



The future strategy for batch testing of medicinal products in Great Britain – consultation document

Contents

The future strategy for batch testing of medicinal products in Great Britain – consultation document.....	1
Contents	1
About this consultation.....	3
Objectives	3
Purpose of the consultation.....	3
Background and current context	4
Understanding batch testing of medicinal products.....	4
Current legislation and policy	5
Scope of this consultation	6
Within the scope of this consultation	6
Outside the scope of this consultation.....	7
Territorial scope and Northern Ireland Protocol.....	8
The policy options	8
Option A: no import testing or UK QP certification/release for listed countries.....	9
Option B: no import testing but implementing UK QP certification/release for listed countries.....	9
Option C: full quality control batch testing and implementing UK QP certification/release for all non-MRA countries.....	10
Option D: reduced number of import tests and implementing UK QP certification/release for all listed countries.....	10
How to respond.....	10
What happens next.....	11

Consultation questions.....	11
Disclaimer: the numbering of questions here does not correspond to the numbering on the survey platform.....	11
Option A	12
Option B	13
Option C	14
Option D	14
All options.....	15
Impact assessment	16
Licensing	16
Option A: no import testing or UK QP certification/release for listed countries.....	17
Option B: implementing UK QP certification/release for listed countries	18
Option C: full quality control batch testing and implementing UK QP certification/release for all non-MRA countries	19
Option D: reduced number of import tests and implementing UK QP certification/release for all listed countries.....	22
Annexes	23
Annex A: Legal basis and assessment of the matters set out in section 2 of the Medicines and Medical Devices Act 2021	23
Annex B: confidentiality of information	26
Annex C: privacy notice.....	27

About this consultation

Batch testing is the process of confirming every batch of medicine has the correct composition through laboratory tests by the manufacturer. It helps to ensure that patients get medicines that are of appropriate quality and have the desired therapeutic effect. It's part of the broader good manufacturing practice (GMP) quality assurance system and is usually an end of process test.

The UK's independence from the European Union (EU) now means the UK can set its own regulatory policy in Great Britain on how, when and if to accept batch testing results from third countries or choose to require batch testing in the UK of products intended for the UK market.

Batch testing policy will ultimately support the aims set out by this government in the [Life Sciences Vision](#) to stimulate a thriving UK life sciences sector and to continue to promote the [Medicines and Healthcare products Regulatory Agency \(MHRA\)](#) as a globally recognised, top-tier regulator.

Objectives

The future batch testing policy will look to strike a balance between 3 objectives.

Objective 1 – protect patient safety and access

Ensure that the UK's approach to batch testing continues to protect patients and enable access to safe, effective and high-quality medicines, for the whole of the UK.

Objective 2 – build the right domestic system for the UK life sciences sector

Support the [Life Sciences Vision's goals](#) to explore new and innovative approaches to regulating while recognising the need for simple and pragmatic solutions.

Objective 3 – drive UK thought leadership and international collaboration

Build the UK's reputation as an attractive place to market and manufacture medicines, while maintaining international relationships and globally harmonised standards.

Purpose of the consultation

The purpose of this consultation is to seek the views of interested people, businesses and organisations on the 4 options outlined in 'The policy options' below. As part of the development of the proposals, we undertook targeted engagement with a cross-section of stakeholders and industry that will be affected by the changes to batch testing policy.

We invite your responses to the consultation questions listed below (in the 'Consultation questions' section of this page) before the consultation closes on 26 July 2022.

Background and current context

Understanding batch testing of medicinal products

Batch testing is the process of confirming every batch of medicine has the correct composition through laboratory tests by the manufacturer. It helps to ensure that patients get medicines which are of appropriate quality and have the desired therapeutic effect. It is part of the broader Good Manufacturing Practice (GMP) Quality Assurance system and is usually an end of process test.

The MHRA played a leading role in the development of batch testing policies, process and guidance while the UK was part of the EU. Outside of the EU, the MHRA continues to lead and push for the standardisation of regulations in international forums such as the Pharmaceutical Inspection Co-operation Scheme (PICs) and bilaterally with trade partners.

The UK's independence from the EU now means the UK can set its own regulatory policy on how, when and if to accept batch testing results from third countries or choose to require batch testing in the UK of products intended for the UK market. Currently, the UK has mutual recognition agreements (MRAs) with several major pharmaceutical nations (Australia, Canada, Israel, Japan, New Zealand, Switzerland and USA) which recognise batch testing of medicines. The UK does not have an MRA with the EU.

The UK previously explored having a mutual recognition agreement (MRA) on batch testing with the EU as part of the Trade and Cooperation Agreement (TCA) negotiations. However, the EU were firmly opposed to this and would not agree. An MRA with the EU is not a policy approach being considered as part of this consultation.

At the end of the transition period, the government implemented a range of standstill measures to support sectors trading with third countries. Currently a 'listing' system removes the requirement to batch test on import medicines from certain non-MRA countries and to therefore allow UK wholesalers to continue importing medicines from the third countries that meet our standards, in order to maintain UK supply. Countries are assessed against an objective standard that tests their equivalence to the UK's own regulatory standards before they can be 'listed'. The EU/EEA were the only non-MRA countries listed.

In March 2021, the government announced a full review into Great Britain's future batch testing policy, to report no later than December 2022. Following the conclusion of this review, there will be a 2-year notice period before any changes to the current policy are implemented.

Current legislation and policy

The longstanding requirements for importation, batch testing and Qualified Person (QP) certification were established in EU Directive 2001/83/EC, and these were transposed into the UK's Human Medicines Regulations 2012 (as amended) (HMR 2012). Manufacture of licensed medicines (and importation from third countries) required a Manufacture and Importing Authorisation (MIA) and a QP.

At the end of the transition period, HMR 2012 was amended to include Regulation 18A, which allowed importation under a wholesale dealer's licence from countries on a list (which currently includes all EU/EEA countries). This preserved the existing pre-EU exit arrangements whereby QP-certified medicines could move between EU/EEA member states (and the UK) under wholesale dealer arrangements.

Among other things, the legislation requires that:

- manufacturers and importers are licensed to carry out their operations (that is, they hold an MIA)
- individual medicinal products are authorised by way of their Marketing Authorisation (MA), which outlines how they are formulated, manufactured, packaged and tested
- every batch of licensed medicinal product requires full qualitative and quantitative testing
- every batch must be certified by a QP (who is named on the MIA)
- for batches which are imported from third countries, full qualitative and quantitative testing must be carried out after import, before the QP can certify the batch
- where an MRA is in place, the import testing can be waived but the batches must still be certified by the QP

Scope of this consultation

Within the scope of this consultation

This consultation will assess the policy options for batch testing where medicines are imported into Great Britain from a third country with which the UK does not have an MRA on batch testing.

Specifically, it will seek views on amending provisions that were inserted into the UK regulatory framework for human medicines and took effect from January 2021. These provisions, the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019, [SI 2019 775], were introduced as part of a range of post EU Exit measures to reduce the possibility of delays to medicines reaching the UK market and supply disruption.

The primary focus of the consultation is on human medicines (including vaccines and blood products), although we will also consider evidence on the implications for veterinary medicines.

The batch testing policy options will affect the following policies and legislation.

- List of approved countries for import – ‘listed countries’: The HMRs were amended as part of EU Exit legislation ([UK SI 2019/775](#)) to introduce the concept of an ‘approved countries for import’ list. This list is of countries that have been deemed to be of equivalent standard to the UK and therefore there is no requirement for batch testing on import. The list is separate from the MRAs the UK has in place. Currently, this list only includes EU/ EEA countries, but this will be periodically reviewed every 3 years to ensure that the list only includes countries that meet equivalent standards. To determine whether a country should be included in the approved country for import list, the MHRA may consider:
 - the country’s system for ensuring that each batch of a medicinal product has been manufactured and checked in accordance with the requirements of its legislation and any authorisation in respect of that product
 - the country’s rules for good distribution practice
 - the regularity of inspections to verify compliance with good distribution practice
 - the effectiveness of enforcement of good distribution practice
 - the regularity and rapidity of information provided by that country relating to non-compliant manufacturers and distributors of medicinal products

- any on-site review of that country's regulatory system undertaken by the licensing authority
- any on-site inspection of a manufacturing site in that country observed by the licensing authority
- any other relevant documentation available to the licensing authority
- Recognition of EU/EEA QP certification/release: A Qualified Person (QP) is responsible for assuring the quality of medicines and is legally responsible for certifying batches of medicinal products before they are released for supply. The UK government instituted a measure to recognise QP certification/release carried out in the EU/EEA. This means medicines can be imported by a UK wholesaler under the [Responsible Person \(import\) \(RPI\) provisions](#), which ensures the batch was certified by an approved QP. If the UK chooses a policy which requires additional import testing in the UK, then UK QP certification will also be required. This is because EU QPs cannot recognise Great Britain test results. Therefore, the scope of the consultation will include UK QP certification and release.

Outside the scope of this consultation

Pursuing an MRA with the EU: This consultation is considering operational solutions for the future batch testing policy and will therefore focus on creating a domestic regime compatible with the deal that we have, while ensuring industry is prepared for the end of the standstill period. An MRA with the EU is not a policy approach being considered as part of this consultation.

Independent control testing of biological medicines: A subset of medicines, 'biological medicines' (which includes products such as vaccines and medicines that are made from human blood), require independent assessment of individual production batches in addition to the batch testing that is performed by the manufacturer to ensure the medicines are safe and effective.

In the UK, this is undertaken by the National Institute for Biological Standards and Control (NIBSC) and in Europe, this function is fulfilled by a network of Official Medicines Control Laboratories (OMCLs).

Independent batch assessment at NIBSC consists of laboratory testing and/or an evaluation of the manufacturer's test data (and a review of the outcome of testing by EU OMCLs where applicable). The processes for independent testing at NIBSC are currently under review and, while not specifically covered by this consultation, will take account of the final policy for manufacturer batch testing.

Territorial scope and Northern Ireland Protocol

We have closely engaged with our Devolved Administration counterparts to seek their input into the review.

Medicines are a reserved policy area but transferred (devolved) in respect of Northern Ireland. Under the Northern Ireland Protocol, however, EU law relating to human medicines (and therefore batch testing) continues to apply in relation to Northern Ireland.

The EU's regulatory system requires batch testing to be conducted within the EU, unless an MRA is in place. Under the terms of the Northern Ireland Protocol, this means batch testing of medicines destined for the Northern Ireland market would need to take place in Northern Ireland or the EU. Any medicines moving from Great Britain to Northern Ireland would need to be re-tested on import into Northern Ireland. Northern Ireland's small market size has made it challenging for operators in Northern Ireland to carry out this repeat batch testing.

Following negotiations with the UK, the EU has adopted new legislative proposals to seek to address these supply concerns. The EU legislative proposals allow for the batch testing of products for the Northern Ireland 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.

The scope of this consultation therefore concerns Great Britain only, covering the territories of England, Scotland and Wales. We will continue to consider the implications of the consultation options and will ensure implementation of the final policy take account of the Northern Ireland Protocol and the protection of medicines supply in Northern Ireland. The government is fully committed to ensuring that citizens across the whole of the UK, including in Northern Ireland, have access to the same medicines at the same time.

The policy options

The following section describes the proposed options for batch testing of imported medicines into Great Britain from a third country with which the UK does not have a batch testing MRA. These are the 4 options on which we seek the views of interested people, businesses and organisations through this consultation.

Option A: no import testing or UK QP certification/release for listed countries

Third countries would undergo a conformity assessment by MHRA to ensure their regulatory standards are sufficient before inclusion on the list. The list would be open to all third countries provided they could demonstrate equivalent regulatory standards. MHRA would initially include all EU/EEA countries on the list, which would be subject to review after 3 years.

UK wholesale dealers could continue to import medicines from the EU/EEA by recognising EU/EEA batch testing and EU/EEA QP certification. Hence, the option relies on the continued recognition of EU QP certification.

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. For this, the importer would only require an 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 should already have RPIs in place, some working for more than one company.

Importers of medicines from countries on the list would not require an MIA and GMP certificate, only a wholesale dealer/distribution authorisation (for medicines for human use) (WDA(H)) with a good distribution practice (GDP) certificate. 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' MA.

Option B: no import testing but implementing UK QP certification/release for listed countries

Countries would undergo a conformity assessment by MHRA to ensure their regulatory standards are sufficient before inclusion on the list. The list would be open to all third countries provided they could demonstrate equivalent regulatory standards. MHRA would initially include all EU/EEA countries on the list, which would be subject to review after 3 years.

This option removes the role of the RPI. This means medicines imported from listed countries would need to be imported by an MIA holder into a GB importation site and certified/released by a UK QP.

Importers would require the MIA and GMP certificate. There would also be a need for importers to apply for a variation to the respective medicines' MA to add to the UK batch certification site.

Option C: full quality control batch testing and implementing UK QP certification/release for all non-MRA countries

This option removes the listed countries and the role of the RPi. It would require full quality control batch testing in the UK. Medicines imported from all non-MRA countries would need to be imported by an 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.

Importers would require the MIA and GMP certificate. There would also be a need for importers to apply for a variation to the respective medicines' MA to add the UK batch certification site and the UK quality control testing site.

Option D: reduced number of import tests and implementing UK QP certification/release for all listed countries

Countries would undergo a conformity assessment by MHRA to ensure their regulatory standards are sufficient before inclusion on the list. The list would be open to all third countries provided they could demonstrate equivalent regulatory standards. MHRA would initially include all EU/EEA countries on the list, which would be subject to review after 3 years.

This option removes the role of the RPi and requires a limited number of tests on medicines imported from listed countries. The tests required would depend on the product, such as identity and assay tests for a small molecule or requiring an impurity test for short shelf-life products. This would be set out in the MA.

Medicines imported from listed countries would need to be imported by an 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.

Importers would require the MIA and GMP certificate. There would also be a need for importers to apply for a variation to the respective medicines' MA.

How to respond

The government invites responses on the specific questions raised in the section above.

Please respond through our online consultation survey.

If you have any queries on this consultation or require an alternative format please email medicines.goods@dhsc.gov.uk

If you do not have internet or email access, then please write to:

Medicines (Goods) Team
Department of Health and Social Care
Floor 5, 39 Victoria Street
London
SW1H 0EU

The consultation is open for a period of 8 weeks, from 31 May 2022 until 26 July 2022. Please submit your response to the questions by 11:45pm on 26 July 2022.

What happens next

The consultation will close at 11:45pm on 26 July 2022. Responses received on or before this date will be carefully considered. Any policy decisions on the future strategy for batch testing in Great Britain will be taken only after full consideration is given to consultation responses, submitted evidence and other relevant information.

A response to the consultation will be published in due course following the closure of this consultation. It will form the conclusion of the review and trigger the 2-year notice period after which the policy will be implemented.

If it is decided to pursue a policy that would require legislation, it will be made using powers set out in Part 2 of the Medicines and Medical Devices Act 2021 and will need to be in force 2 years from the point the review has formally concluded.

Consultation questions

Disclaimer: the numbering of questions here does not correspond to the numbering on the survey platform.

Question 1

Do you import any medicines that are within the scope of this policy, from listed countries (EU or EEA)?

yes

no

Question 2

How many batches of medicines (per year) that are within the scope of this policy do you currently import from listed countries (EU/EEA)?

Option A

Option A is no import testing or UK Qualified Person (QP) certification or release for medicines imported from countries on the approved list. The list would be open to all third countries provided they could demonstrate equivalent regulatory standards and membership would be reviewed at least every 3 years. This option would require 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.

Question 3

Do you expect option A to have an effect on any of the following areas?

- a) Patient safety and access to medicines, including impacts on health disparities and protected characteristics
- b) Making the UK an attractive place for the research, manufacture and marketing of medicines
- c) Your supply chain resilience
- d) Net zero or environmental impacts
- e) Parallel imports
- f) Don't expect option A to have an effect on these areas
- g) Other

Question 4

Please explain your answer

Option B

Option B is implementing UK QP certification and release for countries on the approved list. This would remove the role of the RPi and mean that medicines imported from listed countries would need to be imported by a Manufacture and Importing Authorisation (MIA) holder into a GB importation site and certified/released by a UK QP. The list would be open to all third countries provided they could demonstrate equivalent regulatory standards and membership would be reviewed at least every 3 years.

Question 5

Do you expect option B to have an effect on any of the following areas?

- a) Patient safety and access to medicines, including impacts on health disparities and protected characteristics
- b) Making the UK an attractive place for the research, manufacture and marketing of medicines
- c) Your supply chain resilience
- d) Net zero or environmental impacts
- e) Parallel imports
- f) Don't expect option B to have an effect on these areas
- g) Other

Question 6

Please explain your answer

Option C

Option C is full quality control batch testing in the UK. It removes the listed approach and would require medicines imported by all non-MRA countries to be imported by an MIA holder into a GB importation site. A UK QP would be responsible for certifying and releasing the batch.

Question 7

Do you expect option C to have an effect on any of the following areas?

- a) Patient safety and access to medicines, including impacts on health disparities and protected characteristics
- b) Making the UK an attractive place for the research, manufacture and marketing of medicines
- c) Your supply chain resilience
- d) Net zero or environmental impacts
- e) Parallel imports
- f) Don't expect option C to have an effect on these areas
- g) Other

Question 8

Please explain your answer

Option D

Option D is reduced number of import tests and implementing UK QP certification and release for all listed countries. This would require only a limited number of critical tests, such as identification or assay tests, on products from countries on the list. The list would be open to all third countries provided they could demonstrate equivalent regulatory standards and membership would be reviewed at least every 3 years.

Question 9

Based on the information provided about option D, do you think there will be a difference in impact compared to your assessment of option C?

Yes

No

Question 10

Please explain your answer

All options

Question 11

Please state your preferred policy option

Option A - no import testing or UK QP certification or release for listed countries

Option B - implementing UK QP certification and release for listed countries

Option C - full quality control batch testing and implementing UK QP certification and release for all non-MRA countries

Option D - reduced number of import tests and implementing UK QP certification and release for all listed countries

Question 12

Please explain your answer

Question 13

This policy will have a 2-year implementation period. How much time do you estimate businesses would need to prepare for implementation of option B, option C, option D?

Question 14

If there are products or product types that are more likely to be adversely affected by the extra testing and/or QP release processes, please provide details for each policy option.

Question 15

What mitigations would you put in place to minimise supply disruption for these products?

Impact assessment

To assess the potential impact of the proposed policies, we have produced an impact assessment (IA). This document can be found on the [main consultation page](#). The IA provides initial analysis of the relative costs and benefits of the policy options set out in this consultation.

The following questions will help us gather further evidence and gain insight into the issues raised in the impact assessments.

Please note that any information you provide may be used in our final IA that will be published.

We will not, however, publish any identifiable firm-level information as part of the IA or any other public document.

Licensing

Question 16

Does your organisation currently hold a Manufacture and Importing Authorisation (MIA) and wholesale dealer/distribution authorisation (for medicines for human use) (WDA(H))?

Yes, both MIA and WDA(H)

Only MIA

Only WDA(H)

Neither

If you do not hold an MIA, it is assumed your organisation would need to obtain an MIA licence for QP certification/release should this become required under future batch testing arrangements.

Question 17

Would you need to apply for new licences as a result of options B to D?

Yes

No

For options B to D, importers would need to apply for a variation to the Marketing Authorisation (MA) for every product to add the UK batch certification site.

Question 18

How many products (MAs) would this affect for your organisation?

Option A: no import testing or UK QP certification/release for listed countries

Question 19

Do you agree or disagree with the types of costs and benefits associated with this option as set out in the Impact Assessment?

Agree

Disagree

Question

Please explain your answer

Question 20

Are there any other costs and benefits of this option that you think need to be considered?

Option B: implementing UK QP certification/release for listed countries

Question 21

Will you require additional UK-based QPs to implement this option?

Yes

No

Don't know

Question 22

How many full-time employees?

Question 23

Are you likely to have difficulties employing the staff required by this option?

Question 24

Please explain your answer

Question 25

Is there any additional evidence about the likely costs of implementing this option (initial and ongoing)?

Yes

No

Question 26

Please provide further evidence which could be used to improve our estimates

Question 27

Are there any additional risks of implementing this option that are not included in the IA?

Option C: full quality control batch testing and implementing UK QP certification/release for all non-MRA countries

Question 28

If option C is chosen, how would your organisation resource full import testing of batches from listed countries (EU/EEA)?

Utilise existing testing facilities

Build a new UK-based testing facility

Contract listed country (EU/EEA) import testing to a UK based Contract Lab Organisation

Question 29

Please provide an estimate of the setup and annual running costs to your organisation to implement the approach that you will take.

Question 30

If planning to outsource to a UK-based Contract Lab Organisation / CRO, do you have existing relationships with these organisations?

Yes

No

Question 31

Does your organisation foresee any challenges with establishing a relationship with a UK-based Contract Lab Organisation or CRO to perform full import testing if required?

Question 32

How many additional UK-based QPs would your organisation require under this option to certify and release the volume of product batches that your organisation currently imports from Listed Countries (EU/EEA)?

Question 33

How many contracts do you have with organisations to provide UK based testing?

Question 34

What is your current UK-based testing capacity?

Question 35

Is your existing capacity fully utilised?

Question 36

How many extra batches from listed countries (EU/EEA) could you process per year for full import testing?

Question 37

Please provide any comments on the contract lab sector's ability to support the expansion of the UK's batch testing capacity required under this option.

Evidence has suggested that batch testing requirements can add 4 to 5 weeks on to the supply chain. In the case of some medicines, this may pose a material risk due to:

- inability to stockpile short shelf-life medicines
- reduction in remaining shelf life (RSL) beyond the point where NHS or wholesalers will accept delivery

Question 38

How many products imported from listed countries (EU/EEA) do you anticipate may be at risk of supply due to the extra time required for import testing?

Question 39

Are you aware of products imported from listed countries (EU/EEA) that may be at risk of discontinuation in GB due to the additional cost of repeat import batch testing?

Yes

No

Question 40

Please explain your answer

Question 41

Is there any additional evidence about the likely benefits of this option?

Yes

No

Question 42

Please provide further evidence which could be used to improve our estimates

Question

Are there any additional risks of implementing this option that are not included in the IA?

Option D: reduced number of import tests and implementing UK QP certification/release for all listed countries

Question 43

Would this option require fewer QPs than under option B, and if so, to what extent?

Question

Would this option cost less to implement compared to option C?

Question

Do you see any benefits or risks from Option D compared to Option C?

Annexes

Annex A: Legal basis and assessment of the matters set out in section 2 of the Medicines and Medical Devices Act 2021

The Medicines and Medical Devices Act 2021 (the act) came into force for these purposes on 11 April 2021. Policy options B, C and D outlined above would require legislative changes. These changes would be made using powers in Part 2 of the act, which provides powers to make, among other things, amendments to the HMRs.

This consultation is conducted in line with the consultation requirement in section 45(1) of the act.

Section 2 of the act provides that safeguarding public health must be the overarching objective of the appropriate authority when making regulations. Section 2 requires that when assessing whether regulations would contribute to the objective of safeguarding public health, the appropriate authority must have regard to 3 factors. These are:

1. the safety of human medicines
2. the availability of human medicines
3. the likelihood of the relevant part of the United Kingdom being seen as a favourable place in which to:
 - carry out research relating to human medicines
 - conduct clinical trials
 - manufacture or supply human medicines

As set out in section 2(4) of the act, where regulations under section 2(1) may have an impact on the safety of human medicines, the appropriate authority may make the regulations only if the authority considers that the benefits of doing so outweigh the risks.

Below we have assessed the policy proposals against each of the factors set out in section 2, including the status quo, which would not require legislative changes, for completeness.

Option A: no import testing or UK QP certification/release for listed countries

Safety

This option maintains high safety standards for patients. Listed countries are assessed to ensure their regulatory standards are sufficiently high to assure the safety and efficacy of medicines for patients.

Availability

Maintaining the status quo approach would avoid adding complexity to the supply chain of all medicines, which would not affect the current availability of medicines. However, we recognise that maintaining this policy could result in testing facilities moving outside the UK, which could affect capability for end-to-end supply chain for medicines within the UK. The loss of testing facilities, which can be important in the development of new medicines, could also mean those medicines are first launched in the countries where testing and manufacturing are located, rather than the UK.

Favourability

We consider this option could provide certainty for industry around our future regime with a framework they are familiar with and avoid introducing regulation that could be considered a barrier to bringing medicines to the UK market. Conversely, this policy could affect how favourably industry views the UK as a destination to test medicines compared to listed countries, which could affect the size and resilience of the UK's manufacturing base.

Option B: no import testing but implementing UK QP certification/release for listed countries

Safety

This option could provide an added layer of assurance in addition to the high safety standards of the listing system. This approach would require an assessment carried out by a UK-based QP who is legally accountable for maintaining high safety standards.

Availability

This option could maintain existing supply chain routes and avoid adding additional costs associated with requiring import testing (required under options C and D), thereby having a relatively limited impact on the availability of medicines. However, we recognise there is currently a skills and capacity gap in relation to QPs, which could cause short term disruption and be challenging to address within the 2-year implementation period. The government would need to consider options to reduce possible disruption and support implementation.

Favourability

We consider that this approach could boost the number of UK-based QPs in the long term, which are highly skilled roles that 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 in which to manufacture and test medicines. However, we recognise that this approach would increase the requirements on exporters of medicines to the UK and therefore could affect how favourably they view the UK as a destination to supply medicines.

Option C: full quality control batch testing and implementing UK QP certification/release for all non-MRA countries

Safety

This option would provide full accountability to the MHRA that UK importers have tested medicines destined for the UK market to UK standards, ensuring the safety and efficacy of medicines.

Availability

We recognise this option would be costly for industry to implement, which could have an impact on the commercial viability of some medicines and may see additional costs passed onto the NHS and patients. It adds complexity to supply chains and could delay the release and supply of medicines. This option requires the most amount of testing capacity and expertise, meaning the shortage of QPs and UK testing capacity could cause short to medium term disruption to the availability of medicines, and would be challenging to address within the 2-year implementation period. The government would need to consider options to reduce possible disruption and support implementation.

Favourability

The implementation of this option would require new infrastructure to support increased testing and jobs in the UK testing and QP industry, which could benefit the UK as a place to carry out research, supply or manufacture medicines. However, the changes would represent an upfront cost to industry, and could be viewed as creating additional burdens and diverting investment into testing at the expense of other areas, such as research and development of new medicines.

Option D: reduced number of import tests and implementing UK QP certification/release for all listed countries

Safety

These changes could provide an additional layer of assurance in addition to the benefits of having a UK based QP. Focusing on key tests on import would be a targeted method of assuring the critical aspects of medicines were verified by a UK QP before medicines are

certified and released. This would offer additional assurance for the safety and efficacy of medicines.

Availability

A form of reduced batch testing was applied during COVID-19 where availability of medicines was not compromised. However, we recognise this option could increase the costs of medicines production, which might present risks to manufacturers of certain low-cost medicines with smaller profit margins, who may decide to export elsewhere as a result. We also acknowledge this could affect the commercial viability of some medicines which operate on low margins or rare/orphan drugs and adds complexity to supply chains. As noted above, there is a QP skills shortage and limited amount of UK testing capacity which could cause short term disruption and be challenging to address within the 2-year implementation period. The government would need to consider options to reduce possible disruption and support implementation.

Favourability

The requirement for testing on import could be seen as a barrier towards bringing medicines into the UK and therefore negatively affect how favourably industry view the UK as a destination to supply medicines. Costs in setting up new testing facilities or processes are likely to be viewed unfavourably by industry. Conversely, however, this option could increase UK testing capacity, which may be beneficial for manufacturing and potentially attract inward investment in the long term.

Annex B: confidentiality of information

We manage the information you provide in response to this consultation in accordance with the Department of Health and Social Care's [Personal Information Charter](#).

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

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

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

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

Annex C: privacy notice

The Department of Health and Social Care (DHSC) is the data controller.

What personal data we collect

The type of personal information we will collect is as follows:

- name
- name of organisation
- area of UK respondents are based in
- email address

How we use your data (purposes)

The data we collect is to inform DHSC of the demographic of respondents. The department will process your personal data in accordance with the Data Protection Act 2018 (DPA) and in most circumstances this will mean that your personal data will not be disclosed to third parties. We may need to contact you if we have had a request under the Freedom of Information Act 2000 (FOIA). We will also email you to let you know if we have published a response to the consultation.

Legal basis for processing personal data

Under the UK General Data Protection Regulation (UK GDPR), the lawful basis we rely on for processing this information is:

- your consent

Data processors and other recipients of personal data

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

respondents who have informed us that they are in Northern Ireland will be shared with officials from the Department of Health in Northern Ireland.

International data transfers and storage locations

Any personal information collected will be stored in the UK and managed in line with DHSC's personal information charter.

Retention and disposal policy

We manage the information you provide in response to this consultation in accordance with DHSC's data protection policy. We will retain your data for 12 months after the consultation closes.

How we keep your data secure

Anyone managing and handling personal information understands that they are contractually responsible for following good data protection practice, is appropriately trained to do so and is appropriately supervised.

Your rights as a data subject

By law, data subjects have a number of rights and this processing does not take away or reduce these rights under the EU General Data Protection Regulation (2016/679) and the UK Data Protection Act 2018 applies.

These rights are:

4. The right to get copies of information – individuals have the right to ask for a copy of any information about them that is used.
5. The right to get information corrected – individuals have the right to ask for any information held about them that they think is inaccurate, to be corrected.
6. The right to limit how the information is used – individuals have the right to ask for any of the information held about them to be restricted, for example, if they think inaccurate information is being used.
7. The right to object to the information being used – individuals can ask for any information held about them to not be used. However, this is not an absolute right, and continued use of the information may be necessary, with individuals being advised if this is the case.
8. The right to get information deleted – this is not an absolute right, and continued use of the information may be necessary, with individuals being advised if this is the case.

Comments or complaints

Anyone unhappy or wishing to complain about how personal data is used as part of this programme should contact data_protection@dhsc.gov.uk in the first instance or write to:

Data Protection Officer
1st Floor North
39 Victoria Street
London
SW1H 0EU

Anyone who is still not satisfied can complain to the Information Commissioner's Office. Their website address is www.ico.org.uk and their postal address is:

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Automated decision making or profiling

No decision will be made about individuals solely based on automated decision making (where a decision is taken about them using an electronic system without human involvement) which has a significant impact on them.

Changes to this policy

This privacy notice is kept under regular review, and new versions will be available on our privacy notice page on our website. This privacy notice was last updated on 26 October 2021.

© Crown copyright 2022

www.gov.uk/dhsc

This publication is licensed under the terms of the Open Government Licence v3.0 except where otherwise stated. To view this licence, visit nationalarchives.gov.uk/doc/open-government-licence/version/3.

Where we have identified any third party copyright information you will need to obtain permission from the copyright holders concerned.

