Respreeza (human alpha-1-proteinase inhibitor): Sterility issue with the infusion device co-packed with Respreeza 4.000 mg and 5.000 mg

Dear Healthcare professional,

CSL Behring, in agreement with the European Medicines Agency and the <***National Competent Authority***>, would like to inform you of the following:

Summary

- **Respreeza 4.000 mg and 5.000 mg is co-packed with an infusion set from Becton Dickinson (BD).**
- **The infusion set is being recalled by the supplier as they cannot guarantee sterility, due to quality issues with their third-party sterilisation provider.**
- **Only the BD infusion set included in the packaging is affected by the quality defect; Respreeza itself can be used safely.**
- **Patients who were supplied with Respreeza co-packaged with the BD infusion set must NOT use the infusion set from BD and should use instead the alternative infusion set (BBraun Intrafix® Primeline Art. No. 4062981L).**
- **Pharmacies should ensure that no Respreeza® 4.000 mg and 5.000 mg packs are given to doctors or patients who have BD infusion sets included. Information about the sterility issue with the BD infusion set should be shared with HCPs and patients.**
- **Patients on self-administration will be provided with the alternative infusion set either via the treating physician or pharmacy, depending on their location.**
- **For patients who receive administration through an HCP, if the specified alternative infusion set is not available, please contact the national CSL Behring customer service**.
- **As a result of the BD recall, supply of Respreeza 4.000 mg and 5.000 mg will be limited in <country>.**
- **Patients who currently use Respreeza may need to be switched to a licensed alternative treatment if available.**
- **In case of an absolute health risk for the patient, for example proven intolerance to alternative products, CSL Behring will evaluate individual solutions with the HCP/pharmacy for each patient.**

Background information

Respreeza is indicated for maintenance treatment, to slow the progression of emphysema in adults with documented severe alpha1-proteinase inhibitor deficiency (an inherited condition also called alpha1 antitrypsin deficiency).

Respreeza 4.000 mg and 5.000 mg is co-packed with an infusion set from Becton Dickinson (BD), which is being recalled by the supplier as they cannot guarantee sterility, due to quality issues with their third-party sterilisation provider.

Respreeza itself is safe to use and there is no quality defect with the medicine.

Use of the infusion set affected by a potential lack of sterility may cause a potential risk to patients. HCPs and pharmacies must ensure that for administration of Respreeza no BD infusion set will be used. Instead, the alternative infusion set (BBraun Intrafix® Primeline Art. No. 4062981L), which is also registered for the administration of Respreeza, should be used. This infusion set was tested as administration device with Respreeza and compatibility with our product was confirmed.

The batches of Respreeza 4.000 mg and 5.000 mg affected by the measure are shown in table 1 (Attachment 1).

Please report the number of unused/discarded BD infusion sets in the attached documentation form (Attachment 2).

Please ensure that the instructions for use of the BBraun infusion set, as set out below, are followed by patients or caregivers:

- Place the vial on a flat and even surface. The vial stopper should be punctured **carefully, vertically and with a gentle rotating motion**. Please ensure that you use the predetermined puncture point left by the Mix2Vial.
- The reconstituted solution alternatively can be transferred into an infusion container (e.g., empty intravenous bag or glass bottle (not supplied) via a commercially-available intravenous fluid tubing transfer set (not supplied)), prior to administration.

Call for reporting

Reporting of suspected adverse reactions after authorisation of the medicinal product is important. It allows continuous monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are encouraged to report any suspected adverse reactions with the use of Respreeza 4.000 mg and 5.000 mg to <national spontaneous reporting system, including the details (e.g. name, postal address, fax number, website address) on how to access the national spontaneous reporting system>.

Company contact point

CSL Behring is available to provide healthcare professionals with information about product availability or answer any further questions.

<Contact point details for access to further information, including relevant website address(es), telephone numbers and a postal address>

Annexes

Attachment 1 – Affected product batches
Attachment 2 – Documentation Form <country specific>

Attachment 1:

The quality defect is limited to the Respreeza batches mentioned in the following table:

Batch number	**Product and presentation**	**Expiration Date**
To be included by sending site	To be included by sending site	To be included by sending site

Communication Plan for Direct Healthcare Professional Communication

DHPC COMMUNICATION PLAN	
Medicinal product(s)/active substance(s)	Respreeza (alpha-1-proteinase inhibitor (human))
Marketing authorisation holder(s)	CSL Behring GmbH Emil von Behring Straße 76 35041 Marburg Germany
Safety concern and purpose of the communication	Sterility issue with the infusion device co-packed with Respreeza 4.000 mg and 5.000 mg
DHPC recipients	Nurses, pulmonologists, community pharmacists/hospital pharmacists, patient associations.
Member States where the DHPC will be distributed	Austria, Germany, France.

Timetable	Date
DHPC and communication plan (in English) agreed by CHMP	25 March 2021
Submission of translated DHPCs to the national competent authorities for review	25 March 2021
Agreement of translations by national competent authorities	26 March 2021
Dissemination of DHPC	26 March 2021