Medicines & Healthcare products Regulatory Agency

Government response: consultation on proposals to support the regulation of medicines manufactured at the Point of Care

Published 25 January 2023

Contents

Executive Summary

New types of innovative products, such as those with very short shelf lives, are required to be manufactured and supplied at the point where a patient receives care (POC). The current human medicines legislation is geared for products which can be manufactured at a very small number of sites and supplied globally. In contrast, POC products, may only have a shelf-life of minutes or need to be highly personalised, so have to be manufactured on demand when the patient is present. This could mean manufacturing a POC product at hundreds of sites across the UK alone. A new regulatory framework will support the manufacture and supply of these innovative products.

The MHRA led a joint public consultation with the Northern Ireland Department of Health in accordance with Section 45(1) of the Medicines and Medical Devices Act 2021, seeking views on a legislative proposal to introduce a new regulatory framework for the manufacture and supply of POC products.

Comments and views were expressed from a variety of stakeholders from across the UK and internationally. There was significant support for the creation of a new UK regulatory framework for manufacture and supply at the POC. Responders also supported a wider scope of manufacturing and supply, for the framework to also include modular manufacture and home-based manufacture. Based on this feedback, we will prepare a statutory instrument to introduce the new framework. Future guidance will be developed alongside the statutory instrument to provide the necessary interpretation and procedural support.

The new regulatory framework will be based on and link into the current regulatory systems for medicines approvals, clinical trials, evaluation of regulatory compliance at manufacturing sites and safety monitoring. The safety, quality and efficacy of POC products will remain paramount. This framework is similar in concept to that established for control of blood products, which delivers regulatory control of quality while delivering the necessary flexibilities for the product type.

The new framework will support increased manufacture and supply of new products manufactured at POC whilst ensuring that these products retain equivalent levels of safety, quality and efficacy currently in place for medicinal products manufactured in factory-based locations. Providing a new framework, tailored to these innovative products, will improve the availability of novel products, benefiting patients across the UK.

Introduction

The MHRA hosted a public consultation on point of care (POC) manufacture from 12 August 2021 to 23 September 2021. The consultation sought views on proposals to amend The Human Medicine Regulations 2012 and the Medicines for Human Use (Clinical Trials) Regulations 2004 to create a new framework to enable the supply and increase the availability of innovative new medicinal products to patients. This is the formal Government response to that consultation.

The objective is to provide an enabling framework to support increased manufacturing and supply of innovative medicines that can only be manufactured at the point of care. An enabling framework is particularly important in this area where there are rapid and continued technological developments. This will, in turn, improve the availability of novel products to patients, benefiting patients where there may currently be no or few treatment options. The proposed POC framework will deliver on commitments made in the UK Life Sciences Vision to deliver a progressive UK regulatory offer that supports early patient access to novel treatments by providing regulatory clarity for POC manufacturing of advanced therapies and products.

The consultation proposals included three key areas:

- The requirement for a new regulatory framework: a description of the regulatory impediments hindering or preventing products that are required to be manufactured and supplied at or near the POC.
- A proposed framework that is tailored for products manufactured at POC: a regulatory framework that allows for manufacture and supply at or near the POC and which has proportionate controls across the different stages of development and manufacture to retain equivalent levels of safety, quality and efficacy currently in place for more conventional medicinal products.
- The scope of manufacturing and supply scenarios: a range of scenarios were presented, ranging from those similar to current factory-based manufacture termed modular manufacture, through mobile manufacture, POC manufacture and extending to home-based manufacture.

The proposed new framework sets out a model of regulatory requirements to provide the necessary regulatory oversight to assure that POC products have appropriate quality, safety, and efficacy attributes, whilst allowing the increasing numbers of patients to benefit from these innovative products in clinics and hospitals around the country. The framework is centred on a Control Site, which will be the only location named on the manufacturing authorisation, the Control Site will be required to maintain a POC Master File which amongst other information will name all of the individual POC manufacturing sites and this will be the mechanism to authorise those sites of manufacture. This Control Site will oversee all aspects of the point of care manufacturing system, including the individual manufacturing locations and their activities and be named on clinical trial and marketing authorisation applications. For example, the Control Site would be responsible for ensuring quality of the product and notifying the MHRA of any issues. The new regulatory framework will link into current

regulatory systems for medicines approvals, clinical trials, evaluation of regulatory compliance at manufacturing sites and safety monitoring. Some of the key regulatory foundations are based on those that have successfully been in use for many years in other areas of medicines and related regulations.

This document provides a summary of the feedback received to the consultation and the Government's response.

Overview of consultation activity

A total of 51 complete responses were received, 16 were from individuals and 35 were from organisations. Although some organisational responses were from single organisations or single academic institutions, several were from larger groups that represent many companies or institutions with a range up to approximately 330 companies.

Responses were received from across the UK and internationally. The majority of individuals, 15, were from GB and 1 was from Canada. The organisational respondents' coverage were: 9 from GB, 13 UK wide, 2 Northern Ireland based, 2 operating in both the UK and the EU, 1 from Italy, 6 from global organisations and 1 did not indicate their area of coverage.

The consultation proposals were developed through a series of engagements and workshops with participation from a wide range of groups and organisations. Further discussions were also held during the open period of the consultation with a range of stakeholders. A dedicated patient engagement workshop was held to hear views directly on the proposals from a number of patient representatives from the MHRA's Patient Group Consultative Forum (PGCF), which includes a broad and inclusive membership of organisations and individuals from across the whole of the UK.

Summary of responses

We have carefully reviewed and analysed each of the responses received. The overwhelming majority of responses were positive, where 91% of responders agreed with the need for a new POC framework and 94% agreed with the proposed framework. There was also positive support for the framework to apply across the full range of manufacturing scenarios described i.e. modular manufacture (75%) and home-based manufacture (71%).

Some comments raised concerns about the lack of detail in the measures that will be put in place to assure the equivalent level of quality of products manufactured at the POC. The safety, quality and efficacy of medicinal products is of the utmost importance. In introducing a framework to support these products there will be no compromise on the standards that must be met. Ensuring that appropriate control measures are in place has been a key feature of discussions at stakeholder meetings so far. We intend to run further meetings and workshops to discuss, develop and implement these measures with the benefit of written guidelines. These guidelines will not be in legislation but will provide guidance on the interpretation of the legislation in order to provide operational details for the scheme. Future workshops will be held which will provide a mechanism for the guidance to be reviewed and updated at regular intervals as experience is gained with the new framework.

Further summary details of the responses received to the specific consultation questions are provided below.

Experience with and benefits of POC products

The responses included several from those with direct experience of POC – 3 out of the 16 individual respondents and 8 out of the 35 organisational respondents. This included a range of healthcare professionals, some with direct experience of prescribing or supplying POC products. In describing their experience with POC products, responders highlighted the current need to establish a regulatory framework for these products and how this may bring a range of benefits to:

- Patients and carers – benefiting from new and more personal treatments accessed in a timely and more convenient manner with the potential for less travel and time spent in hospitals.
- Health Care Professionals - by improving the range and effectiveness of treatment options and also improving patients' adherence with those treatments.
- Payers / funders - the potential for reduced overall treatment and social care costs,
- Innovators - can continue to develop or can start to develop new products with clarity of regulatory expectations.

Other comments received included:

- The consultation has raised patient expectations regarding the need to produce a new framework to support this promising means of delivering new treatments.

- The need to ensure good operational and clinical governance to deliver equivalent standards of product quality, safety and efficacy to those that apply currently to manufactured products.

The creation of a proportionate regulatory framework that safely supports the significant and rapid technological advances for the benefit of patients is a key focus for the MHRA. Good governance in healthcare institutions will be an important element in the successful delivery of this framework, and we will work with partners across the healthcare system to support the institutional readiness of healthcare establishments for this new range of activities.

Question 1: Do you agree that point of care manufacturing is sufficiently different to the current 'standard model' of factory-based manufacture of medicinal products that a new framework is required?

Breakdown of responses:

- **individual respondents** **yes 81% (13/16) no 19% (3/16)**
- **organisational respondents** **yes 94% (33/35), no 6% (2/35)**
- **37 written responses**

Overall, there was a high degree of agreement that manufacture at POC is sufficiently different from the current centralised model of manufacture, where medicines are manufactured at a large scale at a central site for distribution to other sites for patient supply. There was strong support for the creation of a new regulatory framework for manufacture and supply at POC or other "decentralised" manufacturing formats, such as modular, mobile and home-based manufacture.

Individual and organisational respondents highlighted that current medicines regulation does not consider or allow for manufacture in distributed locations. Respondents also highlighted the benefits of the proposed Control Site concept, which in essence is the 'hub' in a 'hub and spoke' approach to the control of manufacture at the points of care, which are the 'spokes'. The 'hub and spoke' model involves a central licence of the Control Site (the hub) which through the POC Master File authorises the multiple manufacturing sites (the spokes) that connect to the hub. These benefits included a proportionate and risk-based mechanism to add new manufacturing sites in order to increase manufacturing capacity (i.e. 'scale-out'), without the lengthy and expensive regulatory processes of repeatedly updating clinical trial or marketing authorisations and manufacturing authorisations. Respondents also commented that a new framework could bring a wide range of benefits such as support for a new generation of innovative business, therapies getting to the clinic faster and patients having access to a wider range of new therapies with additional practical benefits such as reduced travel to specialist centres. Further comments were received on the opportunities to build public trust in this new regulatory framework and to prevent the sale of unproven therapies.

Responders did also raise some concerns including:

- Ensuring appropriate controls at the sites of manufacture, particularly given that there would be limited or no time to conduct analytical tests after manufacture and prior to administration to the patient.
- Ensuring that new POC sites and their staff had the requisite qualities to manufacture products that were safe, efficacious and of an appropriate quality.
- Ensuring sufficient oversight of the manufacturing sites by the Control Site, a sufficient number of Qualified Persons, training and competence of operators and robust measures for the release of products that meet specifications and systems to control changes.
- Provision and robustness of reporting systems that link the Control Site and the different POC sites.
- Provision of new regulatory guidance documents.
- Clarity on how this framework fits in with the current exemptions such as those for doctors, pharmacists and manufacture of unlicensed medicines ('specials').

Government response

We welcome the many and well-considered comments and thank the respondents for the time taken to reflect upon and respond to the questions. The majority of comments were positive and agreed with the need for a new framework. We will therefore take forward legislative changes to implement a new regulatory framework tailored for POC products. Where concerns were raised these largely related to operational points that will need to be addressed in how the new framework is implemented in practice and the guidance that will accompany any new legislation, for example new Good Manufacturing Practice (GMP) guidance material.

Ensuring POC products meet the same quality, safety and efficacy as products currently manufactured is central to the new framework. The new framework will outline regulatory control measures to assure a focus on product safety and quality across the lifecycle of each and every product. There will be specific criteria to be met at application for a POC manufacturing authorisation, during clinical trials, at assessment for marketing authorisation, at inspection and also through pharmacovigilance when the product is in routine manufacture.

To ensure control of the quality of products with short shelf life where there is little or no time to conduct product testing after manufacture, we will use manufacturing control mechanisms that currently exist in medicines regulation. Manufacturers will need to comply with GMP, but the expectations will be adapted to suit the nature of POC products. For example, traditional end-product testing may not be appropriate for products that are being used almost immediately after manufacture. As an alternative, we will use the principles of Real Time Release Testing which combines monitoring during the manufacturing process and other GMP controls, such as ensuring the use of appropriate equipment and staff training. Criteria for the evaluation of the suitability of new POC sites, will be included in the responsibilities of the Control Site.

Responders raised a number of areas that are outside of the scope of the proposals, for example, funding and clinical governance cannot be addressed through legislative changes to the Human Medicines Regulations. However, these are important elements that will need to be in place for successful implementation of the new framework and will be discussed with other regulators who have responsibility for those aspects.

The new framework is separate from and does not affect or apply to the current exemptions for doctors, dentists and pharmacists. The POC framework supports the scaled out, consistent and reproducible manufacture of products across a relatively large number of POC sites. This contrasts with the doctors' and dentists' exemption which allows for manufacture of individual treatments directly by the doctor or dentist for their individual patient or a patient under the care of another doctor or dentist in the same group or practice.

Manufacture at POC will still be possible as an unlicensed medicine via the 'Specials' route (through which an unlicensed medicinal product can be supplied in order to meet the special needs of an individual patient). However, considering the potential for manufacture at a large number of sites, the grant of an authorisation to manufacture POC products as a Special (current requirements outlined in Guidance Note 14) will include further requirements within the new POC framework. These include the provision of science-based evidence of product safety and manufacturing consistency at the time of applying for a Specials manufacturing licence with further requirements for pharmacovigilance.

Question 2: Do you agree with the proposals for the new regulatory regime for POC products?

Breakdown of responses:

- **individual respondents** **yes 100% (16/16)**
- **organisational respondents** **yes 91% (32/35), no 9% (3/35)**
- **53 written responses**

There was a high degree of agreement with the proposals for the POC framework. Of the 3 organisational respondents that did not agree with the proposed framework, 2 did not provide further explanation and the third provided comments which supported innovative regulatory models including the POC framework, subject to appropriate product safety and quality safeguards. The other types of safeguards that were requested were a 'level playing field' for all manufacturers, ensuring adequate oversight by the Control Site and Qualified Persons and appropriate manufacturing site controls, such as equipment validation and process validation.

Comments by other organisational respondents stated that POC controls need to be carefully balanced in order to avoid excessive requirements that would hinder patient access. It was noted that that some POC products will be made by additive manufacture (3D printing) and some respondents requested GMP guidance specifically for this class of manufacture. We will work with international regulatory agencies to develop such guidance.

The concept of the POC master file system as the key single source of information on the state of control over the POC system was received positively. This would be used at Clinical Trial and Marketing Authorisation applications in place of naming multiple sites of manufacture. In particular, respondents supported allowing flexibility to add new sites and manage Qualified Person oversight, providing information for MHRA oversight, and to assure the quality, safety, and efficacy of POC-manufactured medicines. Suggestions were made to merge elements of existing documents, such as the Site Master File, Product Specification File and the Trial Master File, to help simplify regulatory requirements. Others suggested the inclusion of product lifecycle management. Some respondents would also welcome further detail as to how post-approval change management protocols may be implemented.

The challenges of implementing medicines manufacture by those at the POC were raised, with responders noting that the professionals manufacturing POC products, in many locations, will be healthcare professionals who may in some circumstances also be involved in providing clinical care. There would need to be assurance of the responsibilities, training and qualities of the nominated individual who would be accountable for complying with the established POC procedures. Reference was made to ensuring appropriate clinical governance arrangements will be in place and the need for industry and MHRA to work in partnership with the NHS.

Government response

The high degree of agreement on the proposals for the POC framework has indicated significant support, and we will take forward the necessary legislative changes to implement the proposed new POC framework.

In developing this framework, patient safety is key and will be based on compliance with established assessment and inspection measures that are in place for current products. These will be adapted to assure the quality and consistency of the manufacture of products in distributed locations and which will have a short shelf life.

We are clear that use of the POC framework should not undermine the current centralised (factory-based) manufacturing model. The current model is expected to represent the default manufacturing option, unless manufacture at POC can be justified as essential because of the nature of the product, e.g. for products with very short shelf-lives.

We welcome the helpful range of comments about specific operational aspects, such as contents of the POC Master File. These operational aspects will be an important part of discussion in further stakeholder meetings and will be considered in detail in the new regulatory guidance documents that will accompany the legislative framework.

Training of staff at the POC manufacturing sites will be very important in ensuring the quality of products and consistency of manufacture between manufacturing sites. The training system, both initial and ongoing training of staff, will be the responsibility of the Control Site and will be a key element of regulatory inspections.

Question 3: We are seeking to clarify the scope of the new POC regulatory framework in relation to the above manufacturing categories.

- ***3a. Do you consider that the new POC regulatory framework should be further adapted to also cover modular manufacturing?***

Breakdown of responses:

- **Individual respondents yes 50% (8/16), no 6% (1/16), unsure or no reply 44% (7/16)**
- **Organisational respondents yes 86% (30/35), no 11% (4/35), unsure 3% (1/35)**
- **26 written responses**

A range of manufacturing options were presented in the consultation which went beyond factory-based manufacture including modular manufacture (self-contained unit operations which are relocatable), mobile manufacture (conducted in specialised technically equipped vehicles), manufacture at point of care and home-based manufacture.

Half of individual respondents and the majority of organisational respondents agreed that modular manufacture should be covered by the POC framework.

Several individual respondents were unsure or did not reply; this could be because they were less familiar with POC manufacturing options. Some organisational respondents believed that existing GMP guidance could cover modular manufacture.

Government response

The majority of respondents, including established pharmaceutical manufacturers and the trade associations, supported coverage of modular manufacturing facilities by the POC framework. Considering this support for increasing the scope of the framework we will look to adapt the legislation and GMP guidelines, which are geared for manufacture at fixed sites, to accommodate relocatable manufacturing facilities.

- ***3b. Do you consider that the new POC regulatory framework should extend to cover home based manufacturing?***

Breakdown of responses:

- **Individual respondents yes 50% (8/16), no 6% (1/16), unsure or no reply 44% (7/16)**
- **Organisational respondents yes 80% (28/35), no 9% (3/35), unsure or no reply 11% (4/35)**
- **31 written responses**

Half of individual respondents agreed that the POC framework should cover home-based manufacture and the majority of organisational respondents were also supportive.

A range of helpful comments were made including the need to avoid excluding home-based manufacture from this framework since new technologies with improved automation and

controls at distance are likely to develop and an enabling framework will create opportunities for new product developments. Several responses cited the improved patient-centric nature of home-based manufacture. Other comments highlighted the need for robust technologies for home use and the need to include human factors in the design and operation of the equipment used for manufacture, plus consideration of the ease to store and use starting materials. Comments were made on the increased communication needs between the patient (and/or their carers) and equipment and starting material supply sites, in order to maintain availability of manufacture and product for the patient.

Government response

Similar to modular manufacture, the majority of respondents supported including home-based manufacturing within scope of the new framework. We will look to adapt the legislation and GMP guidelines to also accommodate home-based manufacture.

The comments were very helpful in focusing in on the issues to address to create a successful home-based manufacturing pathway. The patient and carer perspectives and the benefits they will derive are in line with the MHRA's objectives for greater systematic patient engagement in delivering safe and innovative treatments. The rapid technology developments in this area reinforce the need for the legislation to be enabling and the guidelines that interpret that legislation to be adapted as experience is gained. Additional safeguards will be drawn up for these manufacturing circumstances which will address human factors, considering that users of the home-based equipment may be relatively inexperienced.

- ***3c. Do you consider that there are other areas of POC manufacture that should be covered?***

  23 written responses (7 from individuals, 16 from organisations)

This question gained fewer responses in comparison to the other consultation questions. One comment stressed the need to allow for future POC products without having further recourse to legislative changes to create an enabling legislative framework at the outset. Many organisational respondents echoed this view, to allow for flexibility and future-proofing by including only broad scope and key principles in legislation and to develop operational details as experience is gained.

Other comments related to devices - a request that any devices comply with appropriate International Organization for Standardization (ISO) standards and to clarify the borderline between medicines and devices and to avoid bringing in products that are covered satisfactorily elsewhere such as radiolabelled blood products used for diagnostics.

Government response

The creation of an enabling, future-proofed legislative framework for POC manufacture is fully supported and will be a key focus in drafting the legislation. A primary aim for the new framework is to support future innovations by ensuring that our regulations are enabling to new technologies. The legislation will aim to deliver a coherent legal framework that focuses

on principles, with the working details captured in regulatory guidelines which can be updated as experience is gained.

We understand that the borderline between medicinal products and medical devices is an important area of consideration. Where products are adequately covered through current regulatory frameworks, the POC framework will complement those arrangements. There is a significant opportunity for the UK to clarify regulatory requirements for medicinal products and medical devices where the POC framework will complement existing arrangements and the new arrangements that will be developed following the public consultation the MHRA ran on the future regulation of medical devices.

- ***3d. If you consider that this new framework should not be adapted to cover one or more of these above manufacturing categories, what regulatory controls do you consider are required?***

  11 written responses (2 from individuals, 9 from organisations)

The majority of comments re-stated that patient safety is paramount, in addition comments were received on the need for the regulatory framework to be future proofed, to avoid allowing unregistered or unproven products onto the UK market and to avoid the possibility of products circumventing the rigours of clinical trial assessments and marketing authorisation assessments. Comments also reiterated the wish for legislative clarity on decentralised manufacture (i.e. manufacture outside the current factory-based model) and the need for significant oversight and controls for home-based manufacture.

Government response

We fully agree with the primacy of patient safety. Patient safety will be central to the new regulatory framework, and a major focus will be to ensure that the necessary safeguards are in place.

We also agree with the need to future-proof the regulatory framework since it is clear that new technologies are rapidly emerging. As previously stated, the regulatory framework will comprise legislation that is principle-based, to enable changes and guidelines which will interpret the legislation to provide operational details for the scheme which will be reviewed and updated at regular intervals as experience is gained.

Question 4: Are there other aspects of the POC framework that you believe have not been considered?

38 written responses (9 from individuals, 29 from organisations)

A wide range of thoughtful comments were provided. These included that the new regulatory framework is a key positive impact on the UK in providing high value jobs and the potential for this framework to enable smaller developers to reach the clinic faster and with lower cost

of goods. Comments were made on the how the proposed framework will cover issues such as data security, and the inclusion of failsafe systems particularly in home-based manufacture.

Some comments in this section were repeated from earlier questions. These included:

- continue the engagement with stakeholders across all areas of this framework and to utilise similar or related experiences from other short shelf-life medicines
- keep the legislative development process transparent and at high level
- ensure primacy of patient safety, which is a challenge where there is limited or no ability for end product (Quality Control) testing and remote location of Qualified Persons
- the potential for a range of improvements to patient and carer experiences
- avoid undermining the current standard model of medicines manufacture and to utilise existing skill capabilities in the NHS
- provide clarity on areas of overlap with devices
- provide clarity on the relationship between this framework and the current exemptions and Specials
- provide clarity on manufacturing vs. dispensing and reconstitution
- the potential for the positive effect in UK to influence other regulators including encouraging non-UK based operations

Government response

It was very helpful to see that this framework has a potential significant benefit to many parties, in particular to patients, their families and carers but also to developers, large and small, and to individuals where new job opportunities will be created. The positive effect of this framework should also benefit patients in areas outside the UK – the same medical conditions affect patients across the globe and almost certainly there will be similar regulatory regimes that are focused on factory-based manufacture. To support this, the MHRA has initiated discussion with several regulators outside the UK.

Comments on the need to avoid undermining the current factory-based manufacturing model and to ensure the maintenance of patient safety are fully recognised. The proposed framework will support this, such that the current factory-based manufacturing is the default position with several check points at the different stages of regulation to ensure that manufacture at POC is justified including:

- at manufacturing authorisation application: the need to provide clear justifications on the necessity to manufacture at POC
- at clinical trials: the demonstration of consistent manufacture of product meeting safety, quality and efficacy criteria across a number of POC sites and that the number of sites meaningfully represents the proposed commercial number of POC sites
- at marketing authorisation application: assessment that safety, quality and efficacy data are acceptable
- once the product is on the market: monitoring of safety data continues to support manufacture at POC.

Consideration of the matters set out in Section 2 of the Medicines and Medical Devices Act

For medicines, the appropriate authority is the Secretary of State in relation to Great Britain and the Department of Health in Northern Ireland in relation to Northern Ireland.

The consultation was carried out in accordance with the requirement in Section 45 of the Medicines and Medical Devices Act 2021.

In making regulations under section 2 of the Act, the overarching objective is to safeguard public health.

In considering this policy, and regulations that would be needed to give effect to it, the appropriate authorities have had due regard to:

- the safety of medicines within the scope of this policy
- the availability of medicines within the scope of this policy
- whether the United Kingdom is likely to be seen as a favourable place in which to: research the medicines within the scope of this policy, develop medicines within the scope of this policy or manufacture or supply medicines that come within the scope of this policy.

Throughout this Government response we hope to have demonstrated how the MHRA has listened to the themes concerning patient safety, availability of medicines, and the favourability of the UK for developers. The new POC framework aims to increase the breadth of manufacturing and supply options, and the consultation responses were primarily positive that a new framework would support that aim. Examples included the increased range of products that will benefit UK patients, the improved quality of care due to reduced need for patients and their carers to travel and to stay in hospitals and other healthcare institutions. Additionally, patient benefits were recognised such as improved compliance with their treatment programmes due to their greater involvement with the product.

Positive comments were received on the increased availability of medicines through POC manufacture. These medicines have so far either not been possible to provide to patients or with very substantial limitations. The new framework provides the ability to scale out some elements of manufacture, which will mean greater availability for patients. Another benefit in enabling medicines to be delivered outside of immediate healthcare settings, such as at home, has the potential to help take some pressure off the NHS.

Responders were also generally positive about the POC proposal in terms of supporting the UK as an advantageous place for innovators to develop new products, providing high value jobs, encouraging conduct of clinical trials in the UK and increasing the supply of these new types of products. It was considered that this was a forward thinking / world leading proposal by the MHRA, which had the potential for the positive effect that will be seen in the UK to also influence other regulators and benefit patients outside of the UK.

Conclusion and next steps

This consultation has provided extremely valuable feedback on our proposals which have helped us develop and further refine how best to provide a new framework for POC manufacturing. The overarching response has been supportive to the intent of the proposals and has given a clear indication that stakeholders are supportive of introducing the new UK legislative framework within the Human Medicines Regulations and the Clinical Trial Regulations.

To ensure the successful implementation of this new regulatory framework, the MHRA has started work on a joined-up approach with other regulators within the UK and internationally. For the latter, the aim is to facilitate the development of equivalent regulatory approaches in other territories. This will benefit patients in those additional territories through aligned regulatory approaches and also further encourage innovation and industrial development in this area of medicinal products supply.

We will now take steps to make a Statutory Instrument under the Medicines and Medical Devices Act 2021 to provide a legislative framework for POC manufacture and supply. We recognise that the guidance that accompanies the legislation will be critical for implementation and interpretation of the legislation and we will work with stakeholders in producing those guidance documents.

We wish to thank everyone who submitted a response to this consultation and has engaged with us so far on the proposals for POC manufacture.