Title: Batch Testing Review - Consultation stage IA **IA No:** **RPC Reference No:** **Lead department or agency:** Department of Health and Social Care **Other departments or agencies:** MHRA, OLS	Impact Assessment (IA) **Date: 28/03/2022** **Stage: Consultation** **Source of intervention:** **Type of measure:** **Contact for enquiries:** Helen.mercer@dhsc.gov.uk

Summary: Intervention and Options

RPC Opinion:

Cost of Preferred (or more likely) Option (in 2019 prices)			
Total Net Present Social Value	**Business Net Present Value**	**Net cost to business per year**	**Business Impact Target Status**
£m	£m	£m	

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

Following the end of the Implementation Period, the government agreed to temporarily continue accepting medicine batch tests carried out in EU/EEA countries until 31 December 2022, while it conducts a review of the UK batch testing regulatory system. The government pledged to conclude this review, and announce any changes to the current system of acceptance of batch testing performed in third countries 'listed' as equivalent the UK's standards, by 31 December 2022 at the latest, at which point a 2-year notice period is triggered before any changes take effect. The existence of several market failures e.g. asymmetric information, incentive problems/externalities, and health inequalities necessitate regulation by the government.

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

The purpose of this consultation is to develop the UK's batch testing framework. The new regulatory system for batch testing has the objectives of protecting patient safety and access to medicines for the whole of the UK and build the right system for the Life Sciences industry to ensure that the UK remains an attractive place to develop and market medicines while maintaining the necessary standards.
The policy would aim to find the optimal level of retesting requirement for imported medicines that fully upholds patient safety principles while not overburdening importers of medicines. The intended outcomes of the intervention are to align with our national interests, which include maintaining or improving the supply of medicines in the UK and inward investment by pharmaceutical companies while protecting the price the NHS pays for drugs.

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

A. **(Baseline / Business As Usual): No Import Testing or UK Qualified Person (QP) certification/release for listed countries** which we are content to have sufficient regulatory oversight. Countries undergo a conformity assessment to ensure their regulatory standards are sufficient. The list would include all EU/EEA countries.
B. **No Import Testing but UK QP certification/release for listed countries**. Imported products from listed countries would need to be imported by an MIA holder into a GB importation site and certified/released by a UK QP.
C. **Full Quality Control Batch Testing and Implementing UK QP certification/release for listed countries**.
D. **Reduced Number of Import Tests and UK QP certification/release for listed countries** requiring only a limited number of critical tests, such as identification or assay tests, on products from countries on the list.

A <u>preferred option has not been chosen</u>. This choice will be informed by the consultation exercise.

Is this measure likely to impact on international trade and investment?				
Are any of these organisations in scope?	**Micro** Yes	**Small**	**Mediu m**	**Large**
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)		**Traded:**	**Non-traded:**	
Will the policy be reviewed? It be reviewed. **If applicable, set review date:** /				

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 : _____ Date: _____

Summary: Analysis & Evidence

Policy Option A

Description: **Baseline: No Import Testing or UK QP certification/release for listed countries**

FULL ECONOMIC ASSESSMENT

Price Base Year 2019	PV Base Year 2020	Time Period Years	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	High: Optional	Best Estimate:

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

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

In line with impact assessment guidance the baseline has zero costs or benefits as impacts are assessed as marginal changes against the baseline.

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

In line with impact assessment guidance the baseline has zero costs or benefits as impacts are assessed as marginal changes against the baseline.

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'

In line with impact assessment guidance the baseline has zero costs or benefits as impacts are assessed as marginal changes against the baseline.

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

In line with impact assessment guidance the baseline has zero costs or benefits as impacts are assessed as marginal changes against the baseline.

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:**	

Summary: Analysis & Evidence

Policy Option B

Description: No Import Testing but UK QP certification/release for listed countries

FULL ECONOMIC ASSESSMENT

Price Base Year 2019	PV Base Year 2020	Time Period Years	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	High: Optional	Best Estimate:

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

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

Personnel (£40.9m) and one-off licencing costs (£6.2m) for importing firms to comply with requirements.

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

Increased time to bring products to market, which could adversely impact access to medicines for the relatively small number of products that are at risk.
Administration and overhead costs for firms to complete the required batch certification/release processes

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'

No monetisation of benefits at this stage.

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

Benefits to patients as a result of the process identifying and preventing ineffective or faulty batches of medicines being released for sale.
Increased workforce skills and capability resulting from the requirement for more highly skilled professionals based in GB.

Key assumptions/sensitivities/risks	Discount rate (%)

There is a risk that insufficient supply of Qualified Persons (QPs) will fail to meet demand and regulatory requirements within the defined implementation period
There is limited available evidence about the effectiveness of this policy option in identifying issues with batches of products imported from countries with similarly high regulations and standards
Information about implementation costs is based on voluntary industry engagement, the consultation is designed to gather more evidence and data.

BUSINESS ASSESSMENT (Option 2)

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

Summary: Analysis & Evidence

Policy Option C

Description: **Full Quality Control Batch Testing and Implementing UK QP certification/release for listed countries**

FULL ECONOMIC ASSESSMENT

Price Base Year 2019	PV Base Year 2020	Time Period Years	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	High: Optional	Best Estimate:

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

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

Costs to importing organisations to receive appropriate licensing (£6.2m) and set up (£330m - £615m) and run (£127m + £171m) new batch testing and certification/release process for all medicines batches imported from listed countries (currently EU/EEA countries).

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

Additional costs to bring products to market could lead to products being identified as at risk of discontinuation, creating a risk to patients reliant on these medicines.

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'

No monetisation of identified benefits at this stage

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

Health benefits to patients from identification and prevented use of faulty or ineffective batches imported from listed countries;
Potential for increased long-term investment in the UK pharmaceutical market

Key assumptions/sensitivities/risks	Discount rate (%)

There is a risk that insufficient supply of Qualified Persons (QPs) will fail to meet demand and regulatory requirements within the defined implementation period
There is limited available evidence about the effectiveness of repeat import testing in identifying issues with batches of products imported from countries with similarly high regulations and standards
Information about implementation costs is based on voluntary industry engagement, the consultation is designed to gather more evidence and data.

BUSINESS ASSESSMENT (Option 3)

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

Summary: Analysis & Evidence

Policy Option D

Description: Reduced Number of Import Tests and UK QP certification/release for listed countries

FULL ECONOMIC ASSESSMENT

Price Base Year 2019	PV Base Year 2020	Time Period Years	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	High: Optional	Best Estimate:

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

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

No quantification at this stage, subject to further information about how the option will be operationalised.

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

Type of costs incurred expected to be similar to those described under option C ie. licensing, setup and running costs to businesses.

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'

No monetisation of identified benefits at this stage

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

Potential health benefits to patients from identification and prevented use of faulty or ineffective batches imported from countries listed as equivalent to the UK's standards (currently EU/EEA countries)

Potential for increased long-term investment in the UK pharmaceutical market

Key assumptions/sensitivities/risks	Discount rate (%)

There is a risk that insufficient supply of Qualified Persons (QPs) will fail to meet demand and regulatory requirements within the defined implementation period
There isn't yet sufficient detailed information about how this option would operate (ie. which tests would be applied to which products) to provide a fuller evaluation of this option. We expect the option to generate similar types of costs and benefits to option C but cannot assess the scale of those at this stage.

BUSINESS ASSESSMENT (Option 4)

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

1. **Batch testing** is the process of confirming that every batch of medicine has the correct composition through laboratory and other tests. UK law requires that batch testing is undertaken by industry before medicines are signed off by a Qualified Person[1] (QP) and released to market. QP certification and release is the confirmation that the batch meets the requirements of the Marketing Authorisation (MA) and is suitable for sale and supply or export. This ensures that patients get medicines which are of appropriate quality and have the desired therapeutic effect. In general, batch testing is carried out by the medicine's manufacturer at the end of the production, and it may be repeated if the medicine is imported from a country whose batch tests are not recognised by the importing party.

2. Batch testing involves a lot of different processes and high skilled professionals. Testing equipment is often highly specialised and unique to products, with each product also having specific methods to be followed to get the results set out in the MA. Changes to the environment will have an impact and therefore transferring methods and equipment to a new location can take many iterations to calibrate the equipment. A QP must have a relevant undergraduate degree, be part of a membership group and have two years of experience in good manufacturing practice (GMP) processes. The QP certifying the finished product is responsible for ensuring a full qualitative and quantitative analysis of all the active substances and all other tests listed in the MA. The combination of these factors and the high standard the MHRA demands of manufacturers does create high costs, but also ensures that UK patients get safe and effective medicines.

3. There are three main cases of medicines trade in terms of batch testing requirement:

   Case A. Manufacturing Medicines in UK for Export
   When a medicine is manufactured in the UK, laboratory testing is performed at the end of production by either the manufacturer themselves, or via a third-party contract laboratory. If a medicine is being exported to a country that does not have a Mutual Recognition Agreement (MRA) with the UK, the batch would need to be retested according to the importing country's law. If the medicine is exported to a country with which the UK has an MRA, no repeat batch testing is required.

   Case B. Importing Medicines into Great Britain (GB) from a third country with which the UK has an MRA when the product is manufactured in that country
   If a batch is imported from a country with which the UK has an MRA and is manufactured in that country, re-testing is not required for batch release. The batch must still be certified by a UK QP.

   Case C. Importing Medicines into GB from a Third Country with which the UK does not have an MRA (the focus of this consultation-stage impact assessment)
   If the batch is imported from a country with which the UK does not have an MRA, re-testing is required unless the UK recognises batch testing from the exporting country (in the case of the EU/EEA countries until 31 December 2022).

4. The UK has MRAs in place with Australia, Canada, Israel, Japan, New Zealand, Switzerland, and the USA (ie. Case B) – meaning that batch testing does not have to be repeated when exporting to, or importing from, these countries, provided that the medicine is manufactured in these

[1] Qualified Person (QP) is responsible for assuring the quality of medicines and are legally responsible for certifying batches of medicinal products before they are used in clinical trials or available on the market.

countries, and subject to some exceptions on the types of medicinal products[2]. Batches must be imported by a Manufacturing or Import Authorisation (MIA) holder, into a UK importation site and certified/released by a UK QP based on testing conducted by the manufacturer in the MRA country.

5. Due to the Northern Ireland Protocol, batch testing arrangements in Northern Ireland (NI) are subject to new legislative proposals put forward by the EU. These allow for the batch testing of products for the NI market to be carried out in Great Britain (and the EEA), provided these products are certified and released by a qualified person located in Great Britain, Northern Ireland or the EU applying the equivalent standards of quality as the EU, and that the site of the batch testing is appropriately licensed and subject to inspection.

6. The UK used to have a *de facto* MRA with EU/EEA[3] countries during its EU membership, but the MRA ended at the end of the Implementation Period (IP) on 31 December 2020. Following the end of the IP, the UK implemented a system to list countries which have sufficiently high regulatory standards and recognise batch testing done there. EU/EEA countries[4] were added to this list and it was announced in March 2021 that a full review of its future batch testing strategy ('Review' thereon) would be conducted. The government has pledged to conclude this Review and announce any changes (if applicable) to the current listing system of by 31 December 2022 at the latest, at which point a 2-year notice period will be triggered before any changes take effect[5].

7. The scope of the review only covers legislative changes that are fully within the UK's control. As such, the Review would operate within the parameters of the UK-EU Trade and Cooperation Agreement (TCA) and the Acquis (which NI must follow) and will therefore not consider options such as agreeing an MRA with any country, seeking to renegotiate elements of the Northern Ireland Protocol, or asking the EU or other countries to change their policy to recognise batch testing of medicines in the UK. The Review is limited to batch testing policy and not wider medicines regulations. Two key examples which are out of scope are: Official Medicines Control Laboratory (OMCL) testing to release a vaccine or blood products onto the market; and decisions on recognising EEA QP certification[6]. This consultation-stage impact assessment focusses on batch testing policy in the case of importing medicines into GB from a third country with which the UK does not have an MRA (case C).

8. The justification for government intervention and regulation in this area is the existence of a number of market failures (see examples below) that market participants are not likely to fully take into account in their decisions – leading to suboptimal outcomes in the absence of government intervention. Government intervention is needed to appropriately balance considerations of short term vs long term impacts, impacts on businesses vs patients and wider society and social vs private impacts. Examples for market failures in this area include:

   Information asymmetry: The UK regulator sets testing standards for all medicines manufactured in the UK and for medicines imported from overseas, needs to be satisfied that each batch meets these stringent quality standards. For countries where there is no MRA, intervention is needed to ensure that batches imported from these countries are tested to, and meet, the same high standards and requirements for sale in the UK as domestic products.

   Incentive problems / externalities: Batch testing adds time and costs of getting products to market. These costs fall on the manufacturer/importer whereas the benefits accrue to

[2] https://www.gov.uk/government/publications/list-of-approved-countries-for-authorised-human-medicines/list-of-approved-countries#list-of-countries-approved-for-batch-testing

[3] EEA includes EU countries plus Iceland, Liechtenstein, and Norway.

[4] The UK's policy is to recognise batch testing conducted in countries on a 'list' published by the Medicines and Healthcare products Regulatory Agency (MHRA) which includes all EU/EEA member states.

[5] https://www.gov.uk/government/publications/letter-to-medicines-and-medical-products-suppliers-30-march-2021/letter-to-medicines-and-medical-products-suppliers#batch-testing-of-medicines

[6] Acknowledging that the recognition of QP certifications by other countries requires the recognition of batch testing from the same countries as per the Human Medicines Regulations (Reg 18A).

patients and the health sector. The incentives in the pharmaceutical market to maintain low costs (either due to competition in the case of generics or price controls in the case of branded medicines) could result in manufacturers/importers being less risk averse than society as a whole. Consequently, to correct these externalities, government intervention is needed to ensure that imports from countries whose standards could diverge from the UK are assessed to the level consistent with the UK's risk appetite.

In addition, establishing increased batch testing capacity in the UK over the medium term, could have spillover effects for the UK-based life sciences sector in the longer term. More UK-based testing could: drive greater innovation to improve testing techniques; make the UK a more attractive place to train and practise and, increase UK-based manufacturing for those firms seeking to co-locate production and testing facilities[7]. These outcomes are highly dependent on wider barriers to entry but if achieved, would lead to positive economic impacts and greater availability of medicines for UK patients, hence positive externalities[8].

Issues of equity / health inequalities: Requiring more stringent testing regimes of imported medicines could lead to importers discontinuing imports where this requirement would impact profitability or where there is not enough capacity to carry out more testing. Depending on the types of medicines affected, this could lead to disproportionate negative impacts on certain groups (for example, groups with certain medical conditions). Government intervention is needed to uphold equity considerations – for example by helping industry create additional capacity or exempting certain types of medicines under the retesting requirement.

Rationale and evidence to justify the level of analysis used in the IA (proportionality approach)

9. This is a consultation stage impact assessment. It uses available data and information in order to test assumptions, identify evidence gaps, and consult on filling these evidence gaps.

10. The costs of batch testing largely fall on industry and as such, we are reliant on information provided by private firms to quantify the options presented in this IA. We have undertaken initial engagement activities with industry and used the voluntary returns from those exercises to provide the indicative cost estimates used in this IA. We recognise that the stakeholders providing cost estimates have a vested interest in the policy outcome and where there are alternative published sources of information about the likely costs of batch testing we have used these to sense check the data we've collected directly to date (see Annex B). Through this consultation we are seeking feedback on the evidence presented in this IA and requesting further information to provide a more comprehensive understanding of likely costs and benefits of the options being considered.

11. At this stage, our assessment of option D (see below) is limited by the further work needed to fully specify how the policy would apply across the board. We have made a qualitative assessment for how this option would compare to the scale of costs and benefits identified for option C (see below).

[7] This is most likely for products with short shelf-lives where it's important to minimise the time taken to get products to consumers.

[8] For example, if repeat testing is required for medicines imported from the EU, companies would have somewhat greater incentives to move to the UK the manufacturing of medicines they intend to sell in the UK, compared to the scenario of unilateral recognition of EU batch tests in which case they can manufacture and test medicines in the EU and can distribute these in both the EU or the UK without further tests. At the same time, we recognise that manufacturing decisions will be based on a range of factors and batch testing requirements may only be a very small part of these considerations.

Description of options considered

12. There is a spectrum of options, ranging from the continuation of the current arrangement of recognition of batch testing in listed countries to the requirement of full duplicative testing of medicines from countries with which the UK does not have MRA.

13. The government will ensure the UK's batch testing policy complies with multiple legal considerations, including the UK's Human Medicines Regulations 2012 and public law principles and from a trade perspective, World Trade Organisation (WTO) and Trade and Co-operation Agreement (TCA) requirements. As such, the UK's future batch testing policy must be based on criteria that all trading partners can be assessed against. Due to the timing of this review, during the initial implementation of any policy change, we expect only imports from EU/EEA countries will be affected, with the potential for more countries to come into scope over time.

Option A. (Baseline / Business As Usual): No Import Testing or UK QP certification/release for listed countries

14. Countries would undergo a conformity assessment by MHRA to ensure their regulatory standards are sufficient before inclusion on the list. Currently all EU/EEA countries are on the list and conformity assessments of these countries have not been required due to regulatory alignment between the UK and EU/EEA during the UK's membership of the EU. We expect other countries to be considered for listing at a later stage. This option would reflect the current system of acceptance of batch testing performed in listed countries and is consistent with the requirements in place for EU/EEA countries prior to the UK leaving the EU.

15. In the case of imports from the EU/EEA, UK importers (including wholesalers) could continue to import medicines by recognising the EU/EEA 'Qualified Person' (QP) sign-off of the respective EU/EEA batch testing. Hence, the option relies on the continued recognition of EU/EEA QP certification.

16. This option requires that a 'Responsible Person (import)' (RPi) in the UK verifies that the batch has been batch tested and certified by a (QP) in the EU/EEA. For this, the importer would only require a 'Responsible Person (import)'[9] (RPi) who would verify the EU/EEA QP sign off and EU/EEA batch testing, and no UK QP is necessary for the process. All UK wholesalers currently importing from the EEA already have RPis in place, some working for more than one company.

17. Also, under this option, importers would not require Manufacturing or Importation Authorisation (MIA) and Good Manufacturing Practice (GMP) licences, and instead only a Wholesale Dealer/Distribution Authorisation (for medicines for human use) (WDA(H)) with a Good Distribution Practice (GDP) licence. Equally, as the batch testing location would not change for EU/EEA imports, there would be no need for importers to apply for a variation to the respective medicines' Marketing Authorisation. In other words, there would be no additional cost for existing importers of EU/EEA medicines.

Option B. No Import Testing but UK QP certification/release for listed countries.

18. This option would make the same requirement for listed countries as for countries with which the UK holds a Mutual Recognition Agreement (MRA) on batch testing. Countries would undergo a conformity assessment by MHRA to ensure their regulatory standards are sufficient before inclusion on the list. MHRA would 'list' all EU/EEA countries as their assessments have indicated that these countries' standards are equivalent to that of the UK's on. Other third countries can apply to become a 'listed country'; decisions will be based on whether other third countries meet UK standards.

19. Under this option medicines imported from listed countries would need to be imported by a Manufacturing or Importation Authorisation (MIA) holder into a GB importation site. Rather than

[9] https://www.gov.uk/guidance/acting-as-a-responsible-person-import

having an RPi to ensure the required QP certification has taken place prior to import, A UK based QP would need to certify batches for release to the UK market.

20. Importers would require a Manufacturing or Importation Authorisation (MIA) and Good Manufacturing Practice (GMP) licences. There would also be a need for importers to apply for a variation to the respective medicines' Marketing Authorisation.

Option C. Full Quality Control Batch Testing and Implementing UK QP certification/release for listed countries.

21. This option would make the same requirement for listed countries as for countries with no MRA with the UK. In essence, this would be the 'maximus' policy option, meaning that all imports from EU/EEA would need full batch testing.

22. Medicines imported from all non-MRA countries would need to be imported by a Manufacturing or Importation Authorisation (MIA) holder into a GB importation site. Under this option, the UK QP is responsible for ensuring that the finished medicinal product batch has undergone the required tests in the UK and can then certify/release the batch for sale on the UK market.

23. Importers would require the Manufacturing or Importation Authorisation (MIA) and Good Manufacturing Practice (GMP) licences. There would also be a need for importers to apply for a variation to the respective medicines' Marketing Authorisation.

Option D. Reduced Number of Import Tests and UK QP certification/release for listed countries requiring only a limited number of critical tests.

24. This option would be instituting a reduced number of tests for medicines from a Listed Country relative to the full testing requirements of option C. Countries would undergo a conformity assessment by MHRA to ensure their regulatory standards are sufficient before inclusion on the list. All EU/EEA countries would be on the list to start with (and exempt from initial conformity assessments due to regulatory alignment when the UK was within the EU) and possibly some other countries at a later stage.

25. This is similar to the current COVID-19-related batch testing flexibilities[10] in that medicines from listed countries would need to go through a reduced number of import tests. The current flexibilities were put in place in 2020 to minimise possible supply disruptions during the COVID-19 outbreak. This gave QPs the discretion to only perform identity and assay tests for products if manufactured in a non-Pharmaceutical Inspection Co-operation Scheme (PIC/S) member country[11] in cases where batch testing on import would lead to unacceptable delays in supplying the UK market. The proposals for this option will not give companies or QPs the discretion permitted under the COVID-19 flexibilities and instead, the tests required would depend on the product, such as identity and assay tests for a small molecule or a short shelf-life product requiring an impurity test. This would be set out in the marketing authorisation.

26. This option effectively creates three groups for required levels of testing according to the exporting country's status: For MRA countries, no import testing is required; identity and assay testing will be required for listed countries; and, for all others, full import testing will be required.

27. Table 1 below provides a summary of the requirements for UK-based import batch testing and/or certification/release requirements.

Table 1: Summary of options by key features

[10] Exceptional GMP flexibilities for medicines imported from third countries during the coronavirus (COVID-19) outbreak - GOV.UK (www.gov.uk)

[11] PIC/S countries include EU countries but also a range of developing countries e.g. Ukraine, Turkey, Thailand, Malaysia, Indonesia, South Africa, Mexico, Brazil, Argentina.

Options	Import Testing	UK-based QP certification/ release
A: (Baseline) No Import Testing or UK QP certification/release for listed countries	X	X
B. No Import Testing but UK QP certification/release for listed countries	X	✔
C. Full Quality Control Batch Testing and Implementing UK QP certification/release for listed countries	✔	✔
D. Reduced Number of Import Tests and UK QP certification/release	✔ Limited nr. critical tests	✔

28. An alternative option of “lab audits” has been considered and ruled out due to the lack of operational feasibility. This would be a process whereby MHRA inspectors audit overseas labs, for a fee, enabling the products received from this site to not undertake import testing on arrival to the UK. No non-regulatory alternative has been considered - the legal basis for batch testing in the UK can be found in the Human Medicines Regulations (HMRs). The requirements set out in legislation include manufacturers and importers being licensed to carry out their operations and, that licenced medicines are subject to full testing and certification.

Policy objective

29. In developing the UK’s new batch testing regime, the government’s objectives include:
    - Protecting patient safety and access to medicines for the whole of the UK;
    - Building the right system for the Life Sciences industry;
    - Ensuring the UK remains an attractive place to develop and market medicines while maintaining the necessary standards.

Monetised and non-monetised costs and benefits of each option

30. The consultation is asking for information to assess the likely costs and benefits of the options under consideration. We do not yet have sufficient information on the likely costs and benefits and so the calculations shown are largely illustrative.

31. The options rely on defining a group of listed countries. Although the “list” can include any country that MHRA deems having similarly stringent manufacturing and regulatory standards, as a simplifying assumption for the purposes of this analysis we assume that only EU/EEA countries are listed countries and we expect this to be the case in the initial stages of policy implementation. The impacts of all options will increase as and when more countries are added to the List. The scale of resulting changes in costs and benefits will depend on the scale of imports from each country, the prevailing UK batch testing system and the extent of alignment between the UK and partners’ standards and regulations.

32. This consultation asks stakeholders to provide evidence-based inputs (i.e. in the form of data, case studies, or expert opinion) to replace or update the cost and benefit calculations and underlying assumptions.

33. In line with HM Treasury (HMT) guidance[12] on policy appraisal, the presented calculations provide a simplistic, high-level model of the real-world systems they intend to describe with many important details being omitted. We ask stakeholders to let us know cases where they believe that the omission of details would materially affect the results of these calculations.

[12] https://www.gov.uk/government/publications/the-green-book-appraisal-and-evaluation-in-central-governent

Option A (Baseline / Business As Usual): No Import Testing or UK QP certification/release for listed countries which we are content to have sufficient regulatory oversight (assumed to include all EU/EEA countries)

34. The likely benefits and costs of this option are qualitatively described below. They are not quantified, as Option A is treated as the baseline in this impact assessment and so defined as having zero costs and benefits.

Costs

35. The costs would include:
    - Costs for the necessary licences (a Wholesale Dealer/Distribution Authorisation (for medicines for human use) (WDA(H)) with a Good Distribution Practice (GDP) licence) and personnel (RPis) (costs of £40-60k per year plus on-costs) only for any new companies joining the sector - all UK wholesalers currently importing from the EU/EEA already have the licences and personnel to comply with the requirements under this option.

    - Potential forgone investment and jobs creation in the medium/long term by pharmaceutical companies choosing to test and manufacture medicines in GB: As part of industry engagement exercises, some industry representatives told DHSC that drugs manufacturing ideally requires co-located batch testing facilities and capacity. Under current arrangements, EU testing allows access to both the UK and EU markets but testing in GB only allows access to the UK market. As such, this option is not going to incentivise the build-up of additional batch testing capacity in GB as other options could, and so could lead to lower investment and the associated positive economic spill-overs in the medium/long term. See discussion of the inverse impacts under Option C (benefits).

    - Relocation of testing facilities outside of GB: Since GB testing would only enable products to be sold in UK whereas EU testing would make products saleable in both the EU and UK, this option could lead to firms moving testing facilities to the EU. This could result in slower access to medicines if firms initially prioritise licencing medicines in markets with larger research, manufacture and testing bases.

    - Patient safety and health risks: We acknowledge that it is very unlikely that batches that were already batch tested and QP certified in the EU/EEA would be found faulty or ineffective given the EU's high standards. However, this risk could increase over time as the EU and UK take independent decisions.

    - Reduced incentives for the EU to amend its batch testing policy on the products imported from the UK as a result of the UK's batch testing policy, which adopts a more liberalised approach (recognising the EU as equivalent) than that of the EU.

    - As and when new countries apply to be added to the List, costs incurred by MHRA to conduct conformity assessments of the regulatory standards for compliance with UK requirements. These costs will apply equally to all options.

Benefits

36. The benefits would include:
    - The time and other resources which would have been otherwise spent on duplicating batch testing facilities in the UK can be utilised for other purposes, e.g. developing new and innovative medicines.

    - Minimal disruption to industry when compared to the alternative options and therefore medicine supply to patients is maintained.

    - This option would also have the least potential impact on increasing the overall NHS drugs bill at least in the short/medium term as it does not introduce any new processes into the drugs

supply chain. While we expect firms to seek to increase prices in line with costs under the other options, their ability to do so, and the final impact on the drugs bill is currently unclear.

Option B. No Import Testing but UK QP certification/release for listed countries (assumed to include all EU/EEA countries)

Costs

Licensing costs

37. In contrast to Option A, under this option, all importers would need to hold a Manufacturer or Importation Authorisation (MIA) with a Good Manufacturing Practice (GMP) licence. For the approx. 250 importers who currently instead hold a wholesaler licence (WDA(H) / GDP licence)[13], this would cost £3,143 each, plus inspection fee of £2,655 per day (we assume four days inspection on average)[14]. New companies entering the market would now also face these higher licensing costs.

38. In addition, all importers would need to apply for a variation to the Marketing Authorisation for every product to add the UK batch certification site, as well as a variation to the UK MIA to add each imported product. We assume that this would cost £350 per product on average (including MHRA's £257 notification of changes fee[14] as well as importers' admin costs) for each of the 7,865 EEA-manufactured products that had Marketing Authorisations in 2020.

39. Using these assumptions, we calculate £6.2m one-off licencing costs for current firms and products in the market. The timing for firms to obtain the necessary licences is contingent on both firms and the regulator having the appropriate personnel in place to fulfil their functions; potential challenges for firms are discussed below.

Number of importers without MIA licence		250
Cost of licence		3,143
inspection fee per day		2,655
Assumed average inspection time (in days) per importer		4
Assumed cost to change MA to add the UK batch certification site, and MIA to add each imported product (per product)	£	350
Number of Marketing Authoritsations where the product is manufactured in the EEA		7,865
Licensing costs	£	6,200,000

Personnel costs

40. Aligned with the more stringent licensing requirements under this option, importers would require a head of Quality Control (QC) and a Qualified Person (QP) to certify the EU/EEA batch testing and EU/EEA QP certification before the batch can be released for marketing in GB.

41. A head of QC usually earns £60-70k (the mid-point of £65k is used in the calculation) whereas a QP usually earns around £100-120k (the mid-point of £110k is used in the calculation), not including on-costs (e.g. employer taxes, assumed to be 25%).

42. We assume that this option would require an additional 150 full-time equivalent (FTE) QPs and an additional 250 heads of QC to be employed:

> We assume that the approx. 250 UK businesses who import medicines from the EU/EEA under WDA(H) / GDP licences will upgrade to MIA licences and to comply, would need to employ a full-time head of QC. We assume that none of these firms currently employ a QC as it is not a requirement of their existing licences.

[13] Internal correspondence between DHSC and MHRA

[14] Current MHRA fees - GOV.UK (www.gov.uk); indicative estimate from MHRA that inspections typically take 3 – 5 days, 4 days used as mid-point

At the same time, we assume that many of these companies would be able to group together to share QPs' services, so we assume, based on expert opinion, that each of these companies would only require a 0.4 FTE QP on average – resulting in 100 extra QPs needed by these importers. In addition, we assume that companies with a MIA licence would require an extra 50 QPs in total to be able to continue importing from the EU/EEA under this option.

43. Using these assumptions, we calculate that the personnel cost of QP certification/release would be around £40.9m per year.

Head of Quality Control (QC) salary	£	65,000
Assumed number of head of QC needed (1 per importer who would need to upgrade their licence to MIA)		250
Total QC cost per year	£	16,250,000
Qualified Person (QP) salary	£	110,000
Assumed number of QP needed		150
Total QP cost per year	£	16,500,000
Assumed employer on-costs (e.g. employer's national insurance, levies...)		25%
QP + QC cerficiation/release costs per year	£	40,900,000

Administration and overhead costs

44. As MHRA operates on a cost recovery basis, the administration costs for activities such as issuing new licences and updating records and registers are captured in the licensing fees to be paid by firms identified above. There are no cost differences compared to the baseline for MHRA to conduct conformity assessments to add countries to the List as these will be incurred under all options.

45. As this proposal makes the same batch testing requirement for listed countries as for countries with which the UK holds an MRA, we assume that familiarisation costs will be minimal for QPs and firms already handling MRA country imports as they review the countries that the requirements are extended to. Firms without prior experience of QP certification and batch release will incur higher familiarisation costs to understand the relevant processes and requirements as well as costs to prepare for necessary inspections and to complete relevant certification courses. While we have information that full QP certification courses can cost around £20,000, we do not know enough about the specific requirements of different firms to estimate these initial costs at this stage.

46. We expect all firms to incur additional administration costs to recruit (and register as needed) the extra staff required as well as overhead costs to operationalise this process for listed countries and to support the extra QPs and QCs identified above. These would include resourcing costs to gather, review and store product-specific information from the manufacturing sites for each imported batch. We do not have information to quantify these costs.

Increased costs to consumers

47. We expect suppliers to seek to pass on the limited extra costs of QP certification and release to consumers (ie, patients and the NHS). However, the markets for medicines typically operate effectively to limit cost increases to the NHS budget:

    - In the case of generic medicines, the market is typically highly competitive, with low profit margins, so consumers would be likely to seek alternatives from other import markets.

    - In the case of branded medicines, higher profit margins and limited competition may create more room for costs to be passed on, subject to the controls created by the pricing and access schemes.

48. The quantified annual costs of this option are relatively low, representing less than 0.3% of the total value of EU/EEA imports[15]. For branded medicines, while we expect firms to increase prices to reflect the extra costs, the voluntary and statutory pricing and access schemes are expected to limit the impact on the overall medicines bill to the NHS in the short-term. The voluntary scheme establishes a limit on allowed annual growth on sales of branded medicines to the NHS, achieved by companies making payments to DHSC to bring expected branded sales in line with allowed branded sales limit. The statutory scheme ensures similar limits for firms choosing not to join the voluntary scheme. Higher cost increases may however be seen over the longer term as the current voluntary scheme expires at the end of 2023, with no certainties over the scope or ambitions of any potential successor scheme.

49. Similarly for generic medicines, due to the typically highly competitive market it is difficult for suppliers to increase prices as consumers would be likely to seek alternatives from other import markets. However, we recognise that the additional costs will represent a disproportionate share of costs for some products and there may be some risks of price increases if supply of particular products cannot be substituted from elsewhere. As part of the consultation, we are asking for information about any products or product types that may be at increased risk.

50. If a part of these extra costs were to be absorbed by importers (e.g. in order to maintain competitiveness of their products), in line with HMT policy appraisal guidelines[16], the part that falls to overseas shareholders would not be in scope for this impact assessment. The Department for Business Energy and Industrial Strategy (BEIS) has previously provided an estimate to DHSC that around 10% of drug spend is on domestic production[17]. Assuming that returns to capital are shared between the UK and overseas shareholders in this same proportion, only a small share of any cost absorption would fall to UK shareholders.

Costs if issues are identified with some batches, and increased time to bring products to market

51. Evidence suggests that it is very unlikely issues would be identified with EU/EEA imports. A study on batches imported for re-testing found a batch rejection rate of 0.005%[18] and we assume that the rejection rate under this option would be lower than that because batches are not re-tested, though the QP certification and release requirement is intended to provide assurance that testing has been carried out to an acceptable level. We cannot estimate how much lower the rejection rate would be under this option.

52. A rejection rate of 0.005% on the assumed 47,500 batches imported from EU/EEA annually[19] would result in 3 rejected batches. Therefore, it is likely that only a couple of batches would have issues identified under this option.

Business impacts:

53. If a problem is noted on import, the identified issue(s) with the batch(es) need to be investigated. This could result in the batch(es) being rejected and destroyed or retested in the EU/EEA and subsequently reimported or rejected. Re-testing in the UK is not feasible as the batch testing site needs to be recorded in the medicine's marketing authorisation and it is unlikely that importers would apply for a 'regulatory variation' to facilitate UK testing. While these testing facilities are based overseas, the global ownership of these firms will mean that a proportion of these costs are likely to be borne by UK shareholders. There may also be some storage costs borne by UK importers while the batches are investigated, which we cannot quantify.

Health-related impacts:

54. Where issues are identified, the impact will be disruption to the supply of medicines batches reaching patients. Under the baseline option, we also consider slower access to medicines as a

[15] In 2020, the UK imported drugs from the EU worth £15.9bn. Source: International Trade by Commodity Statistics, Volume 2021, Issue 2, P525 International Trade by Commodity Statistics Volume 2021 Issue 2: Finland, Greece, Iceland, Portugal, Sweden, United Kingdom | READ online (oecd-ilibrary.org)

[16] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/938046/The_Green_Book_2020.pdf

[17] As used in the Impact Assessment "Statutory scheme to control costs of branded health service medicines"

[18] Import Testing of Pharmaceutical Products Has Limited Safety Benefits and Can Add Risk to Patients (pharmtech.com)

[19] See Annex A for calculation

potential, in that case driven by firms choosing to prioritise EU/EEA markets. Further evidence is needed to understand how the scale of this risk compares under each option. The extent that this will have adverse impacts on population health is highly sensitive to the availability of alternative batches or products and the level of health gain the product is expected to deliver. We do not have enough information to understand the contents of the batches facing rejection to estimate any potential health loss.

Impacts of shortages of required professionals

55. Information provided by MHRA suggests that there is a QP shortage in the UK, which could make this option infeasible to implement within the planned 2-year notice period. The total number of QPs currently named on UK licences is approximately 770. Only around 25-30 new QPs qualify each year while some leave the profession (e.g. retire, move into consultancy). This means that it could take several years to fill the potential gap caused by the up to 250 UK wholesalers requiring QPs' services at least on a part-time basis. We are unable to fully quantify these impacts at this stage, including how these shortages might affect the feasibility of this option or its associated costs.

56. The challenges of rapidly expanding QP capacity relate to training and residency requirements:

    The requirements to qualify as a QP are established in the Human Medicines Regulations (and they mirror the equivalent EU laws). A degree in a related science such as pharmacy, chemistry or biology is a starting point, but, to qualify, QPs also need several years' industrial experience in the manufacture and testing of licensed medicines, plus a further course of academic study to cover the particular aspects of pharmaceutical development/manufacture/testing/legislation etc that are not part of a standard science degree. There is then a detailed application process (supported by an existing QP as an industry sponsor) followed by a formal assessment by the UK professional bodies to accept a candidate onto the QP register.

    Although the required degrees (pharmacist, biologist, chemist) are all on the shortage occupation list, making it comparatively easier to obtain visas in theory, all QPs named on UK licences must be resident in the UK, so shortages cannot be filled with temporary staff from other countries.

57. We do not have a formal register of 'Heads of QC' to assess any potential shortages amongst this group against the expected requirement for an additional 250 positions. However, we understand from stakeholders that these individuals often move between QC and other senior roles in the pharmaceutical sector which does create a risk of shortages for Heads of QC too.

Benefits

Identifying potentially ineffective or faulty batches (Health-related impacts)

58. Due to both the UK's historic alignment with EU batch testing regulations and research about the effectiveness of repeat import testing, it is very unlikely issues would be identified with EU/EEA imports. That said, where issues are identified, this represents a benefit to patients in terms of avoided adverse health impacts.

59. Using the same research and assumptions as above (paras 51 - 52), we anticipate that issues are likely to be identified in less than 3 batches per year. A *faulty* batch could provide a small level of harm (HQRL loss) to the patient and therefore identifying this would provide more benefit over identifying an *ineffective* batch. The health benefit generated under this option would be dependent on whether the issue identified is with an ineffective or a faulty batch and the type of medicine, quantity affected and indication that it is used for. We do not have enough information to understand the contents of the batches facing rejection and the potential harm they would generate to the patient though we anticipate the volume of affected products to be very small.

Workforce skills and capability

60. Notwithstanding the challenges created by the current shortage of QPs to meet future increases in demand, any potential boost to the number of UK-based QPs will benefit the wider life sciences sector in future. QPs are highly skilled roles and people holding QP accreditation often move to work in senior positions (e.g. a Managing Director or Global Head of Quality), as industry consultants, or as regulatory inspectors and so could be deployed to support other areas of industry in the future. Maintaining this skill base could make the UK a more favourable place in the future to manufacture and test medicines.

Option C: Full Quality Control Batch Testing and Implementing UK QP certification/release for listed countries.

Costs

Set-up costs

61. To deliver the level of batch testing in GB to test all batches imported from the EU/EEA will require substantial investment in new facilities and specialist machinery and equipment. Based on the evidence below, we assume that there is limited spare capacity in the existing system to absorb the additional testing requirements. As such, even where manufacturers/importers choose to rely on Analytical Method Transfer (AMT) to another facility, that capacity will need to be created. Based on two different sources, we estimate these setup costs to be between £330m and £615m:

    - Responses to the industry engagement exercise suggested total projected set-up costs of £219m. Using our estimate that these responses capture two-thirds of the relevant market, £219m/66% ≈ £330m. This may be an underestimate as some estimates related just to AMT of a product (e.g. £65,000 per product), whereas other estimates were in relation to full infrastructure creation (e.g. £10m to double previous batch testing capacity). The largest estimate provided in relation to estimate one-off set up costs was over £30m.

    - Alternatively, the Office for Health Economics (OHE) estimated that it would cost a “large manufacturer” £40m[20] to transfer all their batch testing and release facilities to the EU/EEA. We assume that: (i) the costs would be similar in the EU-to-UK direction, and (ii) that the category “large manufacturer” would cover the top three pharmaceutical companies in the UK. In 2018, their turnover accounted for 19.5%[21] of the UK market share. Assuming set-up costs to be proportional to market size, this would suggest total set-up costs to be (3x40m)/19.5% ≈ £615m.

Licensing costs

62. As with option B, under this option all importers of medicines from the EU/EEA will need to upgrade their licences to hold a Manufacturers / Importers Authorisation (MIA) with a Good Manufacturing Practice (GMP) licence and apply for a variation of marketing authorisation for each product. So, the one-off licensing costs under this option would be the same as under option B, totalling £6.2m, see paras 37 - 39.

Annual running costs of facilities (overheads only)

63. We assume that the annual running costs of the required testing facilities under this option (including overheads only and not including the variable costs of batch testing) would be £127m. This estimate is based on responses to our pre-consultation industry engagement exercise. The sum of projected annual running costs reported was £84m and we have scaled this up using our estimate that this figure accounts for two-thirds of the sector.

[20] Advice received from the Office for Life Sciences (OLS).

[21] https://pharmaboardroom.com/facts/top-15-pharma-companies-in-the-uk-ranking-2018/

64. As with estimates of set-up costs, there was significant variation in respondents estimates for annual running costs of a testing facility: from £150,000 (likely to reflect overheads associated with AMT to an existing facility) to £20m, (expected to reflect overheads for a large testing facility).

Increased cost to bring products to market

65. Import batch testing increases the cost of bringing products to market, and we estimate that these costs are c.£171m per year based on the following assumptions:
    - As previously, we assume that approximately 47,500 batches are imported from the EU/EEA per year.
    - Responses from industry suggest that on average, the cost of batch testing is around £3,600 per batch (see Annex A).

Number of batches imported from EU/EEA		47,461
'Average' cost of batch testing per batch	£	3,596
Total batch testing costs	£	171,000,000

66. As with option B, we expect importers to seek to pass these extra costs on to consumers (e.g. patients and the NHS) but recognise that their ability to do so may be limited, and more so under this option due to the higher annual costs.

67. For branded products, if the price increase sought by suppliers exceeds their agreed list price, suppliers would need to apply to DHSC for a further price increase. At this stage, we cannot estimate the likelihood of the need for applications to be made, or subsequently being granted.

68. Where costs cannot be passed on, either for branded or generic products, suppliers may seek to discontinue the supply of products to the UK market – see costs of discontinuations below. For generic medicines, this could have subsequent knock-on impacts on prices over the longer-term if discontinuations reduce choice and competition for equivalent products and so increase prices.

69. If a part of these extra costs were to be absorbed by importers (e.g. in order to maintain competitiveness of their products), the part that is absorbed by overseas firm-owners would not be in scope for this impact assessment. As above (para 50), based on estimates provided by BEIS, we assume that overseas shareholders own the majority of UK drugs production and so only a small share of any cost absorption would fall to UK shareholders.

70. Industry representatives told us that the requirement to duplicate batch testing would have other costs that we are unable to quantify in the form of:

    - considerable environmental impacts - caused by, among other factors, increased transport and storage requirements and the need to use single-use consumables in testing (see Wider Impacts); and,

    - requiring resources to be diverted from other high-priority activities in the short term, with opportunity costs that may also impact the UK's ability to innovate and remain a 'first to market' country for medicines. Under the baseline option, we also consider a potential cost of the UK not being firms' highest priority market, in that case due to the decision to locate manufacturing and testing activities in the EU/EEA. Further evidence is needed to understand how the scale of this risk compares under each option.

Personnel costs

71. The additional personnel costs required under this option are captured within the estimates above for the annual running costs (£127m) and batch testing costs (£171m) of implementing import testing. We know that the number of batches requiring UK QPs will significantly increase but we don't yet have a robust estimate of the number of additional QPs needed. We expect that all additional QPs will need to be supported by two lab analysts. As with option B, additional Heads of QC will also need to be recruited by the approx. 250 UK businesses who import

medicines from the EU/EEA under WDA(H) / GDP licences and would now need to obtain MIA / GMP licences (with the requirement for a full-time head of QC).

Increased time to bring products to market

72. Industry stakeholders have suggested that batch testing would add 36 days on average to the time to bring products to market. This will have both stock and flow impacts depending on the shelf-life of medicines and the capacity to hold stocks.

73. The planned two-year policy implementation period is intended to allow sufficient time for importers to adjust supply chains and stock up in the UK before the new batch testing requirement is introduced. Sufficient levels of future supply should then be able to be maintained with the extra time built into the supply chain. As most medicines have shelf lives between 1 and 5 years, we expect this to be the case for the vast majority of medicines imported from the EU/EEA. However, shortening the shelf life of medicines could in some cases result in higher product wastage, at least in the short-term until systems adapt to the changes. We do not have information to quantify the cost of extra facilities and transitioning to increasing stock holdings.

74. Manufacturers and importers are expected to manage their supply chains to take account of the shelf life of the medicine and the time to market and there are processes in place to ensure the supply of medicines with short shelf lives, including:
    - Not manufacturing stocks in advance (as they will sit on the shelf waiting for orders);
    - Co-ordinating manufacturing, packaging, testing and release processes so that the product is not held unnecessarily between steps;
    - Prioritising testing ahead of other products, so that the batch is not held up by the testing lab;
    - Transport by air rather than sea or road; and,
    - Sending samples for import QC testing ahead of the main batch, so that testing can take place whilst the main batch is in transit.

75. However, stocking up will not always be feasible, for example in the case of expensive, low volume, personalised, and/or limited shelf-life medicines. The additional time needed to get products to market could lead to either products: i) being rejected by the purchaser due to having insufficient remaining shelf life or ii) being at risk of discontinuation if short shelf lives mean that imports are no longer feasible.

76. The types of products likely to be affected are those with shelf lives of less than 5 weeks which includes: new products that often have a reduced shelf-life whilst stability testing data is accumulated to support a longer shelf-life; products where urgent release is necessary; and, at the extreme end of the spectrum, Advanced Therapy Medicinal Products (ATMPs) which can have shelf lives of hours as well as Radiopharmaceuticals which can be a matter of days. We do not have data to estimate the number of products potentially at risk due to the extra time needed for import testing.

77. Where the extra time required for testing cannot be managed within the supply chain, products will be at risk of discontinuation. In these cases, suppliers have a responsibility to notify DHSC of the discontinuation risk. These products are then subject to a risk assessment with mitigating actions agreed and taken as necessary. This can include working with MHRA to expediate the pathway for certain products. In the most extreme situation, medicines may need to be exempted from UK batch testing requirements. Some products may be discontinued, for example where alternatives are available and there is minimal risk to patients. This could reduce choice of medicines and over the longer-term, increase costs due to reduced competition for particular products.

Discontinuation of the supply of certain medicines due to reduced profitability and/or the impact of increased price or substitution with more expensive alternatives

78. As above, we consider that importers will seek to pass on the increased costs of the extra batch testing requirement to consumers (i.e. patients and the NHS). Where this cost pass-through is possible, the extra testing requirement would not have a material impact on profitability of imported medicines. However, the risk of negative impacts on profitability is higher for generic medicines due to low profit margins and high competitiveness.

79. There is a risk that some products will be discontinued as a result of increased costs. Given 40% of generics used by the NHS are manufactured in the EU[22], temporary disruptions could have an adverse impact on patients and the NHS but beyond temporary adjustments, we do not expect adverse impacts on the NHS' ability to treat certain medical conditions. This is because (i) there are safeguards to protect the supply of medicines where there are no substitutes or where switching creates a risk for patients; and (ii) we expect that the pledged 2-year notice period before any retesting requirement for EU/EEA imports come into effect, will allow sufficient time for affected businesses to optimise their product mix.

80. These changes may result in a shift to a greater reliance on medicines and supply chains outside of the EU/EEA where medicines with the same molecules are also already likely to be manufactured (e.g. India or China). The switch could have considerable transaction costs if these products are not already licenced in the UK and need to go through the licencing process. There may be other additional cost drivers that we cannot quantify, such as:

    - Fixed costs to set up new supply routes from third countries; and,

    - it is possible that the increased demand on third country manufactured generics would lead to price increases by a few percentage points.

81. On the whole, we do not expect that the two latter drivers would result in price increases above the cost of the extra testing requirement, since in that case importers would not find it viable to switch to third country imports. On balance, we believe that the most likely scenario is for prices to increase by the extra testing costs across the board.

82. Another sector that could be disproportionately impacted by the import testing requirement under this option is the parallel import sector that operates with very tight margins. A decrease in parallel imports is not likely to lead to medicine shortages, since, by definition, it is a process by which medicines that are already sold by the manufacturer or its local licensee in the UK are imported from abroad to take advantage of international price differences or currency fluctuations. However, a decrease in parallel imports would negatively impact the businesses in scope, and could lead to the NHS paying more for some medicines. We do not have enough data to be able to calculate these impacts.

Implementation challenges

83. While the planned two-year notice period is intended to allow sufficient implementation time for any policy change, industry representatives have indicated through prior engagement that, on average, it would take them 51 months to set up the required batch testing facilities for full import testing from the EU/EEA. Assuming linearity, this would suggest that in the first year of implementation (i.e. in the year after the end of the 2-year notice period) only 59% of the current volume of EU/EEA imports could be batch tested, rising to 82% in the second year.

84. Delays in establishing sufficient batch testing capacity creates risks for getting products onto the market and as a consequence, creates risks for patients accessing medicines.

85. As with option B, a shortage of QPs in the UK could also be challenging to address in the two-year notice period. Due to current uncertainty about the number of QPs required under this option, we are unable to estimate the scale of this risk at this stage.

[22] https://www.britishgenerics.co.uk/uploads/BGMA_Resilience_Report.pdf (page 3)

86. Under full quality control batch testing, a considerable expansion of UK based testing capacity would be required. As detailed in annex A, this could amount to over a doubling of the current capacity. To expand capacity, industry is faced with either using in-house facilities (current or new expanded capacity) or relying on contract testing with a UK based Contract Lab Organisation / Contract Research Organisation (CRO).

87. Twenty-four out of the 36 respondents to the industry engagement exercise stated they would use contracting. This suggests a significant increased reliance on the use of Contract Labs to absorb the additional testing requirements under full quality control batch testing. We do not have enough information to quantify current UK based Contract Lab testing capacity and therefore their ability to perform this role if required.

Benefits

Improved patient safety and health benefits via increased likelihood of identifying faulty or ineffective medicine batches (health-related impacts)

88. We acknowledge that it is very unlikely that batches that were already tested and QP certified in the EU/EEA would be found faulty or ineffective[23]. Evidence suggests the batch rejection rate on batches imported for re-testing is 0.005%[24]. On the 47,500 batches assumed to be imported from the EU/EEA annually, this would suggest 3 batches would be identified as faulty or ineffective.

89. As with option B, the scale of benefit from identifying issues is dependent on whether a batch is ineffective or faulty, the size of the batch and the type of condition that it is used to treat (ie. an issue with a batch of drugs used to ease symptoms can be expected to cause less harm than a faulty batch of drugs used to prevent disease progression). We do not have enough information to understand the contents of the batches facing rejection and the potential harm they would generate to the patient though we anticipate the volume of affected products to be very small. The additional layer of assurance for the safety and efficacy of medicines under this option is expected to increase the likelihood of detecting issues with batches compared to other options.

Development of related UK-based services and manufacturing

90. Some stakeholders have suggested that increasing batch testing capacity in the UK could incentivise more investment in related activities in the UK in the medium/long term. This is in comparison to the baseline option where there is no incentive for firms to base manufacturing or testing facilities in GB - placing these functions in a listed country provides access to both that market and GB whereas testing in GB would only allow access to the UK market. Extra capacity may: drive greater innovation in testing techniques, promote the UK as a place to train and practise and/or increase investment in UK-based manufacturing.

91. Increased batch testing will increase laboratory and warehousing capacity requirements and so have knock on impacts for the scale of the medicines supply chain in the UK and potentially create opportunities for innovation as organisations involved in testing respond to the extra capacity demands by identifying ways to improve efficiency.

92. The argument for increased investment in UK-based manufacturing is supported by the idea that some pharmaceutical firms co-locate their manufacturing and batch testing facilities. In the industry engagement exercise, one-third of respondents stated that at least some of their manufacturing and batch testing facilities are co-located. Any increased manufacturing investment is most likely for products that have a short shelf-life and so where the extra time required for repeat testing risks products being discontinued or rejected if they do not rapidly progress through the supply chain. It is hard to quantify how significant a factor this is and not all stakeholders agree that such a mechanism exists.

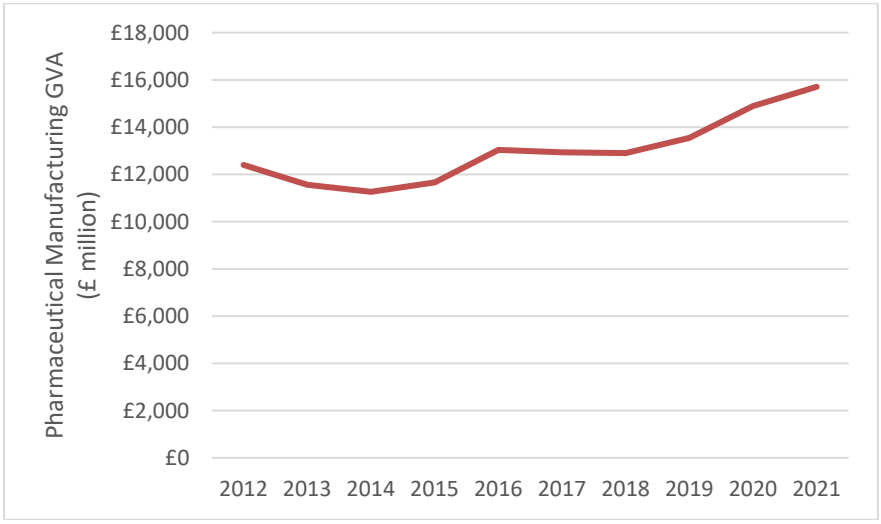
[23] Due to similarly stringent regulations and standards, and FMD, GDP and RP(i) practices, being in place.

[24] Import Testing of Pharmaceutical Products Has Limited Safety Benefits and Can Add Risk to Patients (pharmtech.com)

93. The argument against increased investment is that, for products where time constraints are less of a priority, there are factors more important than testing location that impact pharmaceutical firms' investment decisions for the locations of both manufacturing and Research & Development (R&D). For example, research by The Congressional Budget Office into factors that influence R&D[25] (rather than manufacturing) investment, identified the relative development costs of a new drug and its expected revenue as the main influences on spending[26]. Government policies that affect the supply of medicines (eg. batch testing policy) is a less influential category.

94. To illustrate the potential scale of any impact on investment in *manufacturing*, the Gross Value Added (GVA) of pharmaceutical manufacturing[27] was £15.7bn in 2021 and has been rising in recent years as shown in figure 1 below.

Figure 1: Pharmaceutical Manufacturing GVA, UK, 2012 - 2021



95. Any potential benefit for investment from GB-based batch testing, whether for improving the efficiency of testing processes themselves or relating up-stream manufacturing would likely to be experienced several years after policy implementation. Any potential positive impact may be partially offset if extra funding needed for repeat testing for those products where manufacturing remains overseas, is met by diverting funds away from more value add activities or reduces profitability.

Option D. Reduced Number of Import Tests and UK QP certification/release for listed countries requiring only a limited number of critical tests

96. This option would be instituting a reduced number of tests for medicines from a listed country - following the same approach as option C but with a more limited set of import testing requirements. There are some similarities with the current COVID-19-related batch testing flexibilities[28] in that medicines from listed countries would need to go through a reduced number of import tests.

97. No comprehensive data are yet available on the extent to which these COVID-19 related flexibilities have been used and their impacts. Anecdotal evidence suggests that the policy did not adversely impact the safety of medicines marketed in the UK and we expect the risks of

[25] R&D spending in the pharmaceutical covers a variety of activities, including invention, development, incremental innovation, product differentiation and safety monitoring. (Research and Development in the Pharmaceutical Industry (cbo.gov))

[26] Research and Development in the Pharmaceutical Industry (cbo.gov)

[27] GDP output approach, low level aggregates, UK, Quarter 4 (Oct to Dec) 2021. SIC 21: Manufacture of basic pharmaceutical products and pharmaceutical preparations

[28] Exceptional GMP flexibilities for medicines imported from third countries during the coronavirus (COVID-19) outbreak - GOV.UK (www.gov.uk)

adopting flexibilities for medicines imported from the EU/EEA to be lower than from the third countries that the COVID-19 flexibilities were applied to. This is due to the deep level of cooperation between the UK and EU/EEA countries. The UK is currently fully harmonised with EU/EEA medicines regulations with regulatory authorities, manufacturers and importers working to the same standards as well as programmes for benchmarking and information sharing.

98. We expect this option to incur the same types of costs and benefits as option C but further detailed information about how this option would operate (such as which tests would be applied to which products) is needed to provide a full comparison and assessment against the baseline. The tests required under this option would depend on the product, such as identity and assay tests for a small molecule or a short shelf-life product requiring an impurity test. This would be set out in the marketing authorisation.

Costs

99. The types of costs we expect to be incurred under this option are broadly the same as outlined in the discussion of option C above. As this option is expected to require fewer tests overall compared to option C, the costs per batch tested under this option are expected to be lower but familiarisation costs may be higher due to the novelty of the approach, at this stage, we cannot quantify to what extent.

100. In general, we assume that the fixed costs and overheads required under option C would be less scalable than variable costs, for example a greater proportion of fixed costs from option C would be borne under this option than the proportion of variable costs. In particular, this includes licensing costs that we expect to be the same as options B and C, as well as the majority of setup costs – the same equipment and facilities are likely to be required but they may be used less intensively under this option. In contrast to option C, we assume that this option would not lead to the discontinuation of medicines due to insufficient batch testing capacity as less capacity is needed under this option.

101. It's worth noting that, consistent with the COVID-19 flexibilities, this option is expected to require full re-testing of certain types of products if any issues are identified as part of the surveillance tests, so the capacity would have to be greater than the average amount of testing taking place.

Other considerations

102. We expect this option to require broadly the same number of QPs as option C. This is because the certifying process requires the QP to review information about both the product in general (eg. the licence details, the supply chain, the supporting stability data, trend reports) and the batch-specific details (eg. the manufacturing and packaging records, the QC testing, the shipping data, the inspection of packs). So, the actual time spent on the QC testing is only a small part of the bigger picture. As such, we expect the current QP shortage in the UK to make this option equally as challenging as option C to implement with the planned 2-year notice period, as it could take several years to fill the potential gap caused by the extra QP requirements of this option. We are unable to fully quantify these impacts at this stage, including how these shortages might affect the feasibility of this option or its associated costs.

Benefits

103. As with costs, we expect this option to generate the same types of benefits as described for option C (see the discussion under Option C for the different benefit components). More information is needed to understand the likely effectiveness of this option in terms of identifying faulty batches: while conducting fewer tests reflects a higher risk appetite than option C, by identifying the most critical tests required for each product/product type, we might expect similar levels of effectiveness to option C. Increased testing in GB is also likely to generate some benefits identified under option C relating to development of the sector and associated activities, though likely to a lesser extent as this option will still mean that there are relative advantages for firms to base the majority of their functions in the EU/EEA so that they can meet all the EU/EEA

market's requirements as well as some of GB's. Without knowledge of the types of tests used for various products we cannot estimate the scale of benefits under this option.

Direct costs and benefits to business calculations

104. The options outlined in this Impact Assessment impose costs on businesses to varying degrees; there is no preferred option at this stage.

105. All of the alternative options impose one-off costs on firms intending to import products from listed countries. For businesses that already hold licences to import, they will incur costs to amend the marketing authorisations for all affected products. Others that currently hold wholesaler licences will incur costs to meet the criteria for, be assessed against, and purchase new importer licences new import licences as well as changing all product MAs.

106. Ongoing costs to complete the required testing and/or batch release processes will be borne by businesses. As outlined, we expect firms to seek to pass on cost increases to consumers. For generic medicines and where substitution is possible, firms may seek to discontinue products if the changes adversely impact profitability. For branded medicines, we expect firms to revise their prices to maintain profit margins. The subsequent interaction with the voluntary and statutory pricing schemes to limit branded medicines sales growth may reduce profitability in the short-term, until they are reviewed. The schemes operate at an industry wide level so price increases by some firms that increase overall industry branded sales would affect payments due from all scheme members. We cannot model these impacts at this stage.

107. The benefits of the options predominantly accrue to patients (through reduced health-related risks) and the wider economy (through opportunities for workforce capability and skills development and testing innovations) rather than to the businesses directly impacted by the policy options.

Risks and assumptions

108. The assumptions used in this IA are largely illustrative, reflecting the level of evidence available to us ahead of this public consultation. We intend to use the consultation to gather more information and evidence from key stakeholders to refine the estimates used in this analysis and improve our assessment of the relative costs and benefits of the available policy options.

109. The analysis relies heavily on information provided through an industry engagement exercise in autumn 2021. We have assumed, but have been unable to verify that the information provided at that stage is representative of the sector as a whole.

110. We have assumed that for the most part, firms will be able to pass on to consumers the costs of any new requirements for GB-based testing and/or QP release though we acknowledge that there may be circumstances that limit the ability to pass on costs.

111. There are particular gaps in our understanding of the effectiveness of batch testing in terms of:
- The number of batches that are identified as faulty or ineffective as a result of batch testing;
- the likely impact on patient health of introducing batch testing on import for products that have already been subject to batch testing consistent with EU regulations.

Impact on small and micro businesses

112. Many UK importers of medicines are small operations with less than 10 employees. These businesses will be impacted by changes to the UK's batch testing policy. In our previous industry engagement, eight of 34 respondents identified as small and medium enterprises (SMEs). Information held be the regulator does not enable us to calculate the number of small and micro businesses in the sector and the scale of businesses can change between inspections. We are seeking more information about the size of affected businesses through the consultation.

113. Businesses of all sizes are required to meet the same stringent requirements for batch testing. While some roles and responsibilities can be shared between firms (thereby spreading costs), to ensure appropriate accountability, there are some requirements that each business must meet independently, such as holding an appropriate licence for their activities. All businesses will be subject to the same costs charged by MHRA to amend product marketing authorisations if the preferred outcome is one of options B – D.

114. Options C and D require import testing of drugs batches in GB. These tests can be carried out using either in-house testing facilities operated by the drugs manufacturers or by contracted organisations. Due to their size, we assume that small and micro importing businesses would be more likely to use contract services for testing. As part of the consultation, we are seeking more information about the relationships between importers and contract lab organisations and any potential challenges in securing testing capacity. For example, contract organisations may prioritise serving larger organisations that provide bigger revenue streams.

Wider impacts (consider the impacts of your proposals)

Environmental impacts

115. Options C and D both require some duplication of testing for products imported from listed countries, with batches tested at the end of the manufacturing process and again on import to GB. This repetition could have negative impacts on the environment due to:

- extra energy and consumables used up in re-testing
- extra transport and storage requirements for products to be tested

116. For context, life sciences laboratories use up to 10 times the energy and 4 times the water of a traditional office[29], often needing to be in operation 24/7. For example, cold storage units and cleanrooms, which require carefully monitored Heating, Ventilation and Air Conditioning (HVAC) systems can use between 2 and 50 times more energy than non-validated areas[30].

117. Cold transport also uses 20% more fuel than other heavy vehicle types due to refrigeration equipment[31]. Auxiliary diesel engines used to power the refrigeration systems also emit nitrous oxides and particulate matter.

Investment impacts

118. Options that develop the capacity for batch testing in GB have the potential to increase innovation and investment *in testing* as discussed under the benefits of option C (and D). Initial engagement from industry does not give a clear steer about whether increased testing capacity will create greater incentives for *broader investment* in the life sciences industry GB:

- For products with short shelf lives, GB-based manufacturing will reduce the timescales for products moving through supply chains which could be a driver for investment in GB-based manufacturing for these products.

- Some industry representatives have also indicated a preference for co-locating manufacturing and testing which could suggest an increase in manufacturing.

- However, we recognise that investment decisions are based on a range of factors and batch testing requirements may be one small part of these decisions; and,

[29] Embracing sustainability in Life Sciences | 2021 | JLL Research

[30] Taking on life sciences' big energy costs - European Pharmaceutical Manufacturer

[31] Guide to a greener pharmaceutical supply chain | Pharma Logistics (pharmalogisticsiq.com)

- in cases where firms do not choose to relocate their manufacturing and testing infrastructure to GB, the extra funding needed for repeat testing may divert funds away from more value add activities in the drugs development process.

Equity impacts

119. Options B to D are all expected to add time to getting products to market. For the vast majority of products, we do not expect this to materially impact patients' access to medicines. However, for products that have short shelf lives, the extra time required for import testing may disproportionately impact people reliant on these products. There are process in place to assess and mitigate any risks to patient access to medicines and these will be required to minimise any risks arising as a result of changes to batch testing policy.

A summary of the potential trade implications of measure

120. All medicines, whether produced domestically or imported, must undergo a form of batch testing before they can be released onto the UK market. The consultation specifically concerns the testing requirements for medicines imported into GB.

121. The current GB batch testing requirements for trade in medicines divide countries into two groups: those with which the UK has an MRA and those without. The consultation options create a third group, of "listed countries". Option B would align the batch testing requirements for listed countries to those with an MRA while option C has the same requirements as for non-MRA countries.

122. Under current arrangements, listed countries are those the MHRA has determined to have sufficiently high regulatory standards to be equivalent to the UK. To determine whether a country should be included in the list, the MHRA makes an assessment using objective criteria, which is set out in the Human Medicines Regulations and based on protecting public health and ensuring the safety of medicines. The list will be reviewed every three years to ensure it only includes countries that continue to meet equivalent high standards. All countries can apply to be added to the List, provided the MHRA are satisfied they meet the criteria set out in the Human Medicine Regulations.

123. Future batch testing policy needs to remain compliant with World Trade Organisation (WTO) and Trade and Co-operation Agreement (TCA) requirements and these considerations will be accounted for in developing the policy to minimise risks of any potential challenge.

124. At present, the MHRA have listed as countries which have sufficiently high regulatory standards and therefore batch testing in these countries is currently recognised and accepted in GB without the need for further testing or certification. The alternative options under consideration will add extra testing and/or certification/release requirements for imports from the EU/EEA compared to the current arrangements. Option C, full import testing would mirror the requirements that the EU/EEA has placed on UK imports since the UK-EU Trade and Cooperation Agreement came into force, while the other options institute relatively less stringent requirements than the EU/EEA has for the UK.

125. As outlined under option C (see para 80), we consider whether the extra costs for import testing from listed countries could encourage switching to alternative suppliers in countries with lower manufacturing costs such as India and China - increasing their share of the GB market. The extent to which this could occur depends on the substitutability of products from these markets with those from listed countries and whether these alternative suppliers are already licenced to supply GB.

126. Over time, we expect other countries to apply to be added to the List. Since an MRA is a more comprehensive agreement for bilateral medicines trade overall we only expect non-MRA countries to be added to the list. Options A, B and D are less intensive testing/certification processes than the current batch testing requirements for non-MRA partners and so these

options could be expected to have favourable impacts on trade flows with these countries once listed.

Monitoring and evaluation

127. The approach to monitoring and evaluating the UK's future batch testing policy will be designed as part of the policy development process once the preferred option has been selected. The metrics used to assess the policy will be designed to measure performance against the objectives identified in para 29.

Annex A: Assumptions based on survey returns by industry

In autumn 2021, we invited industry stakeholders to provide further evidence about the costs and benefits of establishing batch testing facilities in the UK. The information provided has been used in this IA to estimate the impacts of different policy options. The key pieces of information that we have used from this pre-consultation engagement are summarised below.

Number of batches imported from the EU/EEA per year: 47,500

Responses from industry covered imports of 5,220 product lines with 31,500 batches per year from the EU/EEA. We know that this represents approximately 66% of the total live MHRA authorisations for product lines, and we used this ratio to calculate 31,500/0.66 ≈ 47,500.

Annual costs of import batch testing: £3,600

We acknowledge that batch testing costs vary widely and could be markedly different across different medicine categories (e.g. generics, branded / over-the-counter (OTC), or biologic medicines). In fact, the figures we received ranged from £300 to £100,000 per batch. We use a weighted average cost figure based on survey responses, weighting companies' average cost submissions by the number of batches the respective respondents stated they import from the EU/EEA per year.

Using an average cost figure across the different medicine types is a simplifying assumption, however, we do not think that disaggregating the calculation to different types of drugs would materially improve the results especially as it may introduce further bias due to increased uncertainty over the larger number of inputs to the calculation.

Current batch testing capacity and required increase: 122%

Companies responding to the pre-consultation industry engagement exercise stated that they import around 31,500 medicine batches from the EU/EEA in total, and they have around 25,800 batches that they either manufacture in the UK (requiring batch testing) or import from non-EU/EEA countries with which the UK does not have MRA (requiring import testing). This would suggest that the required increase in batch testing to provide sufficient capacity to test all batches arriving from the EU/EEA (in addition to those already tested in the UK) would be around 31,500/25,800 ≈ 122%.

Annex B: Published evidence about the costs of import batch testing

There is limited research on the costs of import testing to triangulate with the evidence submitted by industry, with just one study published to date[32]. The study, using batches from companies importing to the US from EU, estimated an overall cost of €6,074 per test. The breakdown of this is detailed below:

€2,950	Direct cost of testing	Local QC analytics (e.g., for testing, samples, contract laboratories)
€1,100	Indirect and hidden costs	Analytical method transfer, training of testing staff, reagents[33]
€2,024	Losses due to blocked capital	Loss by blocked capital due to longer storage duration of the inventory
€6,074	Overall cost per test	

Converting to GBP[34] and multiplying by the 47,500 batches assumed to be imported from EU/EEA[35] aggregated the total costs for import testing to be £240m.

[32] 13.-Import-Testing.pdf (ifpma.org)

[33] 13.-Import-Testing.pdf (ifpma.org) page 149

[34] 1.00 EUR = 0.84 GBP as of 09/03/2022 1 EUR to GBP - Euros to British Pounds Exchange Rate (xe.com)

[35] Calculation in annex A

Using the industry engagement exercise, estimates of the annual running costs and batch testing costs amounted to £127m and £171m respectively, giving a combined total of £298m. As explained in paragraph 71, it is assumed that respondents considered personnel costs within these estimates and these are largely omitted from the research evidence above. The losses due to blocked capital are assumed to have been included in respondents estimates of testing costs.

The scale of costs for import testing reported in the research are broadly similar to those calculated from the industry responses used in this Impact Assessment, giving confidence to the information provided by industry to inform this policy review.