

**Consultation on Point of Care manufacturing**

**Royal Pharmaceutical Society Response**

**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?**

* Yes. However, those products which can employ POC manufacture should have defined criteria. Criteria for products where POC manufacture can be utilised should be unambiguous. For example, defining parameters for “very short shelf life”.
* POC manufacture should apply only where a product is strictly required to be manufactured at POC due to very short shelf life or to meet an immediate patient needorwhere it is not feasible to manufacture using the lower risk standard model. The use of the term “option” should be reviewed.

Additional arrangements are required to support development of POC products including:

* Clarity on where liability and governance lie for POC manufactured products
* In the instance where a clinician administers a product which has “failed”, what liability does the POC site’s legal body hold?
* Clarity on QP oversight:
* Will this continue to be in accordance with current Annex 16?
* Will a QP still be required to be named on each MIA?
* Will QPs be required to retrospectively certify each single batch?
* In the instance where a clinician administers a product which has “failed”, what is the role/legal position of the QP?
* Further detail required on the “nominated individual” at the POC site who would be accountable for complying with the established POC procedure – if QP delegation is an expectation this individual must have knowledge of PQS etc. (Personnel from pharmacy departments are the only HCPs likely to have an insight into the requirements and would be obvious choice in a hospital setting)
* Detail is required on how variations will apply to POC framework. How will they be controlled/reviewed where adding MIA sites to Marketing Authorisations for example?

**Question 2**

**Do you agree with the proposals for the new regulatory regime for POC products?**

* Agree with the scope of the proposal and principle of control site however further details on the regulatory regime are required.

Additional arrangements are required around:

* Clarity of QP oversight
* Implementation of the framework.
* Governance

**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?**

No this framework should not be adopted to cover modular manufacture as:

* MM sites can be regulated via the existing framework. Any change should require a variation to licence.
* MM is already suitably assessed via MIA/ MIA(IMP) application and regulatory audits.

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

* Yes, the same framework irrespective of site of manufacture should cover all POC products including home settings if appropriate.
* The requirement for POC products should be patient centric thus manufacture should occur where is best for the patient (short shelf life/ urgent need), this may be in a home environment.
* Suitability of POC manufacture site will be assessed in the MAA/CTA .

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

* The POC framework should consider pharmacy premises. This would be an effective middle ground between a hospital setting and home. With Primary Care Pharmacists trained to make and administer POC manufacture products

**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?**

* The current regulatory controls are suitable to control modular manufacture (eg: maintenance of quality system ensures validation).

**Question 4**

**Are there other aspects of the POC framework that you believe have not been considered? This could include any additional positive and negative impact that the framework may have on the delivery of healthcare in the UK.**

Aspects that have not been considered:

* The framework has potential to undermine the standard model of manufacture. To ensure this does not occur:
* MHRA should provide set criteria for products where POC manufacture can be utilised.
* POC manufacture should be utilised as the exception rather than the norm.
* Lower risk processes of traditional manufacturing should always be used where possible with POC manufacture employed only where necessary to ensure this adds value rather than creating risk.
* Acknowledgement that the manufacturing capabilities of existing NHS units could provide safer alternatives to POC manufacture where shelf life is short.
* Exemptions in Human Medicines Regulation 2012 may require further consideration with respect to POC manufactured products:
  + Products prepared by a doctor or dentist under regulation 3(5) of the HMR
    - In many cases, the level of risk in allowing an innovative clinician to prepare a POCM is not considered to be outweighed by the level of risk to the patient. Clear instructions for clinicians with innovative products to progress should be available, however.
  + Products prepared in a pharmacy under regulation 4 of the HMR
    - Defined parameters and NHS guidelines should be defined as is the case for S10 exemption to prepare injectable medicines in aseptic pharmacies
  + “Specials” products manufactured under Regulation 167 of the HMR
    - If the clinical area in a hospital is to become a control site as a clinician has an innovative POC product that will benefit a patient under their care , how will this affect the MS held by the hospital? Will it need to be an additional site on the MS? Is the scope limited to commercial MS holders who will bear liability for the quality and safety of the product? How will the quality of the unlicensed medicines be assessed as per GN14?
* The interfaces involved in the processes of POC manufacture require much further detail. Legal responsibilities must be defined.
* Will POC manufacture remain “innovative regulation” when the framework passes through parliament. Risk that this will slow the process, make it more difficult and present barriers to companies who may select EU (where no current POC framework exists) over GB .
* The level of QP oversight required must be clearly defined
* Clarification required on whether there will be specific legal duties for the QP for POC manufactured products.
* Can MHRA provide clear definition of what legal responsibilities can be delegated by the QP?
* Prospective versus retrospective QP certification :
* Prospective certification should be maintained where possible i.e., prospective certification is default.
* Retrospective certification should only occur where prospective release is unavailable and will require real time review at site by a suitably qualified “responsible person” ie the “nominated individual” at the site who is not a QP but is required to perform reviews/checks prior to administration.
* How will this “nominated individual” be prevented from “releasing ” for reasons of convenience or clinician pressures?
* How will the framework link to resource/ safe capacity at POC manufacturing sites?
* Will MHRA Medical Device assessors have the necessary knowledge to determine if a product is a medical device or in fact requires classification as POC manufactured medicinal product?
* Will existing medical devices be reviewed to establish if they are POC manufactured products when this is defined?
  + Existing medical devices which make medicines are not routinely tested to assure quality. Although QP oversight may be difficult these should require routine quality control testing. For example an oxygen purifier in an ambulance should have to comply with quarterly testing in the same way air compressors must comply with HTM-02.
* The consultation document requires more detail on the proposed regulatory framework, perhaps this can be feedback post consultation period?
* More specific examples of POC manufactured products would be beneficial for application of the proposed framework.
* An opportunity to have a wider view of the collective feedback on this consultation to assist in understanding the broader view around the proposed POC framework would be beneficial.