reported from study 023 with a half adult dose in this age group suggest that this might be sufficient there is no important safety advantage for the half adult dose and in the absence of further immunogenicity data there is no reason to amend the current posology for this age group. However, it is agreed that the HI data should be added to the SPC.

During the procedure post-dose 1 HI and safety data in children aged 3-9 years who had received a half adult dose of Pandemrix H1N1 in study 023 have been provided.

The data from study 023 after a half adult dose and from study 010 after a full adult dose have demonstrated a very robust HI response to a single dose of Pandemrix in children from 3-9 years with an advantage for the adult dose only in terms of GMTs and hence SCFs. The safety profiles associated with the first half or full adult doses were broadly acceptable but there was some advantage for a half adult dose in children aged 3-5 and 6-9 years. Overall, there seems no reason to amend the current posology for children aged 3-9 years but the CHMP agreed to add safety and HI data to the SPC as indicated in the Annex.

IV. CONCLUSION

On 20 January 2010 the CHMP considered this Type II variation to be acceptable and agreed on the amendments to be introduced in the Summary of Product Characteristics, Annex II and Package Leaflet.