

Report of a Meeting

Second Partners Meeting on Better Medicines for Children

WHO Headquarters, Geneva, Switzerland 14-15 October 2010



Table of contents

Executive summary	3
Introduction	4
Progress made	5
WHO	5
Countries	6
Ghana	6
The United Republic of Tanzania	7
India	7
Global initiatives	7
Ongoing work	8
WHO	8
Global initiatives	9
Action areas identified	11
Research and development	11
Policy, regulation, procurement and supply in countries	12
Advocacy and communications	12
Funding	13
Partnerships	13
Emerging and other issues	13
Working groups	14
TB medicines for children	14
Weight measurement	14
Human resources capacity	14
Agenda	
List of participants	17



Executive summary

The Better Medicines for Children project aims to promote better use of medicines in children, promote access to medicines for children, fill knowledge gaps about priority medicines for children and promote research and development of essential medicines for children. The project is funded by the Bill and Melinda Gates Foundation and is in the second year.

A partners meeting was held to share information on progress related to the Better Medicines for Children project; to provide a forum for exchange of ideas; to foster commitment to a continued partnership; and to identify the way forward to complete the objectives set out in resolution WHA60.20 on Better Medicines for Children. The meeting was attended by WHO staff from the Medicines, Access and Rational Use team, members of the implementation teams from Ghana, India and the United Republic of Tanzania, and experts, researchers and representatives from organizations having an interest in Better Medicines for Children.

Progress has been made by WHO on a number of areas such as paediatric tuberculosis, with the finalization and publication of a number of studies on medicines and updated guidelines for the treatment of tuberculosis in children. In addition, the WHO Model Formulary for Children has been published, workshops on Essential Medicines Lists have been held and the Pediatric medicines Regulatory Network has been established.

Three countries, Ghana, India and the United Republic of Tanzania have been implementing the objectives to promote access to and use of better medicines for children. Progress has been made in Ghana and India, in completing baseline surveys and the United Republic of Tanzania is preparing for the assessment. A number of global initiatives are under way that contribute to promoting better use of medicines in children, promoting access to medicines for children, filling knowledge gaps about priority medicines for children and promoting research and development of essential medicines for children.

Work is still needed on a number of topics in order to develop effective interventions to improve the use of medicines in children. Action is required on research and development for appropriate dosing and formulations; guidance on clinical trials in children and suitable regulatory pathways to ensure the availability of better medicines for children. Country level training and guidance for procurement and supply chain management, for regulatory procedures, and for the policy adoption process is needed to improve availability of medicines in countries. Funding, advocacy and partnerships with key stakeholders is needed to carry this work forward.



Working groups were set up to consider the following areas: the need for appropriate dosages and formulations for the treatment of tuberculosis in children; the lack of knowledge on human resource capacity for medicines for children; and the need for appropriate weight estimation tools for dosing decisions.

Introduction

Overview

The World Health Assembly resolution WHA60.20 approved in May 2007, called for action for better medicines for children. The World Health Organization, Department of Essential Medicines and Pharmaceutical Policies obtained a grant from the Bill and Melinda Gates Foundation for the Better Medicines for Children project. This project includes work on: promoting better use of medicines in children, promoting access to medicines for children in priority countries, filling knowledge gaps for priority medicines for children and promoting research and development of essential medicines for children by providing clinical evidence, guidance and specifications for missing products.

This report outlines the highlights of the Second Partners Meeting on Better Medicines for Children and the discussion on the way forward. Presentations are available upon request.

Meeting objectives

To share information on progress related to the Better Medicines for Children project.

The Second Partners Meeting on Better Medicines for children took place 18 months after the first partners meeting and 2 years into the Bill and Melinda Gates-funded project. Considerable progress has been made in that time by WHO, in countries and through a number of global initiatives.

To provide a forum for an exchange of ideas.

The meeting was attended by WHO staff from the Medicines, Access and Rational Use team at WHO Geneva, members of the implementation teams from Ghana, India and the United Republic of Tanzania, and experts, researchers and representatives from organizations with a stake in Better Medicines for Children.

To foster commitment to a continued partnership.

With 18 month remaining on the Gates project and much work still to be done, the partners meeting aimed to encourage partners to work together to craft strategies to meet challenges and overcome constraints and to sustain their commitment to Better Medicines for Children.



To identify the way forward to complete the objectives set out in resolution WHA60.20 on Better Medicines for Children.¹

Despite the progress that has been made there is still much work to do to improve access to better medicines for children and to achieve health outcomes and reduce morbidity and mortality in children.

Progress made

WHO

WHO works towards the development of norms and standards including: harmonization of clinical trials, Essential Medicines Lists for children (EMLc) and clinical guidelines. WHO also promotes norms and standards for the quality and safety of children's medicines and works to increase in regulatory capacity. Another important component of work includes making treatment guidelines and information on medicines available. WHO also encourages adequate financing for medicines for children.

During the last year there has been progress on:

- Medicines for paediatric tuberculosis:
 - o Comprehensive review of clinical evidence and safety of tuberculosis medicines for children.²
 - Pharmacokinetic simulations to suggest a fixed-dose combination formulation for pediatric tuberculosis.3
 - A review of fluoroquinine use in paediatrictrics.⁴
 - Feasibility study on fixed-dose combinations for tuberculosis treatment which showed that there are challenges in the production of an appropriate fixed-dosage form for children.
 - Updated guidelines for the treatment of tuberculosis in children.⁵

www.who.int/childmedicines/publications/en/

www.who.int/childmedicines

www.who.int/selection_medicines/committees/expert/17/application/TB_Children.pdf

www.who.int/childmedicines

http://whqlibdoc.who.int/publications/2010/9789241500449_eng.pdf



- Publication of the WHO Model Formulary for Children.¹
 - The first edition of the WHO Model Formulary for children has been prepared, based on the 2nd edition of the Essential Medicine List for children, to provide information about use, dosage, adverse effects, and contraindications for the medicines on the EMLc.
- Publication of the joint UNICEF/WHO Second edition of Sources and Prices of Selected Medicines for Children.²
 - o This edition offers up-to-date information on the availability and price of different paediatric formulations selected from the EMLc.
- Inter-country workshops on Essential Medicines Lists (EML), held in English³ and French:⁴
 - Countries shared information on national EMLs and related activities.
 Potential activities in relation to the development of national EMLc were reviewed.
- Recommendations for the preferred dosage forms of medicines for children adopted by the Expert Committee on the Selection and Use of Essential Medicines; for flexible solid, oral formulations that can be administered at the point of care.

Countries

Work has started in three countries, Ghana, India and the United Republic of Tanzania on implementing strategies to improve access to and use of medicines for children.

Ghana

The BMC project was launched in Ghana in April 2010. Since the start of the project a baseline survey/literature review of existing information about medicines for children, an assessment of local manufacturing capacity and pricing and availability studies have been completed. In addition, a Drugs and Therapeutic Committee (DTC) peer review workshop for the Southern Sector of Ghana has been held and an assessment of the quality of paediatric care has been carried out. The data will form part of the requisite baseline for implementation work in 2011.

www.who.int/selection_medicines/list/WMFc_2010.pdf

² www.who.int/medicines/publications/essentialmedicines/Sources_Prices2010.pdf

³ www.who.int/childmedicines/progress/Accra_final.pdf

⁴ www.who.int/childmedicines/progress/Ghana_French.pdf



The United Republic of Tanzania

Work has commenced with the establishment of a Better Medicines for Children technical working group, the development of DTC guidelines and Standard Treatment Guidelines for children based on the Pocketbook of Hospital Care for Children. Although a work plan was approved in April 2010, the Better Medicines for Children project was delayed due to organizational changes in the Ministry of Health that affected the timing of all funded activities.

India

The Better Medicines for Children project in India aims to improve the availability of essential medicines for children by developing and implementing an Essential Medicines List for children in two states, Orissa and Chhattisgarh. Pricing and availability studies in the two states are planned pre- and post-intervention. Training for the data collection has already been completed. Essential Medicines Lists for children are being developed in the two states as well as by the Indian Academy of Paediatrics at a national level.

Global initiatives

A number of global initiatives are under way which contribute to Better Medicines for Children. Progress on the following initiatives was shared:

- A study was carried out by the Institute for Pediatric Innovation and Dartmouth
 on practices and end-use preference for medicines for children in Tanzania. More
 than six hundred health care workers, caregivers and children were surveyed.
 Preliminary key results show that:
 - Crushed pills mixed with water are the most common method of administration in newborn babies and children under 6. Breaking and swallowing pill fractions was also common. This raises issues of accuracy of dosing, palatability of the mixture and adherence.
 - o An overwhelming preference for sweet liquids or suspensions was expressed by children, parents and healthcare workers.
 - o There was a lack of familiarity with dispersible medicines among all groups surveyed.
- A study was carried out by the Ecumenical Pharmaceutical Network in church health facilities in Kenya to determine the level of availability and the pricing of children's medicines and to investigate the factors impacting access. Notable findings were:



- Responsibility for medicine selection was mostly in the hands of the heads of facilities.
- Lack of adequate financing was the main factor hampering the procurement of medicines for children.
- A review of the decision-making process for policies relating to children's products was carried out by Medicines for Malaria Venture. Key findings showed:
 - That all stakeholders (policy makers, clinicians, procurement managers, donors) need to be informed about options for new products and involved in disseminating the necessary information to facilitate its uptake and correct use.
 - There is a need for efficacy and resistance data for medicines currently in use and also for alternative medicines.
 - Financial resources for purchasing the alternative medicines should be in place.
 - o An agreed process for policy change needs to be established.

Ongoing work

WHO

WHO and UNICEF held a meeting of stakeholders in September 2010 to agree on a
core list of the top 20 priority essential medicines for child survival. The list will be
launched together with a list of priority medicines for maternal care. The aim is to
provide a core list of medicines that must be available to procurement authorities.

- A new objective for the Better Medicines for Children project has been approved, that aims to develop and implement a communications strategy targeting manufacturers in India and key supply chain stakeholders in Ghana and Tanzania to promote the manufacture, procurement and supply of essential paediatric medicines.
- Guidelines for treatment of chronic pain in children are in the final review stages: they will be submitted for approval to the WHO Guidelines Review Committee in November and are planned for publication in the first quarter of 2011.
- The Paediatric medicines Regulatory Network¹ (PmRN) was established as a forum for discussion and to raise awareness on paediatric medicines' regulatory issues. Work to expand the network is progressing and will be discussed further.
- Now that the Model Formulary for Children has been published, plans to actively implement it are being developed.

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www.who.int/childmedicines/paediatric_regulators/en/



- An updated version of the Pocketbook of Hospital Care for Children is in preparation with a target for publication in June 2011.
- There will be a workshop on paediatric medicines at the ICDRA meeting in Singapore, 30 Nov 3 December 2010.

Global initiatives

Information on the following initiatives was shared at the meeting:

- A database has been made public by the European Medicines Agency that lists all clinical trials. Plans to include information on clinical trials in children in an updated version are under way. However, publication of the updated version has been delayed due to the unexpected amount of information that has been identified and received by the Agency for assessment.
- The European Medicines Agency is working on guidance for clinical trials in children with regard to design, assessment and assessment of results.
- The Highly active antiretroviral treatment (HAART) for Children Campaign has been launched by Caritas Internationalis and the Ecumenical Advocacy Alliance in 2009 to communicate to governments and pharmaceutical companies that priority should be given to the needs of children living with HIV and HIV-TB co-infection. A practical advocacy initiative proposed by the HAART Campaign is a children letter writing action Prescriptions for life which encourages young people to write letters to the Ministries of Health of their respective countries and to pharmaceutical company executives to request that these key decision-makers promote additional research and product development within the context of promoting the access better medicine for children living with HIV.
- The Clinton Health Access Initiative (CHAI) is engaged in fostering a 'healthy'
 market for children's medicines, that will give suppliers to access information about
 demand, and thus allowing them to plan their research and development activities,
 and also their production schedules. It will also allow governments and purchasers
 to know about product availability and to negotiate prices.
- UNICEF has been working on many aspects of market shaping and supply management for children's products, including demand management, advocacy, information and communication, and resource mobilization.
 - UNICEF carried out a gap analysis of products required for community case management of pneumonia, malaria and diarrhea based on country and global IMCI guidelines that are used in selected countries in Africa.

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www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/ general_content_000044.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac05800 260a3



This revealed that, in some instances, there are no suitable products to meet the guideline needs, while in other instances, the guidelines requested too many variants of the same product, potentially fragmenting the market.

- UNICEF has published a paper on dispersible tablets to support decision making at country level.¹
- Collaborations to investigate the possibility to provide 'minimum requirements/technical specifications' for taste masking and taste screening for medicines for children', have shown that more work is required to determine optimal formulations.
- MSF is encouraging better formulations of HIV, TB and malaria medicines, needed for their operations. Field activities include antibiotic resistance surveys, adherence studies (such as use of co-blister-fixed dose combinations for artesunate/ amodiaquine in Sierra Leone), lobbying for rectal artesunate and replacement of quinine with artesunate/arthemether.
- The UK Medicines for Children Research Network is providing infrastructure to support studies which address safety and efficacy of medicines in children. It also provides a coordination point for clinical research and works to ensure that research addresses priority needs of children.
- A project to find the best method to estimate body weight easily and reliably in children from infancy to 16 years has been developed and tested by Children's Mercy Hospitals and Clinics. Further validation of this method in low-resource settings is urgently needed so that the children's products that are now becoming available can be administered correctly to individual patients.
- The National Institute for Health has established a Pediatric Terminology Initiative to address the lack of consistent child health terminology with respect to clinical trials in children.
- Ways to bring people together through the International Pediatric Association and
- The International Union of Basic and Clinical Pharmacology, Division Of Clinical Pharmacology were discussed.
- The Global Research in Paediatrics initiative funded the EU 7th Framework Program aims to stimulate and facilitate the development and safe use of medicines in children and endorse a common approach to paediatric needs; to complement research efforts and reduce fragmentations; and to facilitate paediatric medicine innovation. A key element will be development of a global Paediatric Clinical Pharmacology Training Program.

http://www.unicef.org/supply/index_53571.html UNICEF



- The International Federation of Pharmaceutical Manufacturers (IFPMA) Paediatric Task Force will continue a survey of paediatric clinical trials and will participate in the development of global standards. In addition, the IFPMA plans to develop a position paper on flexible solid oral dosage forms as the formulation of choice and will continue to collaborate with the Paediatric medicines Regulatory Network.
- The International Development Research Centre is currently carrying out a pilot project in Uganda to evaluate SMS text messaging to improve integrated community case management of acute respiratory infections, pneumonia, malaria and diarrhea in children.
- There is an increasing number of projects using cell phone technology. Some that were discussed at the meeting included:
 - o A UNICEF project which uses cell phone technology for supply chain management in northern Uganda
 - o The SMS for Life project in Tanzania that addresses needs in supply chain management.

Upcoming meetings				
14th International Conference of Drug Regulatory Authorities	Singapore	30 Nov - 3 Dec 2010		
Health Africa Summit	Accra, Ghana	2-3 Dec 2010		
The International Pharmaceutical Excipients Council Europe, Annual Seminar	Cannes, France	27 Jan 2011		
Expert Committee on the Selection and Use of Essential Medicines	Accra, Ghana	March 2011		
Third International Conference on Improving Use of Medicines	Alexandria, Egypt,	10-14 April 2011		
World Congress of Pharmacy and Pharmaceutical Sciences 2011	Hyderabad, India	2 - 8 Sept 2011		

Action areas identified

Areas for action that were discussed at the meeting were as follows:

Research and development

 Research and development is needed for the development of appropriate children's medicines for HIV/AIDS, palliative care, neonatal care and non communicable diseases such as cardiovascular disease and epilepsy.



- Research and development will also be required to identify appropriate
 formulations that are flexible solid oral dosage forms, appropriate for use by
 children, adapted to low-resource settings and practical for the supply chain.
- Studies on shapes and sizes of tablets that can be swallowed by children should be carried out.
- **Tuberculosis** treatment in children is an area which requires urgent development of a fixed-dose combination. A working group has been established to propose an action plan to address this need (see next section).
- Regulatory pathways need to be defined, for new formulations of well known medicines standards.

Policy, regulation, procurement and supply in countries

- Understanding what is happening in countries with respect to supply chains, policy
 making and reality is required in order to understand the challenges.
- Additional support is needed to map the supply chain to community level.
- **Training and guidance** for procurement and supply chain management, regulatory guidance, clinical trial skills and policy adoption process at country level is essential.
- Understanding country use of Essential Medicines Lists will help to determine their
 role in procurement and supply and to develop the best strategies for dissemination
 and implementation. Too often, Essential Medicines Lists sit on the shelf and are not
 used.
- Guidance is needed to support Ministries of Health on priority setting when preparing procurement lists against limited budgets.
- A working group has been established to propose an action plan to address support for **National Medicines Regulatory Agencies** (See next section).

Advocacy and communications

- Broader communications are called for, particularly with regard to communicating successfully to effect change. Strategies need to be developed which address both supply and demand.
- Advocacy is needed to ensure that national procurement lists have specific sections for medicines for children.
- Continued advocacy will be required to ensure that appropriate financing of medicines for children is obtained.
- Acceptance and use of new dosage forms will require effective advocacy and communications.



Funding

Funding to support the Better Medicines for Children project will be required to carry the work forward in many of the above mentioned areas. In particular areas that require funding include:

- Research and development for medicines that have smaller markets.
- Procurement of medicines for children.
- A technology-based platform to integrate information on EMLc, the WHO Model Formulary for children, supply and procurement, extemporaneous preparations (Global virtual Warehouse), procurement and supply management and all guidance documents on medicines for children.

Partnerships

- Finding **commercial partners** willing to develop paediatric medicines and to produce for **smaller markets** is essential.
- Local manufacturing capacity needs to be assessed taking into account the market scales that are needed to justify investments.
- Thought should be given to procurement interventions such as pooled procurement and registration mechanisms that simplify regulatory procedures.
- It will be important to continue to work with manufacturers that are willing and able to reach prequalification of their products.

Emerging and other issues

- How to harness mobile phone technology to improve access to better medicines for children should be explored further. One challenge, will be how to organize the many different types of hardware, software, add-ons and applications into interoperable systems. Dissemination of standard treatment guidelines using cell phone technology will be a first step.
- Packaging and labeling should be suitable for and understandable by health workers
 and caregivers in communities and sub-district health facilities, as well as in higher
 levels of health services. Research and consultation will be necessary to successfully
 design usable labeling on how to administer medicines in a wide variety of
 situations and by people with little or no education.
- There is a need to find the best method to estimate body weight easily and reliably
 for correct dosing for paediatric medications. A working group has been established
 to propose an action plan to address this need (see next section).



- The extent of **human resource capacity** in the area of children's medicines is not well known. It was decided to create a stakeholder map to identify what resources are available. (See next section.)
- Investigation is required to determine if dispersible tablets can be safely dispersed in **breast milk**. Messaging on use of medicines in the context of Exclusive Breast Feeding should be considered.

Working groups

Working groups were formed to address several priority areas which were discussed during the meeting. The working groups met to discuss initial ideas for proposals and then presented this to the meeting participants for further discussion. Following the meeting the working groups will develop the proposals further.

TB medicines for children

The working group met to discuss the need for a new fixed-dose combination for tuberculosis product for use in children, containing an appropriate amount of active pharmaceutical ingredients. The group agreed that innovation in the formulation was required and that it would be important to meet and engage with manufactures (including those generic manufacturers with advanced formulation capacity) and other stakeholders on this issue. In addition, funding would be necessary in the long term. A proposal will be developed further which will outline the plan for getting a quality assured product to market quickly and for developing flexible solid oral dosage forms of the optimal fixed dose combination products for the treatment of tuberculosis in children.

Weight measurement

Following the presentation on the Mercy T.A.P.E. method of weight estimation in children, the working group discussed the feasibility of validating the method in low-resource settings and concluded that 1 to 2 full time personnel over a 3 month period would be needed to complete the validation. The protocol could be ready within the next 6 months. The implementation phase would then need to be discussed.

Human resources capacity

There is a lack of trained personnel available worldwide to address key needs for better medicines for children and the lack of authoritative data on human resources is a complicating factor. The compilation of an asset map is proposed as a priority with a target date for distribution of a comprehensive report by December 31, 2011. It can be estimated that such an asset map could be compiled by one full time research assistant dedicated to the project for 12 months. An estimated total budget of US\$100,000 would be required.



Agenda

Day 1

Welcome & Introduction				
09.00 - 09.30	Introduction and welcoming remarks	Dr Clive Ondari		
		Coordinator, MAR		
09.30 - 10.00	Objectives of the meeting and WHO "make	Dr Suzanne Hill, MAR		
	medicines child size" initiative - update on progress			
10.00 - 10.20	Questions & discussion			
10.20 - 10.40	Coffee			
Promoting Better Use of Medicines in Children				
10.40 - 11.00	Overview of activities, results and challenges	Ghana BMC project		
11.00 - 11.20	Overview of activities, results and challenges	Tanzania BMC project		
11.20 - 11.40	Overview of activities, results and challenges	India BMC project		
11.40 - 12.00	Some results from the Ecumenical Pharmaceutical	Mr Albert Peterson		
	Network (EPN) "children's medicine project" study	(Ecumenical Pharmaceutical		
	report June 2010 and further planning	Network)		
12.00 - 12.15	Cell phone project in western Uganda	Dr Stuart MacLeod		
		(Child & Family Research Institute)		
12.15 - 13.00	Discussion			
13.00 - 14.00	Lunch			
Promote Access to Medicines for Children in Priority Countries				
14.00 - 14.20	Promoting the child's right to health: Caritas	Ms Francesca Merico		
	Highly Active Anti-Retroviral Therapy (HAART)	(Caritas Internationalis)		
	for children campaign (Campaign for greater access			
	to paediatric HIV and TB testing and Treatment)			
	and the Ecumencial Advocacy Alliance (EAA)			
	actions on paediatric AIDS			
14.20 - 14.40	CHAI's work related to paediatric ARVs	Ms Joanna Sickler		
		The Clinton Health Access Initiative		
		(CHAI)		
14.40 - 15.00	UNICEF	Ms Atieno Ojoo		
		Technical Specialist,		
		Pharmaceuticals, Supply Division		
15.00 - 15.20	Coffee			
15.20 - 15.40	To discuss Netherlands Medicines & Development	Ms Annelies den Boer		
	Partnership (NMDP) objectives: advocate for public	Wemos Foundation / HAI Europe		
	health based interventions across the entire			
	spectrum of pharmaceutical policy - from medicine			
	inception through R&D, supply chain and access			
1= 10	issues and the rational use and misuse of medicines	5.5.116.1		
15.40 - 16.00	MSF activities concerning medicines	Dr Doris Mesia		
		Médecins sans Frontières (MSF)		
16.00 - 17.00	Discussion			



Day 2

Eilling Impanded as Comp for Priority Medicines for Children				
Filling knowledge Gaps for Priority Medicines for Children				
09.00 - 09.20	Results from Institute for Paediatric Innovation	Dr Lisa Adams (Dartmouth's		
	(IPI) study in Tanzania	Global Health Initiative)		
09.20 - 09.40	Medicines for TB in children - update	Dr Anna Ridge, MAR		
09.40 - 10.00	UK Medicines for Children Research Network	Professor Tony Nunn		
	and/or formulation work package of Global	(Alder Hey Children's Hospital,		
	Research in Paediatrics (GRIP)	Liverpool, UK)		
10.00 - 10.20	Coffee			
10.20 - 10.40	Estimating weight in children	Dr Susan Abdel-Rahman		
		The Children's Mercy Hospital		
10.40 - 11.00	The National Institute of Child Health and Human	Dr Steven Hirschfeld (NICHD)		
	Development (NICHD) Standards Initiative			
11.00 - 11.20	Priority Essential Medicines for Children	Dr Sue Hill, MAR		
11.20 - 12.30	Discussion			
12.30 - 13.30	Lunch			
Promote research and development of essential medicines for children by providing evidence,				
guidance, and specification				
13.30 - 13.50	Update of the implementation of the Paediatric	Dr Agnes Saint Raymond		
	Regulation	European Medicines Agency		
		(EMA)		
13.50 - 14.10	Medicines for Malaria Venture's (MMV) work	Mr George Jagoe		
	examining issues of national policy acceptance of	Medicines for Malaria Venture		
	paediatric medicines	(MMV)		
14.10 - 14.20	The International Paediatric Association (IPA) and	Dr Kalle Hoppu		
	International Union of Pharmacology (IUPHAR)	IPA and IUPHAR		
	activities			
14.20 - 14.45	International Federation of Pharmaceutical	Ms Emma Du Four		
	Manufacturers & Associations (IFPMA)			
14.45 - 15.15	Coffee			
15.15 - 16.15	Discussion			
16.15 - 16.30	Identification of needs and gaps	all		
16.30 - 17.00	Wrap up & next steps	Dr Clive Ondari / Dr Sue Hill		



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