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Date: 01st October 2021

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Synagis 100 mg/1 ml solution for injection (palivizumab):
Interim supply of Italian stock to mitigate supply disruption

Dear Healthcare Professional,

Summary: AstraZeneca is currently experiencing supply disruption with Synagis 100 mg/1 ml solution for injection (palivizumab) in Great Britain.

To ensure continuity in supply, AstraZeneca UK Ltd. has obtained approval from the Medicines and Healthcare products Regulatory Agency (MHRA) to supply Italian stock of Synagis 100 mg/1 ml solution (batch number: 384330, ~1100 packs) which is expected to be on the GB market from the beginning of October for approximately a week.

Please note the following:

- This product is considered licenced in GB.
- The product from Italy has the same formulation as the GB product.
- The product from Italy is manufactured according to the same manufacturing process and quality controls as the GB product.
- Please refer to the GB approved Patient Information Leaflet supplied electronically with the Italian packs. Discard the Italian leaflet in the pack.
- For additional copies of the leaflet, please refer to https://www.medicines.org.uk/emc/product/6963/pil or contact the company contact point (see below).
- For approved Summary of Product Characteristics (SmPC), please refer to https://www.medicines.org.uk/emc/product/6963/smpc
- The MHRA has agreed to an exemption granted in accordance with regulation 266(4) (b) of the Human Medicines Regulations (HMR) 2012, from the obligation that the information included on the outer and immediate packaging of Synagis 100 mg/1 ml (palivizumab) must be given in English.

Please ensure all relevant staff are made aware of the content of this letter and that the information is communicated to the patients.

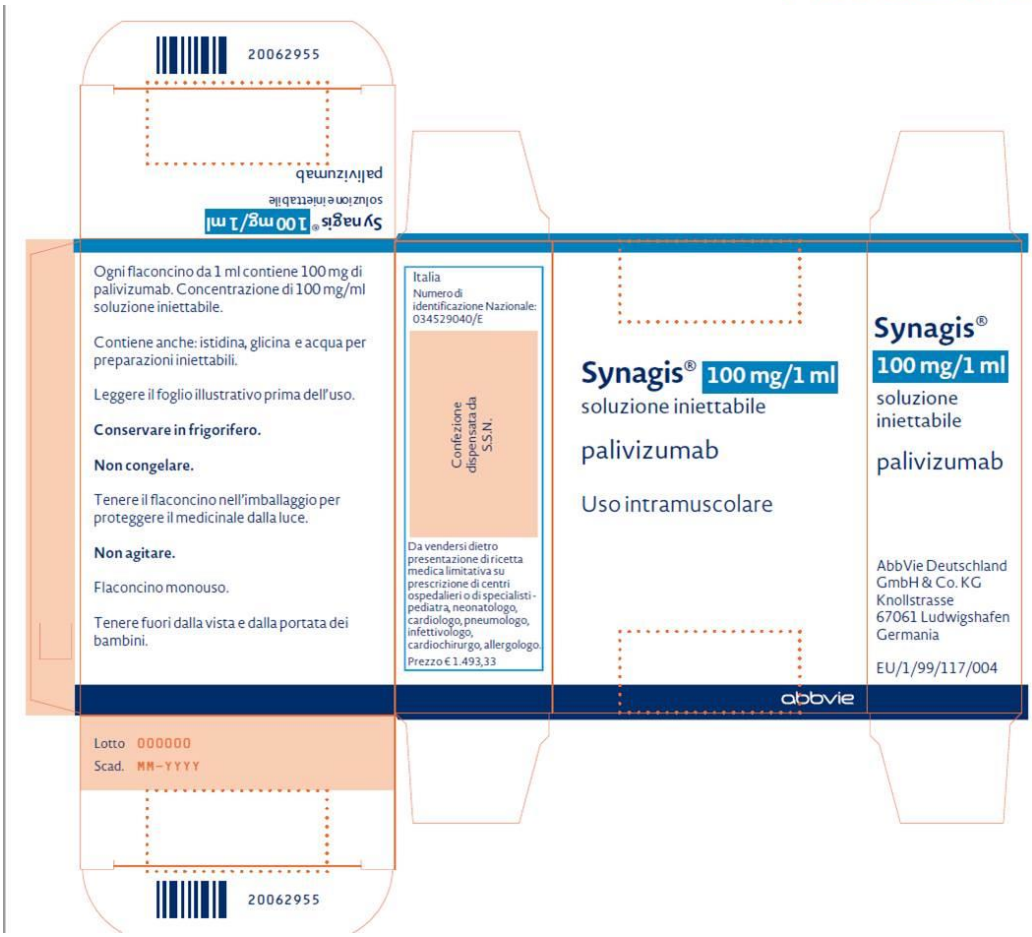

Figure 1. Image of Italian pack to be used in GB market

The Marketing Authorisation Holder was transferred from AbbVie to AstraZeneca Ltd on 01 July 2021. The current stock in market is packed in AbbVie livery whilst the transition to AstraZeneca livery takes place.

Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions to the Yellow Card Scheme electronically. Report via the website https://www.gov.uk/yellowcard, the free Yellow Card app available from the Apple App Store or Google Play Store, and some clinical IT systems (EMIS, SystmOne, Vision, MiDatabank) for healthcare professionals. Suspected side effect can also be reported by calling 0800 731 6789 for free.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset, treatment dates, and product brand name.

Company contact point

If you have any questions about this letter or require more information about Synagis 100 mg/1 ml (palivizumab), please visit our dedicated AstraZeneca Medical Information website (https://medicalinformation.astrazeneca.co.uk/). Alternatively, please contact AstraZeneca Medical Information (medical.informationUK@astrazeneca.com or call 0800 783 0033).

DocuSigned by:
Tom Keith-Roach
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Name: Tom Keith Roach
Title: Country President, UK
Date: 27 September 2021