(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.

- QP certification must take into account NIBSC certification process.

- 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.

18. AZ must notify any changes to or deviation from the manufacture of the product to MHRA for approval on allocation of the batch to NHS use.

Non-clinical

19. 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 AZD1222 in compliance with Good Laboratory Practice (GLP) must be signed by the Study Director. As soon as AZ become aware, it must inform MHRA of any findings that arise in such studies that alter the risk-benefit judgement of the vaccine.

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

Clinical

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

22. AZ (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.

Pharmacovigilance

23. AZ 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.

24. AZ (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.

25. AZ 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.

26. AZ must promptly and regularly liaise with MHRA to ensure the safety specification is adjusted in light of evolving data.

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

Deployment

28. AZ has assured the MHRA that:

    a. Distribution as part of the deployment can be controlled at 2-8 degrees Centigrade throughout its shelf life of 6 months.

    b. Further packing down (splitting of packs) of lots to aid deployment can occur at 2-8 degrees Centigrade within its shelf life and at 'room temperature' <25degrees centigrade within 2 hours. GMP controls are required to ensure there is no detrimental impact to quality, safety or efficacy of the lots by this processing.

29. 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

30. The deployment model developed for the distribution and administration of the product by the NHS in each of the four countries of the United Kingdom, and by the Crown Dependencies and its Overseas Territories, 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.

31. In the United Kingdom, the vaccines will be delivered to designated NHS bodies or NHS contractors that have capacity to hold the vaccines.

32. 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 four 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, 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.

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