

29 June 2018
EMA/351982/2018

EMA reviewing bacterial lysate medicines for respiratory conditions

Assessment to include recent data on effectiveness

The European Medicines Agency (EMA) has started a review of bacterial lysate medicines, which are authorised in some EU member states for treatment or prevention of respiratory tract infections (infections of the airways and lungs) and for chronic (long-term) respiratory conditions.

Recent studies have cast doubt on the effectiveness of bacterial lysate medicines in reducing the number and severity of respiratory infections in adults and children who experience repeated infections. In addition, in very rare cases, these medicines are known to cause serious side effects related to the immune system (the body's natural defences).

This review has been requested by the Italian medicines agency (AIFA). EMA will now review the available information and recommend whether the marketing authorisations for the medicines should be maintained, varied or suspended across the EU.

More about the medicines

Bacterial lysate medicines are used on their own or with other medicines to treat or prevent upper or lower respiratory tract infections or for the treatment of chronic respiratory conditions including chronic bronchitis (inflammation of the airways in the lungs) and chronic obstructive pulmonary disease (damage or blockage of the airways and air sacs in the lungs).

Bacterial lysate medicines are made from bacterial cells that are broken down and are intended to stimulate the immune system to recognise and fight bacterial infections. These medicines are taken by mouth (as capsules, tablets, granules/powder for making up an oral mixture or drops), dissolved under the tongue (as tablets), or inhaled through the nose (as a liquid).

Bacterial lysate medicines have been authorised via national procedures. They are available in Austria, Belgium, Bulgaria, Czech Republic, Germany, Greece, Hungary, Italy, Latvia, Lithuania, Luxembourg, Malta, Poland, Portugal, Romania, Slovakia and Slovenia in under several brand names including Biomunil, Broncho Munal, Broncho Vaxom, Buccalin, Immubron, Immucytal, Ismigen, Lantigen B, Luivac, Ommunal, Paspas, Pir-05, Polyvaccinum, Provax, Respivax and Ribomunyl.

More about the procedure

The review of bacterial lysate medicines has been initiated at the request of Italy, under [Article 31 of Directive 2001/83/EC](#).

The review is being carried out by the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which will adopt the Agency's opinion. The CHMP opinion will then be forwarded to the European Commission, which will issue a final legally binding decision applicable in all EU Member States.