

**ANNEX**

**CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE  
USE OF THE MEDICINAL PRODUCT**

## **CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF MEDICINAL PRODUCT TO BE IMPLEMENTED BY THE MEMBER STATES**

The Member States should ensure that all conditions or restrictions with regard to the safe and effective use of the medicinal product described below are implemented:

The Member States shall agree the final healthcare professional and patient educational pack with the Marketing Authorization Holder (MAH) prior to launch of the product in their territory.

The Member States shall ensure that all physicians who are expected to prescribe or use Colobreathe are provided with a healthcare professional and patient educational pack containing the following:

- The Summary of Product Characteristics
- The Patient Information Leaflet
- The “Physician DVD”
- The “Patient DVD”
- “Physician DVD” information in “leaflet form” for those physicians who do not have access to a DVD player
- “Patient DVD” information in “leaflet form” for those patients who do not have access to a DVD player

The Physician and patient “DVDs/leaflet forms” should contain the following key elements and messages:

- Introduction to the product: provide information on the contents of the box ie that 28 days treatment is 56 capsules and 1 device. Explain that the device should be discarded after 28 days. Explanation of the Turbospin and how it works.
- Information on the need to comply with the treatment in order to maximise the potential benefits. Explanation that using inhaled antibiotics can reduce the need for intravenous antibiotics.
- Detailed instructions about how to use the medication: starting from unpacking of the product and finishing with disposal of the used capsule and device. Some detail about cleaning the Turbospin device.
- Discussion about common side effects and in particular cough and taste abnormality: Explanation that:
  - These are only of nuisance value for most patients
  - Emphasise that patients should persist with the treatment.
  - That cough decreases with repeated use of the product and should stabilize after the first month or so.