



Conditions for authorisation for emergency supply under Regulation 174 for COVID-19 Vaccine Moderna

7 January 2021, and amended 28 January 2021

General

1. This temporary Authorisation under Regulation 174 permits the supply to and by the Crown of COVID-19 vaccine Moderna based on the safety, quality and efficacy data submitted by Moderna to MHRA in the period from 26th October 2020 to 5th January 2021.
2. This authorisation is not a marketing authorisation for the purposes of Part 5 of the HMRs or Chapter 4 of Title III to the 2001 Directive.
3. This authorisation applies to supply within England, Scotland and Wales.
4. As provided in Regulation 174A(2) of the Human Medicine Regulations, the sale or supply of this vaccine will not be deemed to be licensed or approved under this Authorisation if the supply is for the purpose of any use other than the recommended or required use, or if a condition in this authorisation is breached (including the conditions of use incorporated into this Authorisation).
5. The entities responsible for physically supplying the product in the United Kingdom are Moderna Biotech UK Limited (company number 11990046), 11th floor, Whitefriars, Lewins Mead, Bristol, BS1 2NT and Moderna Biotech Spain S.L., Calle Del Monte Esquinza 30, Madrid, 28010 Spain (hereinafter Moderna). These entities will be jointly and separately responsible for placing the product on the market in the United Kingdom for the purposes of The Human Medicines Regulations including Regulation 345(3).
6. Moderna are jointly and separately responsible, with the manufacturers of the product, for the conditions relating to the manufacture of the product and product release to the market under the terms of this authorisation.
7. Moderna are not only responsible for compliance with the conditions expressly applied to Moderna in this authorisation but also, where the conditions apply legislation or guidance that confers responsibilities on marketing authorisation holders, for compliance with any responsibility however worded that applies to a marketing authorisation holder in the applied legislation or guidance.
8. Moderna must promptly provide to MHRA any further data, recommendations or guidance that is generated by them, or which otherwise come into their possession, which is relevant to the risk / benefit profile of the product and/or is relevant to the conditions of use.
9. Moderna must respond in a timely manner to any requests from the MHRA for further supplementary data or requirements relating to the product. Moderna must provide relevant additional data regarding drug product manufacturing process, product quality, non-clinical and clinical data reasonably requested by MHRA.

10. Any deviations from any of these conditions can only be made with the prior agreement of the MHRA.

11. MHRA may review and adjust these conditions for temporary supply in response to any developments which it considers material, including any subsequent market authorisations that might be issued by other medicines regulators.

12. This authorisation will be valid until expressly withdrawn by MHRA or upon issue of a full market authorisation by the MHRA.

13. Without prejudice to any terms that Moderna and its affiliates, may have agreed separately with the Crown, Moderna submits to the exclusive jurisdiction of UK courts for the purposes of any dispute related to, or arising out of, the use or distribution of the Moderna vaccine in the UK, whether or not the dispute involves MHRA.

Product information and Instructions for Use (PIL and SmPC equivalent)

14. Moderna must liaise with the MHRA to agree suitable product information and instructions for the storage, distribution and usage of the product to ensure its quality, stability and efficacy, and its safe and efficient use (“conditions of use”).

15. Moderna must ensure, by promptly liaising with the MHRA, that the conditions of use are promptly updated as additional data becomes available, in order to ensure product quality, stability and efficacy, and its safe and efficient use.

16. The conditions of use, as amended by agreement between Moderna and MHRA from time to time, are to be considered as conditions of this authorisation.

17. Reliance on the stated tolerance margins in the SmPC does not bring the administration of the vaccine outside the scope of this authorisation.

18. This authorisation does not preclude an authorised prescriber administering this vaccine to a patient for whom it is not recommended in accordance with the instructions of use, in circumstances where that authorised prescriber is directly responsible for that patient and the administration of the vaccine is to fulfil the special needs of that patient where, in the professional judgement of that authorised prescriber, the welfare of the patient is likely to be in jeopardy unless the vaccine is administered.

Quality

19. The proposed supply is authorised, subject to independent batch release for each batch in a manner approved by NIBSC, and providing that Moderna ensures that the full product lifecycle is in compliance with the following conditions:

- a. MHRA approves individual batches produced from the European supply chain on the basis that they have consistent quality and production with the batch data obtained for Lot 7006820801.
- b. Any supply proposed from the US supply chain would require further production data to be provided and batch specific approval based on this data.

- c. Any importation or manufacturing facilities located within England, Scotland and Wales are authorised by the MHRA to handle Regulation 174 products.
- d. All drug substance and drug product manufacture are in accordance with EU GMP and the Human Medicines Regulations 2012 (as amended) in facilities with current EU GMP certificates or other acceptable and suitable authorisation to MHRA.
- e. Qualified Person (QP) certification is provided for the final dosage form and applying the approach and standards in EU GMP Annex 16.
- f. QP certification must declare:
 - (i) compliance with all stages of EU GMP (where non-compliant, a gap analysis must be performed, and captured on the QP check sheet (or equivalent), and
 - (ii) that the batch has been manufactured as per the Regulation 174 dossier supplied.
- g. QP certification must take into account NIBSC certification process.
- h. A Certificate of Conformance stating compliance with GMP and the conditions of this Regulation 174 authorisation must be generated by the releasing QP and supplied to the first receiver (only) in the supply chain and to MHRA, to provide evidence of its authorisation status, indicating it can be released for use from its quarantine status.

20. Moderna must notify any significant changes to or deviation from the manufacture of the product to MHRA for approval on allocation of the batch to Crown use.

Non-clinical

21. Good Laboratory Practice studies must be performed to standards in UK national regulations, relevant guidelines and the OECD Principles of Good Laboratory Practice. Final reports for all studies conducted with COVID-19 mRNA Vaccine (embedded in lipid nanoparticles) in compliance with Good Laboratory Practice (GLP) must be signed by the Study Director. As soon as Moderna become aware, it must inform MHRA of any findings that arise in such studies that alter the risk-benefit judgement of the vaccine.

22. Moderna (and its contracted parties) must submit to GLP inspections by national competent authorities should such inspections take place.

Clinical

23. Moderna must ensure that clinical trials are performed to national regulations and relevant guidelines including ICH GCP E6R2.

24. Moderna (and its contracted parties) must submit to MHRA GCP inspections to assess the compliance of any of the clinical trials and applicable data attached to the authorisation by virtue of regulation 174A. The powers of inspection will be the same as those outlined in regulations 325, 326 and 327.

25. Moderna must provide the interim and final study reports for study mRNA-1273-P301 once available to MHRA.

Pharmacovigilance

26. Moderna must operate a comprehensive pharmacovigilance system for this product in accordance with UK legislation for licensed products, as if they were marketing authorisation holders for the product.

27. Moderna (and its contracted parties) must submit to MHRA inspections to assess compliance with any and all pharmacovigilance obligations attached to the authorisation by virtue of regulation 174A. The powers of inspection will be the same as those outlined in regulations 325, 326 and 327.

28. Moderna must ensure full product lifecycle compliance with the risk management plan (RMP) for the vaccine, including the additional pharmacovigilance elements laid out in sections 6b-g of the MHRA core RMP for COVID-19 vaccines.

29. Moderna must liaise with MHRA to finalise the safety specification, and promptly and regularly liaise with MHRA to ensure the safety specification is adjusted in light of evolving data.

30. Moderna must submit protocols for the studies stated in the vaccine RMP pharmacovigilance plan once these become available.

Deployment

31. Moderna has assured the MHRA that:

- a. The product is supplied in Freezer Conditions (FC) and has a stability of seven (7) months at a temperature of -20 +/- 5 (-25 to -15) degrees Centigrade.
- b. Distribution as part of the deployment can be controlled either;
 - i. At FC (-25 to -15 degrees Centigrade) within three transitions, or
 - ii. At 2-8 degrees Centigrade within 30 days of leaving FC.
 1. A secondary label must be affixed by the **the deployment distribution chain** chain to capture this new storage condition expiration.
- c. Packing down (splitting of packs) of lots to aid deployment can occur at 2-8 degrees Centigrade within its 30-day shelf life.
- d. The product can be transported at 2-8 degrees Centigrade for 12 hours.
- e. The product can be handled for 6 hours prior to first use at Room Temperature <25 degrees centigrade.
- f. The product must be discarded 6 hours after first puncture.

32. It is a condition of the authorisation to supply the product that the above assurances are accurate, and that the product can be supplied and held safely in accordance with the above assurances throughout the supply chain.

Supply chain and distribution

33. The conditions under this heading do not expressly apply to Moderna. The deployment model developed for the distribution and administration of the product by the NHS in each of the three countries, and by the Crown Dependencies and its Overseas Territories receiving supplies from England, should comply with the above conditions in order to ensure the safety, quality and efficacy of the product is not compromised. Where appropriate, the above assurances must be reflected in the conditions imposed on NHS contractors by NHS commissioners.

34. In England, Scotland and Wales, the vaccines will be delivered to designated NHS bodies or NHS contractors that have capacity to hold the vaccines.

35. Thereafter, the NHS arrangements for the onward and (if different) final distribution of the products, and their final deployment, are still being developed, but the bodies responsible under NHS arrangements in each of the three countries for any aspect of the distribution or final deployment of the vaccine, and the relevant bodies in the Crown Dependencies and the United Kingdom's Overseas Territories receiving supplies from England, must comply, as conditions of this authorisation, with the conditions that are applicable to that aspect of the distribution or final deployment in this authorisation.

36. The bodies responsible for the transit of the product to the designated NHS bodies or NHS contractors in England, Scotland and Wales from the manufacturer must also comply, as conditions of this authorisation, with the conditions of the authorisation that are applicable to them.

In addition:

37. All wholesalers and manufacturing license holders distributing or holding this product must be authorised to handle Regulation 174 products

38. All activities are to be conducted in accordance with good distribution practice (GDP).

39. A manufacturing licence holder can pack down the authorised product without being named on the Company submission.

40. Pack down prior to distribution must occur in accordance with good manufacturing practice (GMP) and requires QP certification that it has occurred in accordance with GMP and the specification provided by the contract giver.

41. Manufacturers and authorised persons performing the pack down (splitting of packs) activities must be authorised to handle regulation 174 products and immunological products.

42. The WDA(H) receiving the boxes must be authorised for Regulation 174 products and cold chain.

43. Pack down under section 10 of the Medicines Act 1968 or regulation 3 or 3A of the Human Medicines Regulations 2012 for supply by the same legal entity must take place in a manner and environment that ensure and must be subject to NHS governance arrangements and standard operating procedures that ensure, that the safety, quality and efficacy of the product is not compromised. Any guidance in respect of the packing down of the product under section 10 or regulation 3 or 3A published by the licensing authority on GOV.UK must be appropriately adhered to.

44. Final preparation of the product for administration must take place in a manner and environment that ensure, and must be subject to NHS governance arrangements and standard operating procedures that ensure, the safety, quality or efficacy of the product is not compromised. Any guidance in respect of the final preparation of the product published by the licensing authority on GOV.UK must be appropriately adhered to.

