ANNEX

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

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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:

- Prior to launch of the product in the Member State, the national competent authority shall agree the content and format of the educational material with the Marketing Authorisation Holder.

- The Marketing Authorisation Holder (MAH) should ensure that at launch all Healthcare Professionals who are expected to use and/or prescribe Bronchitol are provided with an educational pack.

The educational pack should contain the following:
- Summary of Product Characteristics and Patient Information Leaflet
- Educational material for Healthcare Professionals

The educational material for Healthcare Professionals should be a leaflet that includes information on the following key elements:

- The risk of bronchospasm during treatment
    - The need to perform the Bronchitol initiation dose assessment to identify patients who have bronchial hyperresponsiveness in response to inhaled mannitol by measuring the degree of bronchoconstriction that occurs following sequential administrations of mannitol.
    - How to perform the Bronchitol initiation dose assessment safely and how long to monitor the patient for.
    - How to interpret the results of the Bronchitol initiation dose assessment as Pass, Fail or Incomplete.
    - That therapeutic doses of Bronchitol should only be prescribed if the patient has passed the initiation dose assessment.
    - The need of pre-medication by a bronchodilator 5-15 minutes before the Bronchitol initiation dose assessment and before each therapeutic administration of Bronchitol.
    - The need to check that the patient knows how to correctly use the bronchodilator.
    - The need to review the patient after approximately six weeks to assess for signs and symptoms of bronchospasm.
    - The risk of bronchospasm during long term treatment even if the Bronchitol initiation dose assessment was initially passed and the need to reiterate it in case of doubt.

- The risk of haemoptysis during treatment
    - That Bronchitol has not been studied in patients with a history of significant haemoptysis (>60 ml) in the previous three months.
    - The need for monitoring and when to withhold treatment.

- The potential risk of cough related sequelae during treatment
    - The need to train the patient to minimise cough during administration in using the correct inhalation technique.