Recommendation

On the basis of the available data for Celvapan A(H1N1)v which is limited primarily to quality data and the data of the initially authorised medicinal product Celvapan H5N1, the CHMP considered by consensus that the risk-benefit balance of Celvapan for the prophylaxis of influenza in an officially declared pandemic situation, in accordance with official guidance, was favourable. Therefore CHMP recommended the variation to the marketing authorisation under exceptional circumstances in accordance with Article 8 of Commission Regulation (EC) No 1085/2003 to the terms of the Marketing Authorisation until specific conditions as defined in Annex II.C (points 1 and 2) are fulfilled.