

# The future strategy for batch testing of medicinal products in Great Britain – CRUK consultation response

July 2022

## Option A

*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 x**
- b) **Making the UK an attractive place for the research, manufacture and marketing of medicines x**
- 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 4: Please explain your answer*

Of the options presented in this consultation, Option A is by far the most favourable for cancer patients in the UK. Option A will maintain the current status quo in terms of patient safety and stability of supply of and access to medicines. This is also recognised in Annex A of the consultation document, which states that Option A would not affect the current availability of medicines.

However, the status quo presupposes that all EU/EEA countries remain on the list. Removing any EU/EEA countries from the list would create barriers to the importation of medicines from those countries. This could result in delays and disruption to accessing vital cancer medicines for cancer patients, including those taking part in research studies. While it is a sensible policy to review the list of approved countries at a regular interval to ensure equivalent regulatory standards, the process must also ensure long-term certainty and stability of medicines supply.

The process of reviewing the list of approved countries therefore needs to be risk-based. The process must ensure that any future regulatory divergence between the UK and the EU does not result in EU/EEA countries being removed from the approved list where there is little or no risk to the safety of imported medicinal products from these countries. It is important to acknowledge that the UK imported from EU/EEA countries without duplicative import testing or UK Qualified Person (QP) certification during the period of EU membership without risk to patient safety. Removing EU/EEA countries from the list would therefore be a retrograde step for the uninterrupted supply and availability of medicines for cancer patients in the UK.

Of the options presented in this consultation, Option A is CRUK's preferred option. However, it remains a suboptimal option compared to a Mutual Recognition Agreement (MRA). This point is elaborated on in Question 12.

## Option B

*Question 5: Do you expect option B to have an effect on any of the following areas?*

- h) **Patient safety and access to medicines, including impacts on health disparities and protected characteristics x**
- i) **Making the UK an attractive place for the research, manufacture and marketing of medicines x**
- j) Your supply chain resilience
- k) Net zero or environmental impacts
- l) Parallel imports
- m) Don't expect option B to have an effect on these areas
- n) Other

*Question 6: Please explain your answer*

Option B would raise barriers that could potentially cause delays and disruption to the supply of life-changing medicines for cancer patients who need them urgently. As recognised in Annex A of the consultation document, there is currently a skills and capacity gap in relation to QPs, which could cause short term disruption and would be challenging to address within the 2-year implementation period.

It seems the rationale for Option B is that it could boost the number of UK-based QPs in the long term but could entail some disruption to supply and availability of medicines in the short to medium term. This is not a favourable trade-off and it poses the risk that cancer patients will face delays in accessing medicines which could impact their quality of life and reduce the time they will have with their families. Option B would therefore need to be accompanied by Government reassurances and investment to ensure the current skills and capacity gap in relation to QPs is fully addressed in the 2-year implementation period. We have heard anecdotally from industry actors that this will be a difficult task in the 2-year timeframe without Government support.

CRUK does not think the argument that Option B could provide an added layer of assurance in addition to the listing system is reasonable grounds to implement barriers to importation of medicines from the EU/EEA and impose additional costs associated with increasing QP capacity. As mentioned in Question 4, the UK has imported from EU/EEA countries without UK Qualified Person (QP) certification during our period of EU membership, so it would be a retrograde and unnecessary step to implement it for EU/EEA countries on the grounds of safety.

## Option C

*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 x**
- b) **Making the UK an attractive place for the research, manufacture and marketing of medicines x**
- 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 C is the least favourable option as it could create significant barriers to availability of medicines for cancer patients in the UK. As recognised in Annex A of the consultation document, this option adds significant complexity to supply chains and could delay the release and supply of medicines for cancer patient who need them urgently.

Similarly to Option B the rationale seems to be that Option C would deliver new infrastructure to support increased testing and boost jobs in the UK testing and QP industry, but will cause short to medium term disruption to the availability of medicines. CRUK does not believe this is a favourable trade-off and the risk that cancer patients will face delays in accessing medicines, which can negatively impact their quality of life and reduce the time they will have with their families, is exacerbated in Option C due to more stringent barriers. CRUK has heard anecdotally from industry actors that this will be almost impossible to implement in the 2-year timeframe without significant Government support, which would increase the risk to cancer patients and cancer outcomes.

As with Option B, CRUK does not believe it is reasonable or necessary to implement these barriers on the grounds of safety for EU/EEA countries, considering the UK has imported from EU/EEA countries without duplicative testing and UK Qualified Person (QP) certification during our period of EU membership.

## Option D

*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 x**

*Question 10: Please explain your answer*

It is unclear what the proposed reduced testing regime would look like. Therefore, it cannot be concluded with certainty at this stage that the impact would be different to that of Option C. Any additional testing of medicines from EU/EEA countries would risk some degree of supply chain complication and potential delays or disruption. However, this would likely be proportionate to the level of testing required and the level of support for companies to implement this.

## All options

*Question 11: Please state your preferred policy option*

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

Option A is CRUK's preferred policy option since it maintains the current status quo for importation and supply of medicines and therefore poses no immediate risk to the availability of life-changing medicines for cancer patients. As set out in this consultation response, Options B, C, and D all impose barriers of varying degrees and severity. As Option A maintains the current status quo, we also believe it does not pose an increased risk to patient safety.

Imposing duplicative testing on every batch of imported medicine, as would be the case under Option C and to some unknown extent under Option D, would likely create significant disruption. Every month, 37 million packs of medicine move from the EU/EEA to the UK, and 45 million from the UK to the EU.<sup>1</sup> In practice, it would mean that a certain number of packs or doses from each batch are taken out of the supply chain and put through various laboratory processes. Considering the volume of medicines entering the UK from the EU/EEA, the scale of duplicative testing would likely be substantial.

We have also heard anecdotally from industry actors that any benefits to the UK economy stemming from boosting testing infrastructure and capacity and the QP workforce is likely to be offset by the trade barriers created by Options B, C, and D. Therefore, the investment required from industry – and the Government funding required to support companies – is better spent in areas such as cancer research which deliver clear benefits to cancer patients and the UK economy. Recent CRUK research has found that every £1 invested in cancer research generates £2.80 in economic benefits. This represents a benefit cost ratio (BCR) of 2.8.<sup>2</sup>

While provisions in the TCA annex on medicinal products and current grace periods mean that medicines can currently enter GB from the EU/EEA without substantial trade barriers, it is important to ensure this remains the case. According to research from Nuffield Trust there has been a drop in exports from around £1 billion worth a month to around £700 million worth a month between 2016 and 2021. The research found this drop in UK medicines exported to the EU can likely be ascribed to, among other factors, a lack of clarity over future regulation and barriers to export, whether specific to medicines or due to a general hard customs border.<sup>3</sup> Options B, C, and D would create varying levels of uncertainty and trade barriers which could result in a drop in EU/EEA exports to the UK, posing a threat to supply and availability.

A similar dynamic occurred when uncertainty and potential trade barriers between Great Britain (GB) and Northern Ireland (NI) resulted in the risk of more than 2,000 medicines being withdrawn from the NI market.<sup>4</sup> Any future batch-testing regime must avoid erecting trade barriers and generating uncertainty which could hinder the supply and availability of medicines for people affected by cancer in the UK.

Long term certainty would be best achieved through the agreement of an MRA on batch-testing and QP certification with the EU. While an MRA is not in scope of this consultation, CRUK believes it should be a medium to long term policy objective for the UK Government and the European Commission. An MRA would ensure long-term compatibility between the UK and EU/EEA countries on batch-testing and QP certification which would establish long term certainty of supply of medicines for cancer patients in the UK.

CRUK believes the first step to achieving this is operationalising the Working Group on Medicinal Products as agreed in Annex TBT-2, Article 12 of the EU-UK Trade and Cooperation Agreement (TCA). In a meeting of the Trade Specialised Committee on Technical Barriers to Trade in October 2021, there was a commitment for the Working Group to meet in Q1 of 2022<sup>5</sup>, but we understand this has not happened. The Working Group on Medicinal Products should at the earliest opportunity convene its first meeting, followed by subsequent regular meetings, to ensure cooperation and

regulatory compatibility on medicines. The UK Government and the European Commission should use this Working Group as a forum to work towards a future MRA between the UK and the EU on batch-testing and QP certification.

*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.*

Low-cost generic medicines with small profit margins would likely be adversely affected by the costs involved with setting up new testing infrastructure and acquiring UK QP certification. In cancer treatment, this could negatively affect the availability of anti-sickness medicines (essential for many patients' quality of life), steroids, and some generic chemotherapies.

*Question 15: What mitigations would you put in place to minimise supply disruption for these products?*

Support and ample time for industry to prepare for any changes to regulations and supply chains will be key to avoiding any disruption or delays to the availability of medicines for cancer patients. It is vital that suppliers and logistics companies are well-prepared for any future changes.

We have heard anecdotally from scientists about challenges with the supply of medicinal products since 1 January 2021. For example, in June 2022, a medicine from Sweden was stuck at Stansted Airport at the wrong temperature with scientific experiments delayed until a new medicine could be sent and get through customs. The DHSC National Supply Disruption Response (NSDR) team has been supporting CRUK scientists with shortages since early 2021. The NSDR advised CRUK in 2021 that some logistics companies – it is our understanding from CRUK's research community that FedEx is particularly challenged – have struggled to understand and implement the new regime. The Government and the MHRA must therefore ensure any changes to medicines regulations are fully understood by suppliers and logistics companies to avoid disruption to the supply of life-changing medicines.

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<sup>1</sup> ABPI. 2021. Manifesto for Medicine. Accessed July 2022 via:

<https://www.abpi.org.uk/media/2nxpmbw2/manifesto-2021-published.pdf>

<sup>2</sup> CRUK. 2022. Understanding the economic value of cancer research. Accessed July 2022 via:

[https://www.cancerresearchuk.org/sites/default/files/economic\\_value\\_of\\_cancer\\_research\\_-\\_cruk\\_full\\_report\\_29-06.pdf](https://www.cancerresearchuk.org/sites/default/files/economic_value_of_cancer_research_-_cruk_full_report_29-06.pdf)

<sup>3</sup> Nuffield Trust. 2021. Going it alone Health and Brexit in the UK. Accessed July 2022 via:

[https://www.nuffieldtrust.org.uk/files/2021-12/1639914471\\_nuffield-trust-health-and-brexit-in-the-uk-web.pdf](https://www.nuffieldtrust.org.uk/files/2021-12/1639914471_nuffield-trust-health-and-brexit-in-the-uk-web.pdf)

<sup>4</sup> BBC. 2021. Brexit: More than 2,000 medicines face withdrawal over Protocol. Accessed July 2022 via:

<https://www.bbc.com/news/uk-northern-ireland-57941657>

<sup>5</sup> UK Government. 2021. Trade Specialised Committee on Technical Barriers to Trade, 15 October 2021 Meeting Minutes and Operational Conclusions. Accessed July 2022 via:

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