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Start of review of ambroxol and bromhexine

The European Medicines Agency has started a review of medicines containing ambroxol and bromhexine, which are widely used as expectorants (medicines that help clear the airways), as well as to relieve sore throat. Some formulations are used to treat breathing disorders in premature and newborn babies.

The review of ambroxol and bromhexine was requested by the Belgian medicines agency (AFMPS). This follows concerns over an increased number of reports of allergic reactions, including anaphylactic (severe allergic) reactions with ambroxol. Medicines containing ambroxol have also been linked to severe skin adverse reactions. In addition, the AFMPS was concerned about the use of ambroxol as expectorant in children below 6 years of age and considered that the benefits of these medicines did not outweigh the risks in this population.

Since bromhexine gets mainly converted into ambroxol in the body, and there are some reports linking the use of bromhexine with allergic reactions, the AFMPS considered that the review should also cover medicines containing bromhexine.

The European Medicines Agency will now review the available data on the benefits and risks of medicines containing ambroxol and bromhexine, and issue an opinion on the marketing authorisations of these medicines across the European Union (EU).

More about the medicine

Ambroxol and bromhexine are mainly used by mouth as expectorants to help make the mucus thinner and therefore easier to be cleared away in patients with short- or long-term diseases of the lungs or airways. Lozenge formulations are also available to relieve sore throat. Formulations for injection are also used in premature and newborn babies to treat respiratory distress syndrome (RDS), a condition in which the baby's lungs are too immature for the baby to breathe properly. Some of these formulations are also used to increase lung maturation before birth.

These medicines have been authorised via national procedures in the following countries: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and The Netherlands.

More about the procedure

The review of ambroxol- and bromhexine-containing medicines has been initiated at the request of Belgium, under Article 31 of Directive 2001/83/EC.

The review is being carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines, which will make a set of recommendations. As these medicines are all authorised nationally, the PRAC recommendation will be forwarded to the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), which will adopt a final position. The CMDh, a body representing the EU Member States, is responsible for ensuring harmonised safety standards for medicines authorised via national procedures across the EU.