

## AZ Vaccine Accelerated supply

- MHRA Conditions for Authorisation amended on 23 February 2021**  
**Annex 1: Addition of manufacturer and importer**

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

[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/963841/AZ\\_Conditions\\_for\\_Authorisation\\_final\\_23.02.21.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/963841/AZ_Conditions_for_Authorisation_final_23.02.21.pdf)

Vaccine Characteristics that differs from existing supply chain	AZ Accelerated Supply
<ul style="list-style-type: none"> <li>Manufacturer</li> </ul>	<ul style="list-style-type: none"> <li>The Serum Institute India Pvt. Ltd</li> </ul>
<ul style="list-style-type: none"> <li>Nature and contents of container</li> </ul>	<ul style="list-style-type: none"> <li>5 ml of solution in a 10-dose vial (clear type I glass) with a bromobutyl rubber stopper and an aluminium overseal with a <b>GREEN</b> plastic flip-off cap. Packs of 10 vials.</li> </ul>
<ul style="list-style-type: none"> <li>Vial &amp; Carton Presentation</li> </ul>	<ul style="list-style-type: none"> <li>See picture below</li> </ul>
<ul style="list-style-type: none"> <li>Traceability, Additional Batch Numbering Information</li> </ul>	<ul style="list-style-type: none"> <li>First three batches will have the following format:                             <ul style="list-style-type: none"> <li>- 4120Z001</li> <li>- 4120Z002</li> <li>- 4120Z003</li> </ul> </li> <li>Expiry date will be as DD/MM/YYYY.</li> <li>Expiry will be at 23:59hrs</li> </ul>
<ul style="list-style-type: none"> <li>Shelf life at delivery</li> </ul>	<ul style="list-style-type: none"> <li>Three batches delivered w/c 8 March have short shelf life 31 March to 02 April, depending on allocation by batch.</li> <li>2 further batches for delivery 22 March will have an expiry date in June (Precise date TBC)</li> </ul>
<ul style="list-style-type: none"> <li>Vial and Stopper Dimensions &amp; Specification</li> </ul>	<ul style="list-style-type: none"> <li>Vial dimensions (approx) are: H:52mm , Dia:16.5mm</li> <li>Stopper is grey bromobutyl rubber (no latex). Stopper is 13mm diameter with an aluminium peel off seal.</li> </ul>
<ul style="list-style-type: none"> <li>Doses per vial</li> </ul>	<ul style="list-style-type: none"> <li>MHRA confirmed 10 doses per vial (fill volume is less than existing supply chain – <u>no potential for additional doses</u>)</li> </ul>
<ul style="list-style-type: none"> <li>Vials per pack</li> </ul>	<ul style="list-style-type: none"> <li>10 vials per pack</li> </ul>
<ul style="list-style-type: none"> <li>Pack dimensions</li> </ul>	<ul style="list-style-type: none"> <li>L=98mm, H59mm, W=43mm</li> </ul>
<ul style="list-style-type: none"> <li>Patient Information</li> </ul>	<ul style="list-style-type: none"> <li>The PIL will be identical to existing AZ PIL</li> </ul>

