7m more items dispensed and 1.9m fewer items dispensed, giving a net figure of 1.2m fewer items.

In terms of the time savings for patients, we use data from Department for Transport costs of travel[6], and we have assumed an average distance from a pharmacy of 20 minutes walking time[7]. This led to us using the average travel cost required to get a prescription from the pharmacy is £2.24. We assumed the average cost of a prescription to be £0.48 (£9.65 for 5% prescriptions, after excluding free prescriptions and pre-paid prescriptions, NHSBSA[8]). Applying this to the above figure gives us a total net cost saving of £3.3m (£1.8m additional costs for patients requiring more frequent repeat prescriptions, and £5.1m in savings for patients requiring fewer repeat prescriptions).

It should be noted that these costs and benefits are likely to be an upper estimate for two reasons. First, the analysis has assumed that each item will require a travel cost and a prescription cost. While in practice a patient may pick up multiple items under the same prescription meaning that the costs and benefits will be lower than those shown below. Second, it is assumed that prescriptions costs and those who are exempt from prescription costs are uniform across all patients and items, however it is likely that patients on repeat prescriptions will be more likely to be exempt from prescription charges.

The figures for patients are summarised in the table below:

	(million items)	
Total prescription items	1312.3	
Items that need splitting	266.3	
Of which, could be fulfilled within 10%	49.1	
		Proportion
Repeat prescriptions	37.8	77%
Additional or fewer prescriptions needed	2.5	6.7%
	Fewer prescription required	Additional prescription required
Number	-1.9	0.7
Costs (£m)		
Travel cost (£2.24 per trip)	-£4.2	£1.5
Prescription cost (£0.48 per prescription)	-£0.9	£0.3
Total (£m)	-£5.1	£1.8
Net Benefit (£m)	-£3.3	

[6] DfT on valuing walking times can be found in table A1.3.1 of their data book https://www.gov.uk/government/publications/tag-data-book

[7] Internal analysis, Medicine Pharmacy Analytical Team, as per Hub and Spoke dispensing IA

[8] https://www.nhsbsa.nhs.uk/statistical-collections/prescription-cost-analysis-england/prescription-cost-analysis-england-202021

In terms of the timing of these costs, the above table shows the annual costs for when the policy is fully implemented. However, with repeat prescriptions it will be some time before the difference comes into effect, since for most of the time the difference will only be 2 days. As such we have assumed that this effect will take 15 months to begin showing impacts (2 days per month over 15 months, leading to +/- one month prescription). As such, when considering NPV, in the first financial year (2022/23) we have assumed zero impacts, and then for year 2 (2023/24) we have assumed that only 9 of 12 months will have these impacts. From year 3 onward the impacts per year are as shown in the above table.

In regard to adherence to medication the literature review told us that two studies found higher adherence to treatment when dispensing in exact numbers. The first[9] found that with OPD, adherence was 21% higher (95% confidence interval 14-28%) for antibiotics, while data from Italy[10] showed that adherence to capecitabine, a cancer medication, was 5% higher than with OPD.

Finally, OPD may have additional benefits for patients relating to health impacts and medicines adherence as mentioned through our stakeholder engagement. As previously discussed, the following consequences have been associated with splitting packs:

- If the patient gets the manufacturer's original pack but with some dosage units missing - the tamper evident seal will be broken - they might be concerned either that someone has interfered with the medicine or that the pharmacist has accidentally underfilled their prescription.

- If the patient gets their medicine put into a dispensing box they may get lots of small 'snips' from a blister strip making it difficult to manage their supply and compliance regarding whether they have taken their tablet that day.

- If the patient gets their medicine put into a dispensing box or bottle, they may not get all the patient information such as the PIL. Pharmacists should ensure that a copy of the PIL is included in the dispensing box or bottle when splitting packs, but we know these can be missed when packs are split. Our stakeholder engagement suggested this was rare but were not able to provide an estimate of how often. The additional safety impact from whether or not a patient receives the PIL is likely to be small and we have not been able to quantify this.

- Splitting packs is a manual process which has a higher error rate than an automated process. While the error rates in both are very small, reducing the need to split packs will increase the accuracy of dispensing.

[9] Treibich C, Ventelou B, Lescher S, Sagaon-Teyssier L. The expected and unexpected benefits of dispensing the exact number of pills. PLoS ONE (2017); 12:9.

[10] Cesari R, Santilli G, Scarlattei D, Marotta M, Borsari M. Prescriptions and equipment for unit dose capecitabine in Oncology Pharmacy Laboratory-Ausl Bologna-Italy. European Journal of Hospital Pharmacy (2014); vol. 21.

- Not needing to split packs will mean that for some pharmacies more prescriptions can be dispensed from a Hub/automated dispensing. Again, this means the process does not need to be completed manually and so will have a lower error rate.

This final impact is of particular importance for medicines containing valproate as demonstrated by the written notification from the MHRA Chief Executive and the UK's four Chief Pharmaceutical Officers which stressed the need to provide a PIL with every valproate prescription even when medicines containing valproate are dispensed in dispensing boxes or bottles. This is discussed more under Option 2b.

It is not possible to further quantify the potential patient safety improvements for patients because of OPD. It is not possible to quantify the degree of patient concern currently generated by splitting packs, or to place a monetary value on alleviating this. Further, although the evidence suggests that there may be patient safety benefits from OPD, it is not clear how many patient safety incidences are currently attributable to factors such as missing PILs or small snips reducing medicines compliance, nor do we know what the health impacts of such incidences would be.

GP impacts:

Under the proposed policy, pharmacists will have flexibility to dispense up to 10% more or less than the prescribed quantity if that means they can dispense in the manufacturer's original packs. As previously discussed, this means that for patients receiving a prescription/course of medication they may receive up to 10% more or less medicine than the amount prescribed by their GP.

This could potentially have time implications for the GP due to patients needing repeat prescriptions. Since if a patient is consistently receiving more or less medicine than the prescribed quantity then they will need to contact their GP less or more often for their repeat prescription. As discussed earlier, our analysis suggests that for 72% of cases, OPD would result in more being dispensed than what is on the prescription and 28% where less is dispensed. Therefore, there is an expected net benefit to GPs because overall there will be more time between patients needing a repeat prescription, resulting in a reduction in GP time spent dealing with repeat prescription requests. It is anticipated that this reduction in GP time will mean that GPs are able to see more patients, ultimately leading to a benefit to patients and the NHS.

Using the same number of prescription items as for patients (0.7m more items dispensed and 1.9m fewer items dispensed, giving a net figure of -1.2m items) and applying £1.40 – the average cost of all initial primary care actions in response to an e-consultation for prescription (PSSRU Section 10.4[11]) – our analysis shows a net benefit of around £1.7m (£0.9m in additional costs from patients coming sooner for repeat prescriptions and £2.6m in savings for patients waiting longer for repeat prescription).

[11] https://www.pssru.ac.uk/pub/uc/uc2021/communitybasedhcstaff.pdf

To convert this saving to the ultimate impact on patient health and the NHS, we use the standard unit for measuring health benefits: the Quality-Adjusted Life Year (QALY). While it is not possible to know the specific use to which any individual amount of additional funding provided to the NHS will be put, evidence is available of the average number of QALYs expected to be gained for any given amount of additional NHS funding – by whatever means these gains are achieved. This evidence is expressed as an estimate of the cost per QALY gained "at the margin" in the NHS of £15,000. In other words, the best available evidence indicates that additional health benefits of 1 QALY are generated for every £15,000 of additional funding provided to the NHS. The cost savings of £1.7m pa are therefore expected to lead to the provision of an additional 113 QALYs p.a.

Standard IA methodology entails monetising impacts in order to represent their value to society. It is important to note that the value society puts on a QALY is not necessarily the same as the cost at which the NHS can generate additional QALYs.

DHSC estimates that society values a QALY at £70,000[12]. The corresponding social value of benefits from NHS cost savings is £7.9m p.a. GP Costs and Benefits in the summary tables throughout this IA are expressed in QALYs.

The figures for GPs are summarised in the table below:

	(million items)	
Total prescription items	1312.3	
Items that need splitting	266.3	
Of which, could be fulfilled within 10%	49.1	
		Proportion
Repeat prescriptions	37.8	77%
Additional or fewer prescriptions needed	2.5	6.7%
	Fewer prescription required	Additional prescription required
Number	0.7	-1.9
Cost of e-consultation (£m) (£1.40 per visit)	£0.9	-£2.6
Total (£m)	£0.9	-£2.6
Net Benefit (£m)	-£1.7	
Total (QALYs)	£4.3[13]	-£12.2[14]
Monetised value of QALYs (£70,000 per QALY) (£m)	-£7.9	
Expected additional QALYs (1 per £15,000 saving to NHS)	113	

In terms of the timing of these costs, as described earlier for patients we profile these impacts with no change in 2022/23, 9 months of impacts in 2023/24 and full impacts from 2024/25 onwards.

[12] The Green Book (2022) - GOV.UK (www.gov.uk)

[13] £0.9m * £70,000 / £15,000 = £4.3m QALYs

[14] -£2.6m * £70,000 / £15,000 = -£12.2m QALYs

NHS Community Pharmacy:

It is difficult to get an exact figure for the time taken to dispense an item, or the time saving for not having to split a pack. In practice the time taken will vary depending on the item being dispensed, whether a split pack is needed, whether the item is being dispensed from a store or an automated dispensing location. From the information that stakeholders provided and from internal analysis used in the IA for Hub and Spoke dispensing we have taken the average time to dispense an item as 2-3 minutes and costing £1.20 in pharmacy staff time. From discussion with DHSC pharmacists we assume that the breakdown of staff time to dispense an item is 50% pharmacy dispensing assistant, 25% pharmacy technician, and 25% pharmacist.

In terms of the time taken to split a pack stakeholders provided views that include:

- 30p per split pack in an automated dispensing set up.
- Average 90 seconds per split across all dispensing.
- And that it takes two to four times longer to dispense a split pack than a whole pack although this is likely to relate to automated dispensing.

We have taken the estimate of 90 seconds to be a sensible estimate of the time saving on not having to split a pack, as this figure was an average across in store and automated dispensing, although it should be noted that some pharmacies will not have access to automated dispensing and so their average time saving may differ. We have costed this 90 seconds, by using median hourly pay figures for pharmacy staff from the ASHE survey[15] and assumed that the time saving would be for pharmacy dispensing assistants as they are most likely to be doing the splitting of packs. We have added 30% overhead costs to the hourly wage cost and uprated wages by 6% in line with the new pay deal[16]. Which leads to a saving of around 45p per item that is not split, which is very similar to the 30p estimate for automated dispensing.

These calculations assume that there will be 100% uptake by pharmacies since there is a time saving for pharmacies, so they are incentivised to make use of OPD. If there is less than 100% uptake then these results provide an upper limit for costs and benefits. Using this cost saving on the 49.1m packs that will not need splitting under OPD 10% gives a total saving of £22.2m. This may not be cash releasing but would free time and resource of pharmacy staff time and may allow them to provide additional clinical services, which would benefit patients and the NHS, but this is unquantified.

Pharmacies will also have an additional time saving since as with patients and GPs there will be net fewer prescriptions that need to be dispensed, i.e. 0.7m more items dispensed and 1.9m fewer items dispensed, giving a net figure of -1.2m items. These will save the full time for dispensing a prescription, which we have assumed is £1.20 based on the Hub and Spoke

[15] ASHE Table 15 (4). 5a Hourly Pay – Gross (£) - For all employee jobsa: United Kingdom, 2022

[16] https://www.the-pda.org/nhs-pay-agreement-reached/

dispensing IA[17]. This leads to an additional net saving of £1.5m saving on dispensing time[18]. As before this may not be cash releasing but would free time and resource of pharmacy staff time and may allow them to provide additional clinical services, which would benefit patients and the NHS, but this is unquantified.

This leads to an overall net benefit to pharmacies of £23.7m.

A summary table of the calculations for Pharmacies:

	(million items)	
Total prescription items	1312.3	
Items that need splitting	266.3	
Of which, could be fulfilled within 10%	49.1	
Items with a 90 second time saving	49.1	100%
Cost per 90 seconds for Dispensing Assistant (£)	0.45	
Cost saving (£m)	£22.23	
	Fewer (over dispensed)	Additional (under dispensed)
Prescription items dispensed	1.9	-0.7
Fewer net items dispensed	1.2	
Costs (£1.20 per prescription) (£m)	£2.2	-£0.8
Net Benefit (£m)	£1.5	
Total pharmacy benefit (£m)	£23.7	

We anticipate that the time savings will allow pharmacies and their staff to focus on providing a wider range of services for patients than can be done under the current arrangements in the Community Pharmacy Contractual Framework (CPCF), while continuing to provide patients with the medicines they need.

This increase in clinical service provision may deliver benefits to both the NHS and community pharmacies as follows:

- Increased clinical service provision will result in health improvements for patients, for example, if the pharmacist has more capacity to spend time with patients and providing advice on healthy living and self-care, as well as delivering valued clinical services such as vaccinations, blood pressure monitoring and medication advice.

- The increased capacity to see patients within pharmacies may also help reduce pressure on other parts of the NHS. For example, the Community Pharmacy Consultation Service is designed to allow pharmacies to take referrals for minor illnesses from NHS 111 and GP

[17] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1057447/hub-and-spoke-dispensing-impact-assessment.pdf

[18] Cost of having to dispense more items: 0.7m items * £1.20 = £0.78m
Benefits of having to dispense less items: 1.9m items * £1.20 = £2.24m
NET saving: £0.78m - £2.24m = £1.46m (£1.5m)

surgeries and there are ambitions to further roll this out to cover other health settings. Previous IAs considering the expansion of this service within the CPCF has highlighted the potential for this service to significantly reduce the number of GP appointments and A&E visits required. A 2015 survey of GPs estimated that approximately 2% of GP appointments could have been dealt with by community pharmacy instead, whilst the PSNC community pharmacy advice audit found that almost half of patients who had an informal consultation in a pharmacy, would have visited their GP had they been unable to contact their community pharmacy.

- Pharmacies who offer additional clinical services can increase their income. For example, private clinical services could include the provision of private seasonal flu jabs, travel vaccinations, or test and treat services, whilst NHS services could include taking referrals from the Community Pharmacy Consultation Service (£14 per consultation), the New Medicines Service (approx. £24 per consultation) or the blood pressure monitoring service (£15 for a clinic check and £45 for ambulatory blood pressure monitoring).

However, it is difficult to further quantify these benefits as it is not known what mix of additional clinical services might be offered by pharmacists. It is also important to note that, where NHS clinical services are funded from the CPCF, under the terms of the 5-year deal, the total funding envelope is currently fixed until the end of the 2023/24 financial year at £2.592bn. This flat cash funding deal will naturally constrain the amount of additional income that pharmacies can make from NHS services, at least in the short term.

Dispensing a different quantity of medicine from what is prescribed may also change the amount of medicines that a pharmacist needs to buy. However, whether or not there is a cost implication for pharmacies depends on how pharmacies are reimbursed for OPD. Please see the reimbursement section below for further discussion. Therefore, whilst it is possible to assess the potential change in expenditure on medicines (see next section), it is not possible to determine what proportion of costs might fall to pharmacies vs the NHS.

<u>Additional cost of drugs:</u>

For repeat prescriptions we assume there will be the same number of drugs dispensed over time, and that it is only the frequency or the patient getting a repeat prescription that changes. As such, there will be no additional costs for medicines. Although it should be noted that there may be differences in when the pharmacies buy the drugs if they must have more medicine in stock to begin dispensing whole packs, but this is not quantified here as it is thought to be relatively small.

For acute prescriptions, if pharmacies dispense whole packs under OPD then this will require them to purchase more medicines for those where they over dispense and less where they under dispense. NHS BSA data reports the average cost of branded and generic drugs to be £19.42 and £3.48[19] respectively. We have uprated the cost of each drug by inflation (10.1%[20])

[19] Prescription Cost Analysis England 2021/22: Additional Tables. Table A5 - Cost per item prescribed and dispensed https://www.nhsbsa.nhs.uk/statistical-collections/prescription-cost-analysis-england/prescription-cost-analysis-england-202122

to estimate the cost for branded (£21.38) and generic (£3.83) drugs. The additional cost of drugs would be £6.2m (£9.3m in additional drugs, and £3.1m savings in fewer drugs being dispensed).

Where this cost will fall will depend on the arrangements for reimbursement, see reimbursement section below.

Private/Non-NHS pharmacies:

There are a very small number of private pharmacies that are able to dispense non-NHS prescriptions. It is very difficult to quantify how many since the NHS BSA does not collect information for these pharmacies, but it is thought to be small. They would be able to dispense whole packs under this policy without the further changes to the terms of reference that would be required for NHS pharmacies to utilise OPD.

Based on comparing the number of pharmacy premises registered with the General Pharmaceutical Council ("GPhC") with the number of pharmacies providing NHS services in each of the 3 nations, we estimate that there may be up to 170 non-NHS pharmacies currently operating, approximately 1.2% of all pharmacies. This is summarised in the table below:

Estimate of private pharmacies in GB

	Number of pharmacies	**Source**
GB Pharmacies	13,844	As of March 2022 from Annual Report
English pharmacies	11,712	NHS Business Services Authority, October 2021. General Pharmaceutical Services in England 2015/16-2020/21[21]
Scottish pharmacies	1,250	Based on number of community pharmacies in Scotland
Welsh pharmacies	712	Based on number of community pharmacies in Wales http://www.cpwales.org.uk/CPW-s-work/About/Community-Pharmacies-in-Wales.aspx
Residual	170	The difference between the GPhC registered pharmacies and pharmacies in each country, taken as an estimate of private pharmacies in the GB.

However, as these pharmacies do not receive any NHS funding for the prescriptions that they dispense, we have no data on the number or types of prescriptions that they dispense (with the exception of controlled drugs). On average, we believe that these pharmacies are likely to be smaller than their NHS equivalents, and the pattern of medicines dispensed may also be very different. To illustrate this, we have seen the total impact on GB NHS pharmacies as a saving of £16.5m, and if private pharmacies were 1.2% of this would be a saving of £0.2m. An additional

20 https://www.ons.gov.uk/economy/inflationandpriceindices/bulletins/consumerpriceinflation/march2023#:~:text=The%20Consumer%20Prices%20Index%20(CPI,of%201.1%25%20in%20March%202022.

21 https://www.nhsbsa.nhs.uk/statistical-collections/general-pharmaceutical-services-england/general-pharmaceutical-services-england-201516-202021

impact that is likely to affect private pharmacies is that under OPD we anticipate net fewer prescription items being dispensed, which may lead to a loss of income for private pharmacies as they will lose their charge for dispensing. It is important to note that the changes are permissive i.e., pharmacies will not be required to dispense the manufacturer's original pack – rather they will have the flexibility to do so if they wish to. As a result, it has not been possible to quantify the potential impacts of OPD on these pharmacies.

Manufacturers

Where pharmacies are buying a different quantity of medicines this could also impact on manufacturers and wholesalers. We estimate above that there will be a net cost to pharmacies of £6.2m in additional drugs, where pharmacies will need to buy more drugs, leading to a net benefit to manufactures. From Companies House data on Profit and Loss accounts extracted in August 2021, for manufacturers and wholesalers of pharmaceutical products we estimate that they make 18% profit. This is based on analysis where we excluded zero returns, calculated the operating profit versus the total revenue and then calculated a weighted average for manufacturers. Applying 18% profit to the cost of additional drugs means that there is an estimated £1.1m benefit to manufacturers[22].

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 also anticipate a reduction in the use of plain prescription boxes currently required, although we have not costed this impact. It is thought that there is a small price per unit, which will mean there is a negative impact for manufacturers of plain boxes.

Familiarisation costs

It is anticipated that there will be costs associated with familiarisation of a new policy around OPD. For this we have provided costs:

For pharmacies we have assumed that for each of the 13,844 registered GB pharmacies, it will take one pharmacist one hour to become familiar with the regulations. We have then assumed that it would take that pharmacist 20 minutes to brief other staff in the pharmacy. The average number of staff per pharmacy was taken from Health Education England Workforce Survey[23] which states that on average there are around 6.1 staff per pharmacy, including the breakdown of roles (including 1.82 pharmacists, 0.56 pharmacy technicians and 2.04 dispensing assistants)

[22] Since 2021, manufacturing costs for pharmaceutical companies have increased but these costs have been passed onto consumer in the form of higher prices, which has been evidenced in DHSC's data collection for the Drug Tariff. It is therefore reasonable to conclude profit margins have remained stable. If profit margins were to fall to 10%, the additional costs of drugs would result in an estimated £0.6m benefit to manufacturers (£6.2m * 10% = £0.62m (£0.6m).

[23] HEE Workforce Survey 2021 https://www.hee.nhs.uk/sites/default/files/documents/The%20Community%20Pharmacy%20Workforce%20in%20England%202021%20-%20Survey%20report_0.pdf

The average (median) hourly rate for a pharmacist is £23.17[24] which we have uprated by 30% to £30.12 to account for non-wage costs such as national insurance and pension contributions[25]. We have then uprated wages by 6% to reflect the new pay deal, resulting in a median hourly wage of £31.93[26]. Median hourly rates for other pharmacy staff were taken from the same source and an estimate for 20mins of all pharmacy staff time on average for a pharmacy was calculated. Combining the cost for 1 hour of one pharmacist's time and 20mins of all pharmacy staff time per pharmacy, and then scaling this up to all GB pharmacies leads to an overall familiarisation for pharmacy staff of £985k. This may be an overestimate as some pharmacy staff may not need to know the details of the guidance, for example counter assistants.

There will be some patients who question the different amount, but we have not quantified this based on the following;

- We know from stakeholders that for some patients, getting split packs currently causes confusion and leads to phone calls querying the amount dispensed, so for these patients having an original pack might be less confusing. There may also be gains and less confusion for people who would have received multiple boxes that look the same but would instead receive multiple boxes that are original packs and so easier to differentiate.

- This means that we may have a positive impact for some patients while others may need additional time to explain why they have a different quantity to the prescription. It is difficult to know the net impact of this.

- We anticipate that patients are most likely to question their prescription of an original pack when they receive less medicine than prescribed. But we know from our analysis that the majority of OPD will involve original packs that provide more medicine than the prescription.

Based on this we have not costed familiarisation costs for patients, since we cannot know how often this will be needed for patients. It may be that there are some additional time requirements from OPD but that these are negated by time saving from other patients.

We have not included any familiarisations costs for GPs. While GPs are likely to become familiar with the regulations over time there should be no change to prescribing based on this policy. There may be some patients that question the dispensed medicines with their GP, but we expect most patients will contact their pharmacy.

£m	
0.99	**Total cost for familiarisation**; Cost for pharmacy staff to learn the guidance

[24] ASHE Table 15 (4). 5a Hourly Pay – Gross (£) - For all employee jobsa: United Kingdom, 2022

[25] This is in accordance with standard practice set out in The Green Book.

[26] https://www.the-pda.org/nhs-pay-agreement-reached/

NHS reimbursement arrangements

As previously discussed, dispensing a different quantity of medicines from what is prescribed may also change the amount of medicines that a pharmacist needs to buy.

The impact of this will depend on how pharmacies will be reimbursed where they dispense a different quantity of medicine to what is written on the prescription and whether or not container allowances are changed. Depending on what reimbursement arrangements are put in place will determine whether pharmacies or the NHS ultimately bear the cost of any additional medicines dispensed, as well as any savings associated with a reduction in medicines dispensed.

For example, if reimbursement were to be based on the quantity that is written on the prescription rather than what is dispensed, we would expect the pharmacy to bear the cost and/or cost saving from dispensing more or less medicine than what is written on the prescription, whilst NHS expenditure on medicines would be unchanged. If the opposite were to occur, and reimbursement were based on what was dispensed rather than what is written on the prescription, we would expect any changes in pharmacy medicine expenditure to be passed onto the NHS.

The two example scenarios outlined above are not the only reimbursement options – for example it could be that other options such as paying to the nearest 30 tablets could be agreed upon. As a result, it is not possible to know what arrangements might be put in place and therefore how the costs of the increased medicines expenditure would be distributed between the NHS and community pharmacies.

Final NPV – Option 2a:

The following table summarises costs and benefits per year and over the full 10-year profile.

			Per year (£m)	NPV (£m) 2022/23 to 2031/32
Patients	Costs	Prescription costs	0.32	2.33
		Trips to pharmacy	1.46	10.77
	Benefits	Prescription costs	-0.91	-6.67
		Trips to pharmacy	-4.18	-30.80
GPs	Costs	Additional appointments for repeat prescriptions	4.27	31.44
	Benefits	Fewer appointments for repeat prescriptions	-12.21	-89.92
Pharmacies	Costs	Having to split more packs	0.00	0.00

		Having to dispense more packs	0.78	5.77
	Benefits	Splitting fewer packs (time saving)	-22.23	-191.36
		Having to dispense fewer packs	-2.24	-16.52
Drugs	Cost	Cost of additional drugs dispensed	9.28	79.91
	Benefits	Saving from fewer drugs dispensed	-3.06	-26.37
Familiarisation	Costs	Pharmacy time to learn the new guidance	0.99	0.99
OPTION 2a TOTAL			**-27.73**	**-230.43**

*For repeat prescriptions for patients and GPs we profile it as 0 in year 1, and 9/12 in year 2 because we consider repeat prescriptions as a one month duration, which is commonly prescribed as, and available in pack sizes of 28 and 30. This means that a patient will be getting two tablets more or fewer with each prescription, and it will take approximately 15 months to require one additional, or one less, prescriptions. As such the first 15 months (12 in year 1 and 3 in year 2) show no change for repeat prescriptions. While for pharmacies the time saving starts as soon as they dispense a pack where they do not have to split/repack.

Familiarisation costs apply only to the first year.

All other costs/benefits to be assumed the same per year.

Full table with all 10 years and NPV in Annex B.

Option 2b – As per option 2a (OPD within 10%) plus medicines containing valproate always dispensed as whole pack

For option 2b we propose that prescriptions for medicines containing valproate will always be dispensed as a whole pack. Data was collected and analysed for all formulations of medicines containing valproate that were dispensed in 2021[27]. These items are shown in the table below. As with the previous analysis we looked at the quantity prescribed compared with (up to) the two most common pack sizes.

Medicines containing valproate in the data:
Belvo
Convulex
Depakin

[27] This is different to the main drug sample as highlighted on page 3.

Depakote
Dyzantil
Epilim
Epilim Chrono
Epilim Chronosphere MR
Epilim Intravenous
Episenta
Epical CR
Orlept
Sodium Valproate
Syonell
Valproic Acid

The data from BSA showed the quantity in which valproate formulations had been prescribed, and the number of times each quantity was prescribed. As per option 2a the analysis summarised which quantities could be dispensed as whole packs, which could be dispensed as whole packs to within 10% and which fell outside the 10%. Those that could be dispensed as a whole pack to within 10% are already included in option 2a, so for this option we are interested in the number of prescriptions of medicines containing valproate that fell outside of 10% of whole packs, since under option 2b these will now also be dispensed as whole packs.

The total items we collected data for was around 2.98m (for England) over the twelve-month period. This was scaled up to total items in GB for using the 2021/22 PCA data, which scaled up to around 3.4m medicines containing valproate per year.

Of medicines containing valproate, 54% could be fulfilled with exact pack size (or multiples of), and a further 19% could be dispensed as a whole pack under option 2a (within 10% of prescribed number). Option 2b would mean 27% (915,000 items) would additionally be dispensed as whole packs per year.

From the analysis of medicines containing valproate prescription items, 88% would result in more medicines containing valproate being dispensed than was prescribed. This is partly because a commonly prescribed number in this group is 10 tablets (accounting for over 60% of these items) compared to a pack size of 30. For these prescriptions under option 2b, a pack of 30 tablets would be dispensed. This does not hold for all medicines containing valproate since some of these have smaller pack sizes available and some are liquids and injections.

Given that medicines containing valproate are prescribed to those with Epilepsy we have assumed that these will be repeat prescriptions. This means that when more tablets are dispensed than prescribed, the patient will not need to get a repeat prescription as soon as they would have with the prescribed number. As such, the number of tablets dispensed will not change over time, but the frequency of the prescriptions will change.

Discussion with pharmacists regarding the prescriptions for quantity of 10 suggest that a likely reason for a quantity of 10 is that a patient needs a short-term/stopgap of their medication (for example, maybe they are away and forgot their medication, or to cover a short period before a review appointment or dose adjustment. It is possible that there are a small number of cases where vulnerable patients are prescribed small numbers (i.e. 1 week at a time, or 5-10 days at a

time). It may be that for some of these the pharmacist will make an exception to whole pack dispensing, due to a risk assessment that refers to the need for different packaging such as a MDS. It was thought that these cases would be rare, but it is not possible to accurately quantify this, as such, the estimates through this analysis will be an upper estimate.

Taking this into account and dispensing whole packs for medicines containing valproate that would not be dispensed as a whole pack under OPD to within 10%, means that to provide the same number of tablets will mean that there would be 406,000 net fewer items dispensed per year.

Patients

We have costed the saving to patients for having to make fewer trips to the pharmacy and get GP appointments for repeat prescriptions, as per the analysis for patients in option 2a. For patients this means 468,000 fewer appointments for repeat prescriptions needed, and 62,000 additional appointments needed. As per option 2a we have costed a trip to collect a prescription at £2.24 per item, and £0.48p per prescription charge (£9.65x5% of those that are not exempt from prescription charge or with pre-paid prescriptions). This would lead total benefits of £1.3m and costs of £169k, which leads to a net saving for patients of £1.1m.

For medicines containing valproate, it is important that patients should receive all patient safety information as per the original packs. This is because medicines containing valproate should not be prescribed to girls and women unless the conditions of the PPP are met and only if other treatments are ineffective or not tolerated, as judged by an experienced specialist. If medicines containing valproate are taken during pregnancy, up to 4 in 10 babies are at risk of developmental disorders, and approximately 1 in 10 are at risk of birth defects[28].

The first retrospective data from the non-mandatory medicines containing valproate registry suggests that between April 2018 and Sept 2020, 181 pregnancies have been exposed to medicines containing valproate (approximately 70 per year). While all medicines containing valproate should be dispensed with the PIL it may be that some split packs do not get this leaflet.

Dispensing whole packs will ensure that this is provided on all occasions and lead to an improvement in patient safety. However, it has not been possible to quantify a patient safety impact from this information.

GPs

For GPs we assume this would mean 468,000 fewer appointments per year for repeat prescriptions and 62,000 additional appointments, and as per Option 2a we have assumed the cost of an e-consultation is £1.40. Which leads to a total benefit of £3.1m and a cost of £405k, which is a net benefit of £2.7m in QALYs.

[28] https://www.gov.uk/guidance/valproate-use-by-women-and-girls

NHS Community Pharmacies

As per option 2a we assume that there is a 90 second time saving on not having to split packs when dispensing an item, which as before we have taken to mean a 45p saving based on the average cost of pharmacy dispensing assistants. For medicines containing valproate, we estimate there will be 915,000 items that fall within OPD 10% flexibility and that would not require a split, which leads to a saving of £412k due to not splitting packs of medicines containing valproate.

In addition, given that we are giving out overall more medicine by not splitting, this would also mean 468,000 fewer prescription items and 62,000 additional prescription items net fewer prescription items needed, which we have costed at £1.20 and so leads to a further saving of £561k and costs of £74k.

In total this leads to a net benefit to pharmacy time of around £899k.

Manufacturers

Given the likelihood that those on medicines containing valproate will be taking this on a long-term basis there is assumed to be no additional impact on manufacturers for option 2b, since overall, it is likely that the same quantity of medicine will be purchased over time.

Summary table - Option 2b medicines containing valproate

		(£m)
Patients	Costs	0.17
	Benefits	-1.27
	Total benefits	-1.1
GP (QALY)	Costs	0.4
	Benefits	-3.06
	Total benefits	-2.65
Pharmacy	Costs (more items)	0.07
	Benefits (splitting packs)	-0.41
	Benefits (fewer items)	-0.56
	Total benefits	-0.90
Total		
	Costs	0.65
	Benefits	-5.30
Total benefits		-4.65

Option 2b – Net present value total – as per option 2a plus medicines containing valproate

			Per year (£m)	NPV (£m) 2022/23 to 2031/32
Patients	Costs	Prescription costs	0.32	2.33
		Trips to pharmacy	1.46	10.77

	Benefits	Prescription costs	-0.91	-6.67
		Trips to pharmacy	-4.18	-30.80
GPs	Costs	Additional appointments for repeat prescriptions	4.27	31.44
	Benefits	Fewer appointments for repeat prescriptions	-12.21	-89.92
Pharmacies	Costs	Having to split more packs	0.00	0.00
		Having to dispense more packs	0.78	5.77
	Benefits	Splitting fewer packs (time saving)	-22.23	-191.36
		Having to dispense fewer packs	-2.24	-16.52
Drugs	Cost	Cost of additional drugs dispensed	9.28	79.91
	Benefits	Saving from fewer drugs dispensed	-3.06	-26.37
Familiarisation	Costs	Pharmacy time to learn the new guidance	0.99	0.99
OPTION 2a TOTAL			**-27.73**	**-230.43**
OPTION 2b Medicines containing valproate				
Patients	Cost	Additional prescriptions	0.17	1.45
	Benefits	Fewer prescriptions	-1.27	-10.95
GPs	Cost	Additional appointments	0.40	3.48
	Benefits	Fewer appointments	-3.06	-26.30
Pharmacies	Cost	Additional items dispensed	0.07	0.64
	Benefits	Fewer packs split	-0.41	-3.54
	Benefits	Fewer items dispensed	-0.56	-4.83
		Total additional	-4.65	-40.05
OPTION 2b TOTAL			**-32.39**	**-270.49**

Direct costs and benefits to business calculations

We believe that the impact for NHS pharmacies is out of scope as NHS pharmacies are acting on behalf of a public authority and so under the Small Business, Enterprise and Employment Act 2015 their dispensing activity would not be classed as a business activity. The Better Regulation Framework Manual states that:

"A key indicator of what counts as "on behalf of a public authority" is whether there is a statutory duty in respect of that provision, for example legal duty of a local authority under the Childcare Act 2006 to ensure that prescribed childcare is available free of charge. Childcare providers in receipt of funding under section 7 of that Act would be considered as acting on behalf of a public authority."

We believe that this is applicable for community pharmacy as there is a statutory footing for pharmacies to act on behalf on the NHS. This is set out in Section 126 of the National Health Service Act 2006, which requires the NHS Commissioning Board to make arrangements for pharmaceutical services. These arrangements enable pharmacy contractors (such as retail pharmacy outlets), appliance contractors and dispensing doctors to provide, between them, a range of NHS community pharmaceutical services to patients including dispensing of medicines.

In addition, we believe that any impacts on NHS pharmacies would be indirect as the amendments will include a transitional provision, so the OPD flexibility to dispense up to 10% more or less does not automatically apply in NHS pharmaceutical services in England, NI 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 a transitional provision because of arrangements already made so pharmacists will be able to utilise the OPD flexibility within their NHS pharmaceutical service provision straight away. Furthermore, there will not be any transition arrangements for whole pack dispensing of medicines containing valproate, therefore these changes will apply for both NHS and private prescriptions in the UK as soon as they come into force in the HMRs.

For private prescriptions, our analysis suggests that the impact on pharmacies would fall under the de-minimis threshold, currently costed at £0.24m efficiency saving a year (an average saving of £0.24m per year (170/13844 x £19.24m), and an average increased cost of £0.01m (170/13844 x £0.86m), giving an average net saving of £0.23m per year). This figure is based on our assessment of the number of purely private pharmacies.

Finally, there may also be some impacts on manufacturers and wholesalers of medicines if the total quantity of medicine bought by pharmacists' changes as a result of their decision to dispense a manufacturer's original pack (for example if they on average tend to dispense more medicine than is prescribed). We judge this impact to be indirect and therefore not included in the EANDCB as it is dependent on the purchasing/dispensing decisions of pharmacies. Our analysis suggests that, if pharmacies always chose to make use of this in every case where it is likely to be clinically appropriate, there could be a benefit to manufacturers and wholesalers of medicines in the region of £1m. However, in reality we do not know if this would be the case. For example, it could be the case that some pharmacies may decide to only make use of the flexibilities when it allows them to dispense less medicine than prescribed, whilst other pharmacists may choose to adopt a different approach. Any decisions taken on how the flexibilities should be applied to NHS pharmaceutical services in England, Northern Ireland and Wales could also affect pharmacy decisions in this area. Ultimately, the combined effect of the different choices made by individual pharmacies would significantly alter the scale and direction of any impact on manufacturers and wholesalers.

Overall, whilst it has not been possible to precisely calculate an EANDCB figure, the RPC have confirmed that it would be comfortably below the de minimis threshold of £5m.

Risks and assumptions

Some of the main estimates and assumptions used in these calculations are:

- We have used a sample of drugs which we have used to represent all drugs. It is possible that the sample of drugs that we selected do not represent all drugs. We tried to mitigate this by drawing the sample randomly using stratification by brands and generics and by total NIC. We used the same methodology as that used to draw the drug sample for the medicine margin survey. In addition, a lot of our findings are consistent with the information we received from our stakeholder engagement.

- The time saving for pharmacies for not having to split packs and instead dispense whole packs was assumed to be 90 seconds per prescription. This figure was from engagement with stakeholders, and only one gave us an explicit figure for time saving. Other comments on the level of saving through not having to split packs was relative or difficult to extract the actual time saving. It is difficult to know whether this assumption is accurate, and whether it applied across all pharmacies (maybe this will differ by different dispensing methods, e.g. automated versus in store). The estimate of 90 seconds came from the difference in average times between prescriptions that needed splitting versus those that did not.

- The cost of pharmacy staff time to dispense a prescription – we have taken information from engagement with stakeholders and for this IA and internal analysis of Hub and Spoke dispensing to assume that the average cost for dispensing a prescription item is £1.20. This approximately matches cost estimates if we take dispensing to take around 2-3 minutes and taking staff time of dispensing assistants, pharmacy technicians and pharmacists in a ratio of 50%/25%/25%. However, we appreciate that it was difficult to determine an estimate that matched all the information we received through the stakeholder engagement.

Given the two large areas of uncertainty around the impact on pharmacies – the time saving and the cost of time – there is a risk that the impact for pharmacies is different to what we have estimated in this IA.

We have assumed that any health risks due to under or over dispensing medicines under OPD is mitigated by the pharmacist's professional judgement and the limit of 10% of prescription quantity.

As described above, for repeat prescriptions, at an overall level, we do not expect there to be any change in overall costs of medicines since any additional medicine dispensed initially would be offset by the patient delaying pick up of their next prescription, and vice versa where less medicine is dispensed. However, as patients do not always use the same pharmacy, this could shift the distribution of medicines dispensed across pharmacies, creating winners and losers. It is not possible to quantify this effect further since we do not have any information about how often patients switch pharmacies.

In addition, changing the timing of when medicines are dispensed could potentially have implications for pharmacy cashflow. In the example above, pharmacies would have to purchase more medicine up front to dispense more than what is prescribed, whilst the saving from patients delaying their subsequent repeat prescriptions would arise further down the line.

We have also treated all dispensing equally and assumed that the effect will be an average across all OPD dispensing, however, the impacts may differ depending on whether prescriptions are dispensed in store or via automated dispensing, this is discussed further in the below section on small and micro businesses.

Impact on small and micro businesses

We have estimated the number of GB pharmacies that would be considered a micro business as around 20% (2,800 of the 13,800) registered pharmacies (see summary table below). This estimate was produced by using the average number of FTE employees across pharmacies in England[29] from table 5 in the report on Community Pharmacy Workforce report, 2021. This showed the average FTE staff for community pharmacies in England was 6.1. We then used BSA data on pharmacies by group code – an arbitrary number used to link pharmacies that are part of chains – and then applying the average number of staff per pharmacy to the number of pharmacies in a chain. This is based on England only, and we then scaled up the estimates to 13,800 as per the GPhC registered premises.

Pharmacies that are independent, i.e. not part of any chain, were considered micro businesses, since on average they would have 6.1 employees (against the definition 1-9 employees). Groups of pharmacies where there were 2-7 pharmacies were considered small businesses (with 10-49 FTEs on average), while groups where there were 9 or more pharmacies in the chain were considered medium or above.

Summary GB pharmacies	No. businesses	No. pharmacies stores/branches	%	Total average employees
Micro (1-9 employees)	2,754	2,754	20%	16,745
Small (10-49 employees)	760	2,2618	16%	13,744
Medium + (50+ employees)	99	8,829	65%	53,682
Total		13,844	100%	84,172

Some independent pharmacies will be considered small or micro businesses. While overall the impact will be positive for pharmacies (and manufacturers) it is not possible to assess whether impacts will differ between small and medium-sized businesses (“SMBs”) and larger organisations. One possible example could be that large organisations will be able to employ fewer pharmacists due to the savings from OPD, while SMBs will have only 1 pharmacist who will still be needed, but now at less than full capacity. However, it is thought that additional time would not be wasted, and staff may be able to deliver new clinical services.

[29] https://www.hee.nhs.uk/sites/default/files/documents/The%20Community%20Pharmacy%20Workforce%20in%20England%202021%20-%20Survey%20report_0.pdf?dm_i=21A8,7PCVL,QZXL6D,VEFN8,1

If for some reason independent pharmacies decide that OPD does not benefit them they retain the choice to dispense part-packs as per the prescribed number.

It is more likely that larger organisations will have access to automated dispensing (or dispensing from a hub) which independent pharmacies may not have access to, and automated dispensing may see a greater efficiency than in-store dispensing, although it is not possible to quantify this.

Annex A – Literature search:

Key words: Original pack dispensing (OPD), whole pack dispensing, splitting packs, pharmacy, prescription.

Interested in the following areas:

1. time saving, efficiency, frequency

2. patient safety, patient information leaflet

3. Medicines containing valproate

By; UK, Europe, Worldwide.

Results

Wastage:

- An experiment carried out among pharmacies in France compared OPD (the existing system) with dispensing in exact number prescribed for antibiotics. The study found that in 60% of all prescriptions the prescribed number did not match the original pack size, and that dispensing in exact numbers reduced the number of pills supplied by 10%. Hence there were less pills wasted when dispensing the exact number rather than using OPD [1].

- Data from Italy showed that moving from OPD to dispensing in exact number prescribed for capecitabine, a cancer medication, reduced wasted tablets, and hence expenditure on drugs by 19.6% [2].

- Two studies found repackaging of certain drugs from an original container could lead to reduced shelf-life due to the storage climate for trametinib and regorafenib, two expensive cancer drugs [3], and exposure to moisture for medicines containing sodium valproate, a drug which is sensitive to moisture [4].

- A study of pharmacists in Granada, Spain highlighted the lack of information in leaflets for patients and pharmacists on how best to store drugs outside original packaging [5].

Adherence to medication:

- Two studies found higher adherence to treatment when dispensing in exact numbers. [1] found that compared to OPD, adherence was 21% higher (95% confidence interval 14-28%) for antibiotics, while in Italy adherence to capecitabine, a cancer medication, was 5% higher than with OPD [2].

Leaflets:

- PILs were rarely mentioned in the reviewed abstract, and were not compared for OPD versus exact number dispensing.

1. Treibich C, Ventelou B, Lescher S, Sagaon-Teyssier L. The expected and unexpected benefits of dispensing the exact number of pills. PLoS ONE (2017); 12:9.

2. Cesari R, Santilli G, Scarlattei D, Marotta M, Borsari M. Prescriptions and equipment for unit dose capecitabine in Oncology Pharmacy Laboratory-Ausl Bologna-Italy. European Journal of Hospital Pharmacy (2014); vol. 21.

3. de Lemos ML, Mathers B, Badry N, Hamata L, Lo K. Challenges of dispensing costly tablets with short shelf-life. Journal of Oncology Pharmacy Practice (2019); 25:1; p. 210-21.

4. Redmayne N, Robertson S, Kockler J, Llewelyn V, Haywood A, Glass B. Repackaged sodium valproate tablets--Meeting quality and adherence to ensure seizure control. Seizure (2015); 31:108 p11. doi: 10.1016/j.seizure.2015.07.007.

5. Fajardo Paredes P, Baena Parejo MI, Fernandez-Llimos F, Faus MJ. Analysis on information about preservation conditions of the most prescribed medicines when removed from their original package. Pharmaceutical Care Espana (2001); 3:6; p. 422-432.

Annex B – Data analysis

NHS BSA provided DHSC with data on frequency of prescriptions by drug and by quantity prescribed for a sample of drugs. The sample was drawn as a stratified random sample consisting of 200 generics and 150 brands. Strata were based on number of prescriptions by drug such that those that were most prescribed had a greater chance on inclusion in the survey. This follows the sampling methodology of the Medicine Margin Survey, which is a quarterly survey used to capture a representative sample of drugs purchased in community pharmacies in England. This was considered a practical way to provide data for a representative sample of drugs. The data covered prescription items by quantity prescribed for the sampled drugs for the six months Dec 2020 – May 2021, for example in the below table there were 18,552 occasions (item) where a quantity of 14 paracetamol tables was prescribed, and 187 occasions when a quantity of 15 tables was prescribed.

Example data – Paracetamol 500mg tablets:

BNF Presentation	Items	Quantity
…		
Paracetamol 500mg tablets	18,552	14
Paracetamol 500mg tablets	187	15
Paracetamol 500mg tablets	3,321	16
Paracetamol 500mg tablets	2	17
Paracetamol 500mg tablets	311	18
Paracetamol 500mg tablets	10	19
Paracetamol 500mg tablets	1,751	20
Paracetamol 500mg tablets	6,238	21
Paracetamol 500mg tablets	49	22
Paracetamol 500mg tablets	19	23
Paracetamol 500mg tablets	2,679	24
Paracetamol 500mg tablets	872	25
Paracetamol 500mg tablets	42	26
Paracetamol 500mg tablets	5	27
Paracetamol 500mg tablets	131,290	28
Paracetamol 500mg tablets	11	29
Paracetamol 500mg tablets	11,269	30
…		
Paracetamol 500mg tablets	179	672
Paracetamol 500mg tablets	1	684
Paracetamol 500mg tablets	14	700
Paracetamol 500mg tablets	4	720
Paracetamol 500mg tablets	1	728
Paracetamol 500mg tablets	2	730
Paracetamol 500mg tablets	2	736
Paracetamol 500mg tablets	2	740
Paracetamol 500mg tablets	17	800
Paracetamol 500mg tablets	2	900
Paracetamol 500mg tablets	2	960
Paracetamol 500mg tablets	17	1000
Paracetamol 500mg tablets	2	1009
Paracetamol 500mg tablets	2	1120
Paracetamol 500mg tablets	1	1200

Paracetamol 500mg tablets	2	1300
Paracetamol 500mg tablets	1	1344
Paracetamol 500mg tablets	1	1512
Paracetamol 500mg tablets	1	2224
Paracetamol 500mg tablets	1	5600
Paracetamol 500mg tablets	2	10000

The above table shows the different quantities of Paracetamol 500mg tablets that were prescribed Dec 2020 – May 2021. The quantity ranges from below 14 to 10,000 although these were prescribed in small numbers (BSA verified the prescriptions of 10,000 and confirmed that that was the prescribed number – although they were unable to confirm whether that was what the GP intended). The most frequently prescribed quantity in this table is 28 tablets (131,000) and 30 tablets (11,000). Based on this data, we determined for each prescribed quantity the boundaries for 10% OPD.

			Within 10% of prescription	
BNF Presentation	**Items**	**Quantity**	**Lower**	**Upper**
…				
Paracetamol 500mg tablets	18,552	14	12.6	15.4
Paracetamol 500mg tablets	187	15	13.5	16.5
Paracetamol 500mg tablets	3,321	16	14.4	17.6
Paracetamol 500mg tablets	2	17	15.3	18.7
Paracetamol 500mg tablets	311	18	16.2	19.8
Paracetamol 500mg tablets	10	19	17.1	20.9
Paracetamol 500mg tablets	1,751	20	18	22
Paracetamol 500mg tablets	6,238	21	18.9	23.1
Paracetamol 500mg tablets	49	22	19.8	24.2
Paracetamol 500mg tablets	19	23	20.7	25.3
Paracetamol 500mg tablets	2,679	24	21.6	26.4
Paracetamol 500mg tablets	872	25	22.5	27.5
Paracetamol 500mg tablets	42	26	23.4	28.6
Paracetamol 500mg tablets	5	27	24.3	29.7
Paracetamol 500mg tablets	131,290	28	25.2	30.8
Paracetamol 500mg tablets	11	29	26.1	31.9
Paracetamol 500mg tablets	11,269	30	27	33
…				

For each prescribed quantity, if there is a pack size available that falls between the upper and lower bound (or multiples of pack size) then the prescribed quantity could be dispensed as a whole pack under OPD to within 10%.

Available pack sizes were determined from the BSA's Dictionary of Medicines and Devices (DM&D) and the pack sizes listed in the Drug Tariff and compared with other available data. For example, the two most common pack sizes for paracetamol 500mg were 100 tablets and 32 tablets, which are the two available pack sizes listed in part VIII of the Drug tariff, and while there are many other available pack sizes listed on the Dictionary of Medicines and Devices (DM&D) these were thought to be less commonly available.

The pack sizes were compared to the different quantities prescribed that were recorded by BSA. In the above example, the boundary for quantity of 28 is 25.2 to 30.8, and the available

pack size of 32 (and 100) falls outside this range, therefore prescriptions with a quantity 28 can not be dispensed as a whole pack under a 10% OPD policy. However, the boundary for prescription quantity 30 is 27 to 33. The pack size of 32 does fall within these bounds and so a prescription quantity of 30 could be dispensed as a whole pack of 32 and be within 10% of the prescribed quantity.

A reference table was set out to show for each prescription boundary what the ranges were for pack sizes that would fall within 10% of the prescription number. This was compared with BSA data showing frequency of each quantity for the sampled drugs. From this we were able to sum the prescription items that could be filled to be exact packs, with whole packs within 10% or could not be filled by whole packs within 10%. For each quantity we could determine whether the available packs would provide fewer or more tablets than prescribed (whether medicine would be over or under dispensed if whole packs were dispensed).

The items from the sample data were scaled up to total items using NHS BSA annual data for 2020/21 by BNF section name – this was done since it is likely that BNF sections would contain similar drugs with similar prescribing patterns and that these could vary between sections (there are 203 BNF sections). The BNF sections were reviewed by a DHSC pharmacist who flagged whether whole sections should be excluded from OPD (for example, sections that were mostly steroids). Since we assume that a pharmacist will use their professional judgement to dispense the prescribed quantity for steroids and not dispense a whole pack. The same was done for whether a BNF section contained medicines that would be considered as repeat medicines, however the majority of sections contained medicine that could be repeats but it was acknowledged that not all prescriptions in the sections would be repeat prescriptions, so this was not used further in our analysis and we found alternative evidence for the number of prescriptions that would be repeats.

Table summarising results for total items that are appropriate for OPD:

	Items (million)	Description
Total items	1,312.3	Prescription Cost Analysis - England 2020/2021 totals, NHS BSA data. Scaled up to GB
Items deemed appropriate for OPD	1,080.8	After DHSC pharmacist has assessed BNF sections and excluded those that should always be as prescribed
Items that need splitting	266.3	Matching our sampled drugs to available pack sizes, and scaling up to all items
Items that could be OPD 10%	**49.1**	Those in our sample where a whole pack could be dispensed to within 10% scaled up by BNF section

Medicines containing valproate were analysed separately, using the same methodology, since under option 2b all prescriptions for medicines containing valproate would be dispensed as whole packs to the nearest pack.

From this analysis we applied impacts for Patients, GPs and Pharmacies as described above.

Full NPV table;

Option 2a			Per Year (£m)	22/23	23/24	24/25	25/26	26/27	27/28	28/29	29/30	30/31	31/32	NPV
Patients	Costs	Prescription costs	0.32	0.00	0.24	0.32	0.32	0.32	0.32	0.32	0.32	0.32	0.32	2.33
		Trips to pharmacy	1.46	0.00	1.10	1.46	1.46	1.46	1.46	1.46	1.46	1.46	1.46	10.77
	Benefits	Prescription costs	-0.91	0.00	-0.68	-0.91	-0.91	-0.91	-0.91	-0.91	-0.91	-0.91	-0.91	-6.67
		Trips to pharmacy	-4.18	0.00	-3.14	-4.18	-4.18	-4.18	-4.18	-4.18	-4.18	-4.18	-4.18	-30.80
GPs	Costs	Additional appointments for repeat prescriptions	4.27	0.00	3.20	4.27	4.27	4.27	4.27	4.27	4.27	4.27	4.27	31.44
	Benefits	Fewer appointments for repeat prescriptions	-12.21	0.00	-9.16	-12.21	-12.21	-12.21	-12.21	-12.21	-12.21	-12.21	-12.21	-89.92
Pharmacies	Costs	Having to split more packs	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
		Having to dispense more packs	0.78	0.00	0.59	0.78	0.78	0.78	0.78	0.78	0.78	0.78	0.78	5.77
	Benefits	Splitting fewer packs (time saving)	-22.23	-22.23	-22.23	-22.23	-22.23	-22.23	-22.23	-22.23	-22.23	-22.23	-22.23	-191.36
		Having to dispense fewer packs	-2.24	0.00	-1.68	-2.24	-2.24	-2.24	-2.24	-2.24	-2.24	-2.24	-2.24	-16.52
Cost of drugs	Cost	Cost of additional drugs dispensed	9.28	9.28	9.28	9.28	9.28	9.28	9.28	9.28	9.28	9.28	9.28	79.91
	Benefits	Saving from fewer drugs dispensed	-3.06	-3.06	-3.06	-3.06	-3.06	-3.06	-3.06	-3.06	-3.06	-3.06	-3.06	-26.37

Familiarisation	Costs	Pharmacy time to learn the new guidance	0.99	0.99	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.99
			-27.73	**-15.03**	**-25.54**	**-28.72**	**-28.72**	**-28.72**	**-28.72**	**-28.72**	**-28.72**	**-28.72**	**-230.43**
TOTAL 2a													
Option 2b													
Valproates	Patients	Costs for needing more prescriptions	0.17	0.17	0.17	0.17	0.17	0.17	0.17	0.17	0.17	0.17	1.45
		Benefits for needing fewer prescriptions	-1.27	-1.27	-1.27	-1.27	-1.27	-1.27	-1.27	-1.27	-1.27	-1.27	-10.95
	GPs	Costs for more appointments	0.40	0.40	0.40	0.40	0.40	0.40	0.40	0.40	0.40	0.40	3.48
		Benefits of fewer appointments	-3.06	-3.06	-3.06	-3.06	-3.06	-3.06	-3.06	-3.06	-3.06	-3.06	-26.30
	Pharmacies	Cost of more prescriptions	0.07	0.07	0.07	0.07	0.07	0.07	0.07	0.07	0.07	0.07	0.64
		Benefits of not splitting packs	-0.41	-0.41	-0.41	-0.41	-0.41	-0.41	-0.41	-0.41	-0.41	-0.41	-3.54
		Benefits of dispensing fewer items	-0.56	-0.56	-0.56	-0.56	-0.56	-0.56	-0.56	-0.56	-0.56	-0.56	-4.83
Total Valproates		Net	-4.65	-4.65	-4.65	-4.65	-4.65	-4.65	-4.65	-4.65	-4.65	-4.65	-40.05
OPTION 2b TOTAL			**-32.39**	**-19.68**	**-30.19**	**-33.37**	**-33.37**	**-33.37**	**-33.37**	**-33.37**	**-33.37**	**-33.37**	**-270.49**