12 February 2014
EMA/PDCO/798803/2013
Human Medicines Research & Development Support Division

Paediatric Committee (PDCO)

Minutes of the 15-17 January 2014 meeting

Chair: Dirk Mentzer

I Introduction

I.1 Adoption of the minutes from previous meeting

Adopted.
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/document_listing/document_listing_000192.jsp&mid=WC0b01ac0580028eab

I.2 Adoption of the Agenda

Adopted with modifications.

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/document_listing/document_listing_000192.jsp&mid=WC0b01ac0580028eab

I.3 Declaration of Conflict of Interest

See Annex I

I.4 External attendance

Please refer to the January 2014 PDCO monthly report published in the EMA Website:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/document_listing/document_listing_000192.jsp&mid=WC0b01ac0580028eab

I.5 Leaving/New Members and Alternates

Please refer to the January 2014 PDCO monthly report published in the EMA Website:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/document_listing/document_listing_000192.jsp&mid=WC0b01ac0580028eab

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II Opinions

II.1 Opinions on Products

II.2 Opinions on Compliance Check

II.3 Opinions on Modification of an Agreed Paediatric Investigation Plan

Please refer to the January 2014 PDCO monthly report published in the EMA Website:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/document_listing/document_listing_000192.jsp&mid=WC0b01ac0580028eab

III Discussion of applications

The PDCO discussed 91 procedures in total[1], of which:

- 44 paediatric investigation plan applications;
- 9 product-specific waiver applications;
- 5 compliance check procedures (interim and final);
- 33 requests for modifications of an agreed paediatric investigation plan.

IV Nomination of Rapporteurs and Peer reviewers

• List of letters of intent received for submission of applications with start of procedure March 2014[1] for Nomination of Rapporteur and Peer reviewer • Nomination of Rapporteur for requests of confirmation on the applicability of the EMA decision on class waiver	The PDCO approved the lists of Rapporteurs and Peer Reviewers.

V Update and finalisation of opinions and requests for modification

All opinions taken at this meeting (relating to adoption of opinions, recommendations, requests for modifications and applicability of class waivers) were made in the presence of the required quorum of members.

The opinions adopted during the Paediatric Committee meeting of January 2014 are published in the same month's meeting report published in the EMA website: http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/document_listing/document_listing_000192.jsp&mid=WC0b01ac0580028eab.

[1] The procedures discussed by the PDCO are on-going and therefore are considered confidential. Additional details on these procedures will be disclosed in the PDCO Committee meeting reports (after the PDCO Opinion is adopted), and on the Opinions and decisions on paediatric investigation plans webpage (after the EMA Decision is issued).

VI Discussion on the applicability of class waiver

Active substance	Proposed indication	Condition	Outcome	Potential paediatric interest of this medicine suggested by PDCO
vemurafenib	Treatment of patients with BRAF V600 mutated hairy cell leukaemia	Treatment of hairy cell leukaemia	Confirmed	Melanoma (PIP agreed), leukaemia, low and high grade gliomas, papillary thyroid carcinoma, Langerhans histiocytosis, neurofibromatosis-related malignancies, juvenile myelomonocytic leukaemia (JMML), rhabdomyosarcoma
	Treatment of patients with BRAF V600 mutated non-small cell lung carcinoma	Treatment of lung carcinoma (small cell and non-small cell carcinoma)	Confirmed	
	Treatment of patients with BRAF V600 mutated multiple myeloma	Treatment of multiple myeloma	Confirmed	
	Treatment of patients with BRAF V600 mutated ovarian carcinoma	Treatment of ovarian carcinoma (excluding rhabdomyosarcoma and germ cell tumours)	Confirmed	
	Treatment of patients with BRAF V600 mutated breast carcinoma	Treatment of breast carcinoma	Confirmed	
	Treatment of patients with BRAF V600 mutated cholangiocarcinoma/cancer of the biliary tract	Treatment of liver and intrahepatic bile duct carcinoma (excluding hepatoblastoma)	Confirmed	
Selumetinib (AZD6244; ARRY-142886)	In combination with docetaxel, treatment of patients with locally advanced or metastatic KRAS mutation positive NSCLC after failure of one prior anticancer therapy	Treatment of lung carcinoma (small cell and non-small cell carcinoma)	Confirmed	Not defined by the PDCO
AZD9291	Treatment of lung carcinoma (small cell and non-small cell carcinoma)	Treatment of lung carcinoma (small cell and non-small cell carcinoma)	Confirmed	Not defined by the PDCO
Anti PD-L1 monoclonal antibody	Treatment of lung carcinoma (small cell and non-small cell carcinoma)	Treatment of lung carcinoma (small cell and non-small cell carcinoma)	Confirmed	Treatment of paediatric solid tumours

VII Discussion on the inclusion of an indication within a condition in an agreed PIP/waiver

PIP number	Active substance	Proposed indication	Condition	Outcome
EMEA-001213-PIP02-12	Ferric citrate (KRX-0502)	Treatment/control of hyperphosphataemia in patients with end-stage renal disease on dialysis and the improvement (increase and maintenance) of iron stores	Treatment of hyperphospha-taemia	The PDCO is of the view that the proposed indication "The control of hyperphosphataemia and the increase and maintenance of iron stores in adult chronic kidney disease (CKD) patients", is not covered by the condition "treatment of hyperphosphataemia" listed in the Agency Decision.

VIII Annual reports on deferrals

Annual report based on PIP decision for	Substances (abbrev.)	Product Name	Orphan	Difficulties progress-ing the PIP?	Outcome
EMEA-000279-PIP01-08	raltegravir	Isentress	No	Yes	Clinical measure 4: enrolment difficulties in the neonatal subset. Clinical measures 3 and 5: clarification that this is a 240-week study (LPLV Dec 2017). PIP modification planned for 21/02/2014.
EMEA-000636-PIP01-09	3-[[[6-Deoxy-4-O-(3,5-dichloro-2-ethyl-4,6-dihydroxybenzoyl)-2-O-methyl-β-D-man...	Dificid	No	Yes	Delay due to recruitment issues. A modification request has been submitted.

Annual report based on PIP decision for	Substances (abbrev.)	Product Name	Orphan	Difficulties progress-ing the PIP?	Outcome
EMEA-000709-PIP01-09	rufinamide	Inovelon	Yes	Yes	Recruitment issues are reported. The applicant is undertaking measures to enhance recruitment and planning an alternative approach to PK analysis.
EMEA-000456-PIP01-08	Insulin degludec	Not available at present	No	No	The PDCO has been informed that there are no issues as regards the progression of the PIP studies.
EMEA-000479-PIP01-08	Insulin aspart / Insulin degludec	Not available at present	No	No	The PDCO has been informed that there are no issues as regards the progression of the PIP studies.
EMEA-000878-PIP02-11	Colestilan	BindRen	No	Yes	Delay due to recruitment issues. A modification request is planned for May 2014.
EMEA-001181-PIP01-11	Agomelatine	Valdoxan, Thymanax	No	Yes	Delay due to recruitment issues. A modification request is planned to be submitted.

Annual report based on PIP decision for	Substances (abbrev.)	Product Name	Orphan	Difficulties progress-ing the PIP?	Outcome
EMEA-000139-PIP01-07	N.meningitidis 961c purified antigen / N.meningitidis 287-953 purified antigen /...	Bexsero	No	No	Despite no difficulties have been reported, multiple deferred studies have been completed with slight delays (less than 3 months). One study has been completed with one year delay. 2 ongoing studies are expected to be completed with 2 years delay. A modification procedure is planned.
EMEA-000311-PIP01-08	ustekinumab	Stelara	No	No	The PDCO has been informed that there are no issues as regards the progression of the PIP studies.
EMEA-000311-PIP03-11	ustekinumab	Stelara	No	No	The PDCO has been informed that there are no issues as regards the progression of the PIP studies.
EMEA-000480-PIP01-08	Ticagrelor	Brilique	No	Yes	The PDCO is informed of ongoing recruitment issues and issues with ethic committees and NCA's. A modification of the PIP is planned for March 2014.
EMEA-000056-PIP01-07	Bevacizumab	Avastin	No	No	The PDCO noted the report.

Annual report based on PIP decision for	Substances (abbrev.)	Product Name	Orphan	Difficulties progress-ing the PIP?	Outcome
EMEA-000056-PIP03-10	Bevacizumab	Avastin	No	Yes	The PDCO noted the report and that an opinion on a modification has been adopted in December 2013.

IX Other topics

Guidelines	
Concept paper on the revision of the guideline on conduct of pharmacovigilance for medicines used by the paediatric population*	The draft concept paper on the revision of the guideline on conduct of pharmacovigilance for medicines used by the paediatric population was presented and discussed at PRAC and PDCO January meetings. Further comments on the concept paper are awaited from PRAC members. Once these have been incorporated, the PDCO members will be asked to add any additional comments they may have to the concept paper. The final draft concept paper will then be presented again at PRAC and PDCO meetings for an adoption by both Committees.
Working groups	
Paediatric inventory	The meeting was cancelled.
Paediatric oncology	The group discussed briefly participation in external meetings and working groups as well as contributions to the forthcoming inventory of needs.
Extrapolation	The meeting was cancelled.
Formulation	No non-product related issues where reported to the Committee.
Non-Clinical	No non-product related issues where reported to the Committee.
Other topics	
PDCO and Companies meeting on Paediatric trials in *Clostridium difficile* infections	Actelion Pharmaceuticals Ltd (Actelion), Astellas Pharma Europe B.V. (Astellas) and Cubist Pharmaceuticals Inc. (Cubist) initiated a meeting with the PDCO to discuss if children below 2 years of age should be included in PIPs for the development of anti-infective treatments for *Clostridium difficile* infection (CDI). External experts invited by industry: Saul Faust (professor of paediatric immunology & infectious diseases, University of Southampton), Mark Wilcox (professor of medical microbiology, University of Leeds). External experts invited by PDCO: Jan Taminiau (gastro-enterologist, University Hospital Antwerp), John Hartley (consultant microbiologist and director of infection prevention and control, Great Ormond Street Hospital,

	London), Susanna Livadiotti (Children's Hospital Bambino Gesù Rome). The PDCO acknowledged difficulties regarding the diagnosis of CDI in very young children without underlying risk factors, due to high rates of asymptomatic colonisation and lack of validated diagnostic tests in that population. One company expert stated that there would be no unmet need for CDI treatment below two years of age. However, this was not confirmed by other experts and the PDCO. Based on the presented information, the PDCO could not agree that CDI does not occur in children below 2 years of age but it was acknowledged that specific trials dedicated to the youngest age subsets (particularly neonates) will face feasibility issues. The PDCO discussed the need for at least safety (including PK) data in children below 2 years of age. Taking into account the above issues, the committee concluded that further considerations regarding feasibility of clinical trials or potential grounds for waivers may be discussed in the context of individual development programmes. Further information on the epidemiology of CDI in the youngest children, as well as on the performance of diagnostic tests in the paediatric population will help to make more informed decisions in the future.
Election/designation of the new FWG Chair	The PDCO Chair called for PDCO Members interested in becoming the new FWG Chair.
Project 2014 - Move to Churchill Place	An update on the EMA move to Churchill Place in July 2014 was presented. The PDCO will be informed monthly of the status of the plans.
CHMP update on paediatric topics	The PDCO members were informed about the final CHMP opinions on medicinal products with paediatric interest adopted in December 2013. No new paediatric indications were granted.
Outcome of PDCO/CAT informal meeting in Trieste	The PDCO was informed about the ATMP-topics discussed at the PDCO CAT informal meeting. The future direction for Hepatitis C therapies was mentioned and the suggestion to involve experts for an informed discussion about future directions of PIPs in that field.
Outcome of ECDC-EMA Workshop on Vaccine schedules in PIPs*	The workshop held on 11 December 2013 in ECDC premises, co-chaired between EMA and ECDC, gathered a dozen of experts responsible for vaccination schedules. The experts were in agreement that the “worst case scenario” should be chosen for the clinical trials, allowing extrapolation to the less stringent schedules. DTP-Polio-Hib was considered the vaccine of choice for the purpose of the standard PIP, as not all countries have routine vaccination against Hepatitis B. The experts concluded that clinical trials with a new DTP-Polio-Hib vaccine should evaluate the following priming schedule: 2, 4 months (+/- 2 weeks), which is the one recently adopted by France. A booster dose should be studied at 12 months (+/- 1 month). Concomitant

	administration of the pneumococcal vaccine should be also evaluated as part of the standard PIP. Studies should include the 2 different conjugated pneumococcal vaccines (tetanus toxoid and CRM), as well as an arm with no pneumococcal vaccine. A paper explaining the rationale behind the French schedule has become available after the meeting. It was explained to the Committee that there is a risk of interference with maternal antibodies at 2 months of age. It is possible that the meeting conclusions are still valid, but clinical studies should not be run in France due to the overimmunised maternal population in this country. This will have to be rediscussed with the expert working group. A follow-up TC will be planned and the standard PIP will be drafted. The PDCO recommended publishing the draft standard PIP for public comments at the last stage of the process.
Minutes of the meeting on appropriate duration of the placebo controlled phase of the pivotal paediatric studies in type 2 diabetes	On 13 December 2013 members from the PDCO, CHMP and EMA scientific staff discussed the issue of the appropriate duration of the placebo-controlled phase of the pivotal paediatric studies in type 2 diabetes. Following advice received in previous expert workshops held at the Agency, and the EMA guidelines, the EMA has so far decided on a case-by-case basis on a duration of 3 or 6 months. The decision has depended on the type of drug and its pharmacologic potential (e.g. long-acting medicinal products, potential effect on weight and/or blood pressure,..). Currently there is no data that clearly supports either a 3 or 6 months duration of the placebo-controlled phase in adolescents. Both scenarios have conceptual advantages and disadvantages (reported below). Therefore, the participants agreed that for the time being the PDCO could agree to a 6 months placebo controlled phase if this is proposed by the applicant. However, in these cases glycaemic control (i.e. HbA1c) must also be measured at the 3 months timepoint to allow comparisons. Applicants should consider, in case of a 6-month duration, limiting the upper HbA1c at inclusion at 9% or 9.5%. Once the first results from pivotal paediatric studies in type 2 diabetes become available, for products from the different classes (i.e. GLP-1 agonists, DPP-4 inhibitors, SGLT-2 inhibitors,…), this approach will be reviewed. Arguments in favour of a 3-month duration of placebo-controlled phase: • This duration should be sufficient to demonstrate a similar treatment effect as in adults. • Trials may include some highly uncontrolled paediatric patients (up to HbA1c 10% or 11%) and stringent rescue criteria in a 6-month study may lead to a high drop-out rate and inconclusive results. • Compliance to treatment is an issue in the paediatric T2D target

	population; a 3-month placebo-controlled phase is likely to be more feasible, also from an ethical perspective. • Even though there are some pathophysiologic differences in adolescents vs adults with T2D (i.e. faster beta cell decline), it is unlikely that any impact of this difference can be captured with a 6 months study duration. Arguments in favour of a 6-month duration: • The effects of the medicinal products on beta cells may be slow in paediatric T2D patients (i.e. slow recovery from glucotoxicity). • A 6-month duration may be more predictive of the durability of the treatment effect in children, on theoretical grounds. • Some of the paediatric patients have very limited metabolic control and patients above HbA1c 8.5% very often remain above, with or without additional treatment. These conclusions were endorsed and the minutes were adopted by the PDCO on 17 January 2014.
Measures vs. studies in PIP Opinions	The PDCO agreed to define more clearly in the opinions which measures of the PIP are considered studies and which ones are not. A new Annex I template will be implemented soon by the Agency.
Reminder of copyright - Use of the slides, images and graphs produced by EMA	The PDCO was reminded that the relevant rules are published in the Agency's website. Briefly, information and documents made available on the Agency's webpages are public and may be reproduced and/or distributed, totally or in part, irrespective of the means and/or the formats used, for non-commercial and commercial purposes, provided that the Agency is always acknowledged as the source of the material. Such acknowledgement must be included in each copy of the material. Citations may be made from such material without prior permission, provided the source is always acknowledged. The above-mentioned permissions do not apply to content supplied by third parties. Therefore, for documents where the copyright vests in a third party, permission for reproduction must be obtained from this copyright holder.
Propylene glycol in IV formulations for children under 4 years of age (EMEA/H/A-5(3)/1317)*	The PDCO was informed that members could send comments to this paper. It was decided that these comments will be finalized and sent to the Rapporteurs after the next PDCO meeting.

Any other business

- PCWP draft work plan 2014* and HCPWP draft work plan 2014*

  The PCWP and HCPWP 2014 work plans were presented to the PDCO with a reminder to nominate a PDCO representative. It was clarified that PDCO can nominate any PDCO member, not solely a representative from health care professionals.

- Guideline on Duchenne and Becker muscular dystrophy*

  This GL has been updated after external consultation and is now open for further comments by the PDCO.

- Call-for-interest to join Neonatal Working Group

  A call for interested PDCO members to join this new working group was made.

- Compliance checks – Regulatory aspects

  The PDCO was informed that to avoid undue delay in marketing authorisation procedures, in selected instances the compliance check procedure may be done via written procedure. In this case, the PDCO members and alternates would receive the Summary Report with a proposed outcome (letter or Opinion) via Eudralink, and a deadline for submitting one's vote (silence/assent applies).

- Guideline on format and content of PIP

  The PDCO was informed that the European Commission has submitted to the Agency the comments received to the proposed revision of the Guideline on Format and Content of PIP/waiver Applications. The EC has requested that the Agency, with its Committee, proposes a further revised version, after discussion of the comments received, for evaluation and final adoption by the EC. A panel composed of the PDCO Chair, two other PDCO members, and the Head of Office of Paediatric Medicines was formed to work on the proposals.

Note on access to documents

Documents marked with an asterisk* in these minutes cannot be released at present as they are currently in draft format. They will become public when adopted in their final form.

Annex I to the Minutes of the PDCO of January 2014

Documentation on Declaration of interest of members, alternates and experts

Based on the Declarations of interest submitted by the Committee members, alternates and experts and based on the topics in the agenda of the current meeting, the Committee Secretariat announced the restricted involvement of Committee members for the upcoming discussions.

In accordance with the Agency's revised Policy and Procedure on the handling of conflicts of interests, participants in this meeting were asked to declare any conflict of interests on the matters for discussion (in particular any changes, omissions or errors to the already declared interests).

Member, alternate, expert name	Outcome restriction following evaluation of electronic evaluation form	Topics on the current Committee Agenda for which this restriction applies
Adriana Ceci	Restriction level DP	EMEA-001371-PIP01-12
Adriana Ceci	Restriction level DP	EMEA-70-2013 (EMEA-000978-PIP01-10)
Adriana Ceci	Restriction level DP	EMEA-71-2013 (EMEA-000978-PIP01-10)
Adriana Ceci	Restriction level DP	EMEA-72-2013 (EMEA-000978-PIP01-10)
Adriana Ceci	Restriction level DP	EMEA-73-2013 (EMEA-000978-PIP01-10)
Carine de Beaufort	Restriction level XR	EMEA-000128-PIP03-13
Christoph Male	Restriction level DP	EMEA-001114-PIP01-10-M02
Paolo Rossi	Restriction level DP	EMEA-000872-PIP02-13
Paolo Rossi	Restriction level XR	EMEA-000128-PIP03-13
Paolo Rossi	Restriction level XR	EMEA-001430-PIP01-13
Paolo Rossi	Restriction level XR	EMEA-001458-PIP01-13

Note: the procedures identified in the table above are on-going and therefore considered commercially confidential. Additional details on these procedures will be disclosed in the PDCO Committee meeting reports (after the PDCO Opinion is adopted), and on the Opinions and decisions on paediatric investigation plans webpage (after the EMA Decision is issued).

No new or additional conflicts were declared.

Discussions, deliberations and voting took place in full respect of the restricted involvement of Scientific Committee members and, where relevant, experts attending the plenary meeting, as announced by the Scientific Committee Secretariat at the start of meeting.

Restriction levels:

Evaluation of the conflict of interest	
Outcome	Impact
R-P	To be replaced for the discussions, final deliberations and voting as appropriate in relation to the relevant product or a competitor product.
XP	Where Individual product involvement is declared - PRODUCT INDICATION: - No involvement with respect to procedures involving the relevant product or a competitor product in the relevant indication i.e. no part in discussions, final deliberations and voting as appropriate as regards these medicinal products. - Cannot act as Rapporteur for these products - [Cannot act as Rapporteur for development of guidelines in concerned therapeutic area].
XC	Where cross product / general involvement is declared - COMPANY: - No involvement (as outlined above) with respect to products from the specified company. - Cannot act as Rapporteur for products from the relevant company(ies).
DP	Where Individual product involvement is declared - PRODUCT INDICATION: - Involvement in discussions only with respect to procedures involving the relevant product or a competitor product i.e. no part in final deliberations and voting as appropriate as regards these medicinal products. - Cannot act as Rapporteur for these products.
DC	Where cross product / general involvement is declared - COMPANY: - Involvement in discussions only with respect to products from the specified company. - Cannot act as Rapporteur on products from the relevant company(ies).
XR	Committee member cannot act as Rapporteur or Peer reviewer in relation to any medicinal product from the relevant company.
R-C	To be replaced for the discussions, final deliberations and voting as appropriate in relation to any medicinal product from the relevant company

Annex II to the Minutes of the PDCO of January 2014

List of Participants

Chair

Dirk MENTZER

Members appointed by Member States or CHMP

Karl Heinz HUEMER	Austria
Koenraad NORGA	Belgium
Violeta IOTOVA	Bulgaria
George SAVVA	Cyprus
Jaroslav STERBA	Czech Republic
Marianne ORHOLM	Denmark
Irja LUTSAR	Estonia
Pirjo LAITINEN-PARKONNEN	Finland
Birka LEHMANN	Germany
Agnes GYURASICS	Hungary
Gylfi OLKARSSON	Iceland
Paolo ROSSI	Italy
Dina APELE-FREMIANE	Latvia
Carine de BEAUFORT	Luxembourg
John Joseph BORG	Malta
Hendrik van den BERG	The Netherlands
Siri WANG	Norway
Marek MIGDAL	Poland
Dana Gabriela MARIN	Romania
Stefan GROSEK	Slovenia
Viveca Lena ODLIND	Sweden
Julia DUNNE	United Kingdom

Alternates appointed by Member States or CHMP

Christoph MALE	Austria

Jacqueline CARLEER	Belgium
Marta GRANSTRÖM	Denmark
Jana LASS	Estonia
Immanuel BARTH	Germany
Brian AYLWARD	Ireland
Francesca ROCCHI	Italy
Jolanta WITKOWSKA-OZOGOWSKA	Poland
Hugo TAVARES	Portugal
Maria Jesus FERNANDEZ CORTIZO	Spain
Ninna GULLBERG	Sweden
Angeliki SIAPKARA	United Kingdom

Members representing patients' organisations

Tsveta SCHYNS-LIHARSKA

Alternates representing patients' organisations

Gerlind BODE

Members representing health care professionals

Adriana CECI

Anthony James NUNN

Alternates representing health care professionals

Paolo PAOLUCCI

Experts

Peter BAUER	Medical statistician
Martina RIEGL	Medicines and Healthcare Products Regulatory Agency, United Kingdom
Catherine DEGUINES	National Agency for Medicines and Health Products Safety, France

Observers

Aina Jannnicke OVREBUST	Norwegian Medicines Agency
Tove Lill STENDAL	Norwegian Medicines Agency

European Medicines Agency

Jordi Llinares GARCIA	Head of Product Development Scientific Support Department

Paolo TOMASI	Head of Paediatric Medicines
Sophie OLIVIER	Scientific Officer, Paediatric Medicines
Andrea ECKER	Scientific Officer, Paediatric Medicines
Benjamin PELLE	Scientific Officer, Paediatric Medicines
Cecile OLIVIER	Scientific Officer, Paediatric Medicines
Chrissi PALLIDIS	Scientific Officer, Paediatric Medicines
Dobromir PENKOV	Scientific Officer, Paediatric Medicines
Emilie DESFONTAINE	Scientific Officer, Paediatric Medicines
Giovanni LESA	Scientific Officer, Paediatric Medicines
Gunter EGGER	Scientific Officer, Paediatric Medicines
Irmgard EICHLER	Scientific Officer, Paediatric Medicines
Janina KARRES	Scientific Officer, Paediatric Medicines
Peter KÁROLYI	Scientific Officer, Paediatric Medicines
Ralf HEROLD	Scientific Officer, Paediatric Medicines
Ralph BAX	Scientific Officer, Paediatric Medicines
Richard VESELY	Scientific Officer, Paediatric Medicines
Thorsten OLSKI	Scientific Officer, Paediatric Medicines
Ramona ZEMACHE	Assistant, Paediatric Medicines
Aurelie HERVIEU	Assistant, Paediatric Medicines
Thomas GIRARD	Regulatory Affairs Officer, Regulatory Affairs Office