European Medicines Agency

London, 25 August 2009
Doc. Ref. EMEA/PDCO/518054/2009

Meeting highlights from the Paediatric Committee held by written procedure, 19-21 August 2009

Opinions on paediatric investigation plans
The Paediatric Committee (PDCO) adopted opinions agreeing paediatric investigation plans (PIPs) for the following medicines:

- Propranolol hydrochloride, from Pierre Fabre Dermatologie, in the therapeutic area of dermatology;
- Clopidogrel, from Sanofi Pharma Bristol-Myers Squibb SNC and Bristol-Myers Squibb Pharma EEIG, in the therapeutic area of cardiovascular diseases;
- Influenza virus surface antigens (haemagglutinin (HA) and neuraminidase) of strain: A/California/07/2009 influenza like virus, from Novartis Vaccines & Diagnostics GmbH & Co. KG, in the therapeutic area of vaccines[*];
- Split influenza virus, inactivated containing antigen equivalent to A/California/7/2009 (H1N1)-like strain (A/California/7/2009 (NYMC X-179A)), adjuvanted), from Sanofi Pasteur SA, in the therapeutic area of vaccines[*];
- Split influenza virus, inactivated containing antigen equivalent to A/California/7/2009 (H1N1)-like strain (A/California/7/2009 (NYMC X-179A)), non- adjuvanted, from Sanofi Pasteur SA, in the therapeutic area of vaccines[*];

A PIP sets out a programme for the development of a medicine in the paediatric population. The PIP aims to generate the necessary quality, safety and efficacy data through studies to support the authorisation of the medicine for use in children of all ages. These data have to be submitted to the European Medicines Agency (EMEA), or national competent authorities, as part of an application for a marketing authorisation for a new medicine, or for one covered by a patent. In some cases, a PIP may include a waiver of the studies in one or more paediatric subsets, or a deferral.

Opinions on product-specific waivers
The PDCO adopted a positive opinion for a product-specific waiver, recommending that the obligation to submit data obtained through clinical studies with children be waived in all subsets of the paediatric population, for the following medicine:

- Pegaptanib sodium, from Pfizer Global Research & Development, in the therapeutic area of ophthalmology.

Waivers can be issued if there is evidence that the medicine concerned is likely to be ineffective or unsafe in the paediatric population, or that the disease or condition targeted occurs only in adult populations, or that the medicine, or the performance of trials, does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

[*] PIP approved under the accelerated procedure for evaluation of paediatric investigation plans for pandemic influenza vaccines during a pandemic (http://www.emea.europa.eu/pdfs/human/paediatrics/40577909en.pdf)

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Opinion on compliance check
The PDCO adopted a positive opinion on compliance check for Valsartan from Novartis Europharm Limited, in the therapeutic area of cardiovascular diseases.

A compliance check is performed to verify that all the measures agreed in a PIP and reflected in the EMEA decision have been conducted in accordance with the decision, including the agreed timelines. Compliance is one of several prerequisites for obtaining the rewards and incentives provided for in Articles 36 to 38 of the Paediatric Regulation.

Before the submission of a request for a compliance check, applicants are encouraged to consult the EMEA Procedural advice for validation of a new marketing authorisation application or extension/variation application and compliance check with an agreed PIP.

The next meeting of the PDCO will be held on 16-18 September 2009.

– END –

Notes:

1. PDCO opinions on PIPs and waivers are transformed into EMEA decisions within the timeframe laid down by the Paediatric Regulation (Regulation (EC) No 1901/2006, as amended). The decisions can be found on the EMEA website at: http://www.emea.europa.eu/htms/human/paediatrics/decisions.htm
2. As of 26 January 2009, pharmaceutical companies that submit an application for a marketing authorisation for a medicinal product, or those that submit an application for an extension of indication, a new route of administration, or a new pharmaceutical form of a medicinal product already authorised in the EEA, have to provide either the results of studies in children conducted in accordance with an approved PIP, or an EMEA decision on a waiver or on a deferral.
3. More information about the PDCO and the Paediatric Regulation is available in the 'Medicines for children' section of the EMEA website.
4. This meeting report, together with other information on the work of the EMEA, can be found on the EMEA website: http://www.emea.europa.eu

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Annex of the August 2009 PDCO meeting report

	2007 (August to December)	**2008** (January to December)	**2009** (January to current month)	**Cumulative total**
Total number of validated PIP/waiver applications	**85**	**271**	**182**	**538**[1]
Applications submitted for a product not yet authorised *(Article 7*[2]*)*	39	186	127	352 *(65%)*
Applications submitted for a product already authorised and still under patent, in view of a submission of a variation/extension for a new indication, pharmaceutical form or route of administration *(Article 8*[2]*)*	45	75	47	167 *(31%)*
Applications submitted for an off-patent product developed specifically for children with an age-appropriate formulation *(Article 30*[2]*)*	1	10	8	19 *(4%)*
PIPs and full waiver indications covered by these applications	**202**	**395**	**240**	**837**

Number of Paediatric Committee (PDCO) opinions	**2007**	**2008**	**2009**	**Cumulative total**
Positive on full waiver	10	48	46	104
Positive on PIP, including potential deferral	2	81	93	176
Negative opinions adopted	0	4	9	13
Positive opinions adopted on modification of a PIP	0	8	22	30
Positive opinions on compliance with a PIP	0	5	5	10
Negative opinions on compliance with a PIP	0	0	1	1

[1] Of which 133 have been requests for a full waiver.
[2] Applications submitted in accordance with the referenced article of Regulation (EC) No 1901/2006, as amended.

Areas covered by PIPs/waiver applications	**2007** *(%)*	**2008** *(%)*	**2009** *(%)*
Neurology	12	6	3
Uro-nephrology	-	3	4
Gastroenterology-hepatology	9	3	4
Pneumology-allergology	8	6	7
Infectious diseases	12	8	9
Cardiovascular diseases	12	14	9
Diagnostics	-	1	1
Endocrinology-gynaecology-fertility-metabolism	19	15	20
Neonatology-paediatric intensive care	-	1	1
Immunology-rheumatology-transplantation	5	6	6
Psychiatry	5	3	2
Pain	1	3	5
Haematology-haemostaseology	1	5	5
Otorhinolaryngology	-	1	1
Oncology	11	12	10
Dermatology	1	3	6
Vaccines	2	6	4
Ophthalmology	1	2	2
Anaesthesiology	-	1	1
Nutrition	1	1	0