The European Agency for the Evaluation of Medicinal Products
Evaluation of Medicines for Human Use

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WITHDRAWAL OF THE MARKETING AUTHORISATION FOR THE MEDICINAL PRODUCT "Rotaschield-Rotavirus vaccine " EU/1/99/105/001

- On 7 May 1999, the European Commission issued a Marketing Authorisation valid throughout the European Union for the medicinal product Rotaschield, which contains one rhesus rotavirus serotype (serotype 3) and three reassortant rotavirus serotypes derived from rhesus and human strains (serotypes 1, 2 and 4). The pharmaceutical company responsible for this medicinal product is Wyeth-Lederle Vaccines S.A.
- On 2 November 2000, the Marketing Authorisation holder notified the European Commission of its decision to withdraw the Marketing Authorisation for Rotaschield.
- On 22 January 2001, the European Commission adopted the decision withdrawing the Marketing Authorisation for the medicinal product for human use "Rotaschield – Rotavirus vaccine". Pursuant to this decision the European Public Assessment Report for Rotaschield has been removed from the EMEA website.
- For information, it should be noted that the product has never been marketed within the European Economic Area.

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