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PUBLIC STATEMENT PREVENAR – RESUMPTION OF SUPPLIES

The marketing authorisation holder for Prevenar, Wyeth Lederle Vaccines, has informed the European Medicines Agency (EMA) that they are now able to deliver enough doses of the vaccine to the EU Member States in which it is marketed. This follows an earlier statement by the EMA on 22 March 2004 concerning supply shortages (<http://www.emea.eu.int/pdfs/human/press/pus/665904en.pdf>).

While delivery capacity is being resumed, the EMA and its Committee for Medicinal Products for Human Use (CHMP) recommend that the appropriate national authorities implement the following revised proposals on the use of Prevenar:

- *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)*
- *Wherever immunisation is recommended for the other children, children who have not yet been vaccinated and children who have been incompletely vaccinated should follow the recommended vaccination regimens as detailed in the attached table.*

It should be noted that the current national official recommendations for administering Prevenar vary in the different Member States according to vaccination policy. Consequently, the current recommendations may 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.

Recommended 7-valent pneumococcal conjugate vaccination regimens

Age (mos)	Previous pneumococcal conjugate vaccination history	Recommended regimen*
2-6	0 doses	3 doses at least 1 month apart, 4th dose in second year of life
	1 dose	2 doses at least 1 month apart, 4th dose in second year of life
	2 doses	1 dose, 4th dose in second year of life
7-11	0 doses	2 doses at least 1 month apart, 3rd dose in second year of life
	1 or 2 doses before age 7 months	1 dose at 7-11 months, with another dose in second year of life (≥ 2 months later)
12-23	0 doses	2 doses ≥ 2 months apart
	1 dose before age 12 months	2 doses ≥ 2 months apart
	1 dose at ≥ 12 months	1 dose ≥ 2 months after the most recent dose
	2 or 3 doses before age 12 months	1 dose ≥ 6 months after the most recent dose

Children more than 24m up to Five years not immunised before: one single dose

* For children vaccinated at age <1 year, the minimum interval between doses is 4 weeks. Doses administered at ≥ 12 months should be at least 8 weeks apart.

Should vaccination of Prevenar coincide with any other vaccine, please refer to the approved SPC for further information on concomitant administration.

For further information contact:

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