28 June 2018
EMA/421929/2018
Press Office

Start of community reviews

CHMP meeting of 25-28 June 2018

Table 1. Start of reviews for non-centrally authorised medicines

Name	INN	Type of procedure	Scope
Bacterial lysates	bacterial lysate of haemophilus influenzae / klebsiella pneumoniae / moraxella catarrhalis / staphylococcus aureus / streptococcus mitis / streptococcus pneumoniae / streptococcus pyogenes, bacterial lysate of haemophilus influenzae / klebsiella pneumoniae / moraxella catarrhalis / staphylococcus aureus / streptococcus pneumoniae / streptococcus pyogenes, streptococcus pneumoniae / streptococcus agalactiae /	Article 31 of Directive 2001/83/EC	Procedure triggered by Italy asking for an opinion on the impact on the benefit/risk balance of bacterial lysates based medicinal products in respiratory conditions of recent studies casting doubts on the efficacy, also taking into consideration the known risk of serious immunological reactions with these products.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Name	INN	Type of procedure	Scope
	staphylococcus aureus / haemophilus influenzae haemophilus influenzae / klebsiella ozaenae / klebsiella pneumoniae / moraxella catarrhalis / staphylococcus aureus / streptococcus pneumoniae / streptococcus pyogenes / streptococcus viridans vaccine haemophilus influenzae / membrane fraction of klebsiella pneumoniae / ribosomal fractions of klebsiella pneumoniae / streptococcus pneumoniae / streptococcus pyogenes vaccine Escherichia Coli / Klebsiella Pneumoniae/ Staphylococcus Aureus / Staphylococcus Epidermidis / Streptococcus Salivarius / Streptococcus Pneumoniae / Streptococcus Pyogenes / Haemophilus Influenzae / Corynebacterium / Moraxella Catarrhalis		

Table 2. Start of harmonisation procedure

Name	INN	Type of procedure	Scope
SEPTANEST and associated names	Articaine (hydrochloride) /Adrenaline (tartrate)	Article 30 of Directive 2001/83/EC	The Committee started a harmonisation exercise for SEPTANEST / SEPTANEST FORTE and associated names. The review was triggered following a request from the Marketing Authorisation Holder, due to the need of harmonisation of the Summary of Product Characteristics and the Quality Module across Member States.