Respreeza (human alpha-1-proteinase inhibitor): batch-specific product recall

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

- **CSL Behring cannot guarantee that the manufacturing of Respreeza (human alpha-1-proteinase inhibitor, powder and solvent for solution for infusion, 1.000 mg, 4.000 mg and 5.000 mg) met aseptic conditions during the filling operations of the vials at all times. As a precaution, the company is recalling affected batches.**
- **This recall is at hospital and pharmacy level. The list of affected product batches is attached to this communication as attachment 1.**
- **Pharmacies/hospitals are requested to immediately stop the use and the distribution of the affected product batches. Any remaining packages in stock of the affected product batches are to be returned to CSL Behring.**
- **The recall will be initiated on <date>.**
- **As a result of the recall supply will be limited in <country>.**

  CSL Behring is prepared to provide supply required to serve the majority of patients with current prescriptions for Respreeza but foresees limitations to serve all patients with a prescription.
- **Patients who currently use Respreeza may need to be switched to a licensed alternative treatment if available and deemed necessary by the HCP. In some circumstances, patients may have to attend clinic for administration of the alternative therapy or home administration by an HCP may be organized, in line with alternative product information.**

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).

The batches listed in the attached table are voluntarily recalled as a precautionary measure, as it cannot be guaranteed that the aseptic conditions were adequately met at

all times during the filling process. Any product from these batches should no longer be used and returned to the company.

To implement this recall, please take the following actions:

1. Do not distribute any remaining stock of the product batches listed in the attached table (**Attachment 1**).
2. Place any remaining product batch packages in quarantine and mark clearly to avoid any further use of stock. Note the number of packs you have placed in quarantine on the forms attached.
3. Please set aside any remaining stock of the concerned batches, which will then be collected and a credit note will be issued. If you have purchased quantities of the concerned batches from wholesalers, we ask you to return the product to us via wholesalers.
4. Please ensure that any stock detailed in the forms attached is ready for collection, which we will arrange for our distribution partner to undertake. All product for return should be clearly marked 'RECALL MATERIAL'.
5. Please email or fax by return the completed "Return Form" attached, as it is imperative that we can reconcile all recalled stock.
6. Any queries regarding this matter should be directed to the following contact:
   <Tel. no.>
   <Fax no.>
   <email address>
   <to be added country-specific>

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 1.000 mg, 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 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 1:

The recall 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

Please note: Product batches of Respreeza in shelf life, which are not listed in the table, are not part of this product recall.

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	Voluntary recall of specific batches of the medicinal product Respreeza in the European Union as a precautionary measure due to the potential for inadequate aseptic conditions during the filling process.
DHPC recipients	General: Community pharmacists, hospital pharmacists The DHPC recipient(s) may deviate in some countries based on the country-specific distribution ways (e.g. direct distribution).
Member States where the DHPC will be distributed	Austria, Croatia, Czech Republic, Denmark, France, Germany, Greece, Ireland, Italy, Netherlands, Portugal, Slovakia, Spain

Timetable	Date
DHPC and communication plan (in English) agreed by CHMP	**06 February 2021**
Submission of translated DHPCs to the national competent authorities for review	**08 February 2021**
Agreement of translations by national competent authorities	**11 February 2021**
Dissemination of DHPC	**12 February 2021**