European Medicines Agency
Pre-Authorisation Evaluation of Medicines for Human Use

London, 23 April 2009
Doc.Ref. EMEA/CHMP/212696/2009

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
NYMUSA

International Nonproprietary Name (INN): ***caffeine***

On 23 April 2009 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product Nymusa, caffeine citrate 60 mg/3 ml, solution for infusion and oral solution intended for the treatment of primary apnoea of premature newborns.

Nymusa was designated as an orphan medicinal product on 17 February 2003 The applicant for this medicinal product is Chiesi Farmaceutici SpA.

The active substance of Nymusa is caffeine citrate, a Xanthine derivative *(*N06BC01) which acts through the adenosine receptors as a respiratory stimulant.

The benefits with Nymusa are its ability to decrease the frequency of apnoeic episodes, increase respiratory rate and blood pH, decrease pCO2, and improve the function of the respiratory muscles in premature infants with recurrent apnoea. The most common side effects are CNS stimulation, irritability, tachycardia, hypertension.

A pharmacovigilance plan for Nymusa, as for all medicinal products, will be implemented as part of the marketing authorisation.

The approved indication is: “treatment of primary apnoea of premature newborns”. It is proposed that Nymusa is prescribed by physicians experienced in neonatal intensive care.

Detailed recommendations for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for Nymusa and therefore recommends the granting of the marketing authorisation.

* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the Opinion.

** Applicants may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

7 Westferry Circus, Canary Wharf, London E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 86 13
E-mail: mail@emea.europa.eu http://www.emea.europa.eu