16 March 2015
EMA/180225/2015
Committee for Medicinal Products for Human Use (CHMP)

CHMP assessment report for paediatric studies submitted in accordance with article 46 of regulation (EC) No1901/2006, as amended

Pandemrix

(H1N1 influenza vaccine)

Procedure No: EMEA/H/C/000832

P46 099

Assessment Report as adopted by the CHMP with all information of a commercially confidential nature deleted

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

1. ASSESSMENT

Introduction

This report covers the submission of the following data from a paediatric study that was commenced under the terms of the PIP but was later abandoned due to poor enrolment:

Article 46 submission of study **D-Pan-H1N1-012** (not part of any FUM):
Safety and immunogenicity study of GSK Biologicals' pandemic influenza candidate vaccine (GSK2340272A) in children aged 8 to 12 weeks

This report follows earlier notification to the CHMP that the study was stopped due to lack of willing participants.

The current submission consists of:

- A cover letter
- A short critical expert overview - which the assessor did not find in the package received 12 July 2011 after asking the MAH to send the data directly to the MHRA. Supposedly these data were submitted to EMA in early June such that the clock was started as on page 1 of this report.
- The final report on D-Pan H1N1-012, dated 16 May 2011. The study was actually terminated on 25 November 2010.

Assessment

Study D-Pan-H1N1-012 was conducted at three centres in Norway between November 2009 and November 2010. The study had planned to evaluate the safety and immunogenicity of a two-dose schedule of HA derived from A/California/7/2009 (H1N1)v manufactured in Dresden in infants aged from 8-12 weeks at the time of the first dose. The study enrolled 8 subjects only.

The study had planned to enrol 60 children aged 8 to 12 weeks and of at least 36 weeks gestation at birth, allocated to two parallel vaccine groups with a ratio of 1:1 as follows:

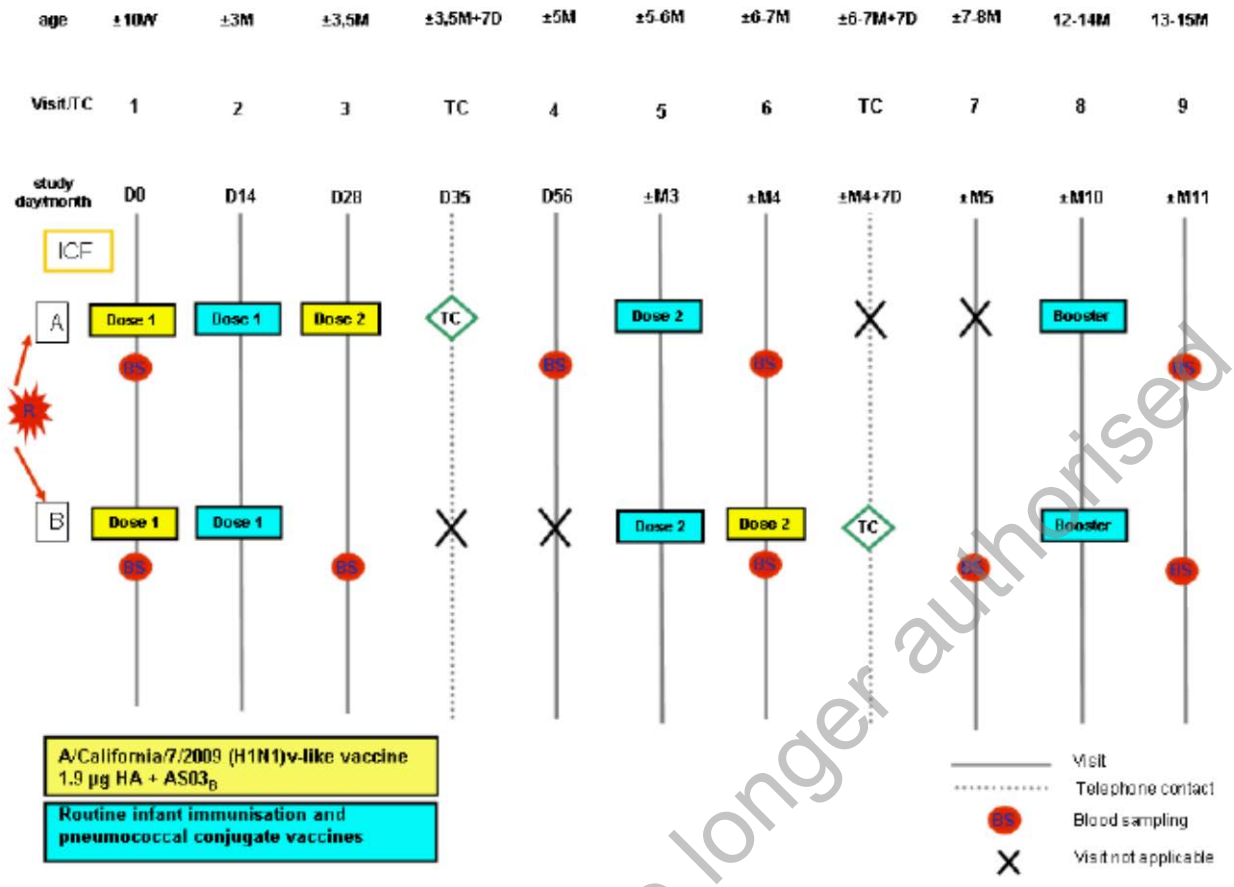
- Group A: 30 subjects receiving two primary intramuscular (IM) doses of theA/California/7/2009 (H1N1)v-like candidate vaccine containing 1.9 µg of haemagglutinin (HA) antigen and AS03B (i.e. half the usual adjuvant dose), according to a 0-28 day schedule.
- Group B: 30 subjects receiving two primary IM doses of the A/California/7/2009 (H1N1)v-like candidate vaccine containing 1.9 µg of HA antigen and AS03B, according to a 0-4 month schedule.

The injection volume was 0.25 mL.

Blood samples were to be taken:

- Group A: at Day 0 and Day 56, Month 4 and 11
- Group B: at Day 0 and Day 28, Month 4, 5 and 11

Infanrix-IPV/Hib and Prevenar were also administered but in a staggered fashion as shown in the diagram below.



Of the 8 subjects enrolled 5 were in group A and 3 in Group B.

One subject of Group A reported one grade 3 pain event after the first dose of vaccine.
☐ No grade 3 solicited general AEs, including fever, were observed.
☐ Unsolicited AEs reported were unremarkable and not related to vaccination.
☐ No SAEs and no ILI episodes were reported.
☐ All 8 enrolled subjects developed an immune response in terms of HI antibodies.
☐ An immune response against most of the pneumococcal antigens was observed for all subjects.
☐ For the 5 subjects that were tested, a polio immune response was observed.

2. RAPPORTEUR'S OVERALL CONCLUSION AND FURTHER ACTION IF REQUIRED

The CHMP had already acknowledged that this study had been terminated due to lack of participants. The provision of this summary of the study closes the matter. No further action is required.