The European Agency for the Evaluation of Medicinal Products
Post-authorisation evaluation of medicines for human use

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PUBLIC STATEMENT
PREVENAR – SHORTAGE OF SUPPLY

In February 2004, Wyeth Lederle Vaccines S.A. – the Marketing Authorisation Holder of the vaccine Prevenar[1] – informed the EMEA and the CPMP that the company is experiencing problems in supply of Prevenar that are expected to last until mid-2004.
The resulting supply shortages are due to the extended shutdown of the Prevenar filling line in the US manufacturing site in November 2003 for preventive maintenance and equipment modifications. Filling has resumed in February 2004.

Having analysed the available data, the CPMP recommends that the concerned National Competent Authorities take the following interim precautionary measures in order to minimise the potential impact of Prevenar supply shortages to infants most in need of the product:

- *High-risk children (those with medical conditions such as splenic dysfunction, immunodeficiency or chronic disease) should continue to be vaccinated according to the approved vaccination schedule (complete primary vaccination schedule consisting of 3 doses and fourth dose in the second year of life).*

- *For other children, the decision to vaccinate should be taken according to the policy of local authorities. If vaccination is recommended, a two-dose only schedule should be used; the first Prevenar injection should be administered at 2 months of age and the second injection at 4 months of age. This dose schedule should be strictly adhered to. These children should receive a third and fourth dose once the vaccine supplies return to normal.*
  A two-dose regimen is currently not fully validated, however, preliminary data support sufficient protection. In addition, this approach is necessary in the context of the supply shortage of Prevenar.

It should be noted that the current national official recommendations for administering Prevenar vary in the different Members States according to vaccination policy. Consequently, the current new interim recommendations do not apply directly to all Member States.

For more information on local immunisation programmes, you are advised to directly contact your National Competent Authority. Please note that healthcare providers will be directly informed as appropriate.

[1] Prevenar is a 7-valent pneumococcal conjugate vaccine indicated for active immunisation of infants and young children against invasive disease (including bacteraemia, sepsis, meningitis, bacteraemic pneumonia) caused by *Streptococcus pneumoniae* serotypes 4, 6B, 9V, 14, 18C, 19F and 23 F. The approved immunisation schedule for infants under the age of 6 months is a 3-dose primary vaccination (usually starting at 2 months of age and with an interval of at least 1 month between doses) and a fourth dose ("booster") recommended during the second year of life. The Commission Decision for Prevenar was issued in February 2001 and the vaccine is now available in the following European countries: Austria, Denmark, Germany, Spain, France, Finland, Italy, Ireland, Netherlands, Portugal, Sweden and United Kingdom, as well as Cyprus.

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The stock and supply situation of Prevenar are continuously and closely monitored. Updated information will be provided if required.

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