



make medicines *child size*

Report of the Partners Meeting on Better Medicines for Children

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This publication contains the Report of the Partners Meeting on Better Medicines for Children and does not necessarily represent the decisions or policies of the World Health Organization.



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Executive summary

This report provides a brief summary of discussions held at the first WHO' Partner's meeting on work on Better Medicines for Children. The purpose of the meeting was to provide an opportunity for interested stakeholders (1) to be informed about WHO's activities in relation to the World Health Assembly Resolution 60.20 and the project funded by the Bill & Melinda Gates Foundation, and (2) to provide comment on other aspects of work that would be relevant to improving quality of, and access to medicines for children.

Agreed next steps were:

1. WHO will continue to facilitate communications between the various groups, aimed at developing a global community of interested partners and reducing duplication of effort. Opportunities this year include professional society scientific meetings (e.g. Commonwealth Pharmacy Association, August 4-8, Ghana), the research summit scheduled for Amsterdam in October and other meetings to be identified. The next partners' meeting should be scheduled for May 2010.
2. WHO will support the development of 'topic-based' collaboration to promote activities designed to improve medicines for children. The meeting to be hosted by NIH in November 2009 may present an opportunity to discuss the issue in a multi-disciplinary and multilateral way. There may be a need to agree on priorities for research and development based on public health need, feasibility, scientific opportunity, available infrastructure, potential impact, and identification of motivated people.
3. Three research questions have been identified as priority topics:
 - a. How to obtain information about the value and impact of providing or switching to 'child friendly' dosage forms of medicines , such as dispersible tablets
 - b. How to obtain data to define a dosing aid that can be used in resource poor settings
 - c. How to obtain further data to validate the new recommendations for first-line TB medicines.

WHO will work with academic partners and research organizations including NIH to identify potential funding sources for research support for these questions.



4. WHO and IUPHAR will work together to develop standards for pharmacokinetic research in particular, initially with the development of a position paper by IUPHAR
5. WHO will work with NGOs and other partners to develop a communication plan to advocate for better medicines for children
6. Some 'case studies' of specific products will be developed, to examine and test possible strategies for reducing development time and eventually increasing access. Examples proposed are
 - a. dispersible amoxicillin (development of an approach for use in community acquired pneumonia) – in collaboration with the Clinton Foundation and academic partners
 - b. dihydroartemisinin-piperaquine (development of an appropriate paediatric dosage form) – in collaboration with MMV
 - c. efavirenz (expediting completion of paediatric clinical trial data) – in collaboration with UNITAID and MSF.
7. The current year of the 'rights of the child' provides an opportunity to document a rights based framework for access to medicines for children, in addition to the existing framework on this topic.
8. Long term goals include acceptance of and implementing research guidelines, establishing credible and feasible outcome measures to assess the impact of interventions and process changes, seeking regulatory harmonization across regulated activities such as manufacturing, licensing and research. All of the goals will rely on culturally aware behavioral changes with new opportunities to explore different types of partnerships and collaborations that will extend across disciplines and geographic regions.

Meeting objectives

- To share information on activities related to WHA A60/25 on better medicines for children.
- To provide a forum for partners to exchange their perspectives on progress of the initiative.
- To identify the key gaps in research, regulation, supplies, and optimal use for better medicines for children.
- To identify and prioritize strategies to improve the provision of better medicines for children, with respect to resources, needs, and likely impact.
- To suggest additional strategies to improve access to better medicines for children.

Introduction

Following the World Health Assembly resolution WHA60.20, the Department of Essential Medicines and Pharmaceutical Policies commenced work on activities to lead to 'better medicines for children'. In October 2007, the first WHO Model List of Essential Medicines for Children was published, and this was launched on December 6 as part of a campaign to 'make medicines child size'. The purpose of the campaign is to raise awareness and accelerate action to address the need for improved availability and access to safe child-specific medicines for all children under 15, by encouraging research and development into appropriate medicines for children as well as improved access to them.

In order to prepare a list of essential medicines for children, the Executive Board approved the establishment of a Subcommittee of the Expert Committee on the Selection and Use of Essential Medicines. The Subcommittee met in July 2007¹ and September 2008², and in October 2007³ the Expert Committee approved the report of the July 2007 meeting containing the first WHO Model List of Essential Medicines for Children. In preparing the List, the Expert Committee took account of the priority diseases identified in resolution WHA60.20 and WHO treatment guidelines. Many important research and product gaps were identified. At its September 2008 meeting, the Subcommittee recommended further work to maintain and expand the List.

In order to promote use of the List and the related treatment guidelines, WHO has received initial donor support from the Government of the Netherlands, and the Bill & Melinda Gates Foundation for a three-year programme of work commencing in 2009. During the lifetime of the project, the following tasks will be addressed: promoting national standards for medicines for children, improvement of availability of child-specific medicines, and development of strategies with Member States to enhance access to, and ensure better use of, essential medicines for children. In WHO regions, work has already begun to promote national adoption of the List, including through regional workshops in the South-East Asia and Western Pacific Regions.

A two-day pre-conference was held before the 2008 International Conference of Drug Regulatory Authorities to discuss regulation of medicines for children. As a result, an international regulatory working group will be formed to review existing standards for regulation of these medicines and to enhance the availability of quality medicines for children.

1 http://archives.who.int/eml/expcom/children/INDEX_children_07.htm

2 http://www.who.int/selection_medicines/committees/subcommittee/2/en/index.html

3 http://www.who.int/medicines/publications/essentialmeds_committeereports/TRS_950.pdf



Preliminary data from a multicountry study suggest that one of the problems with access is that if a pediatric dosage form of a medicine exists, it is substantially more expensive than an equivalent adult dosage form. This results in countries preferring to use fractions of adult medicines to treat children. The risk with this approach is that dividing adult dosage forms can result in inappropriate doses for children, leading to overdose and potential toxicity or under-dose and potential inefficacy.

Summary of discussion

Update on Better Medicines for Children project

Dr Suzanne Hill provided the participants with an update on the project, noting in particular that the provision of optimal medicines for children is limited by various barriers that include deficiencies of research in children, delays in licensing medicines for children, development of appropriate formulations for children, and deficiencies in knowledge that would enable optimal prescribing. The work plan for the project in 2009 includes further developing the work on optimal dosage forms for children, developing a model formulary to improve prescribing information, a survey of suitability of current dosage forms and dosing aids, and advocacy and planning for interventions to improve use of medicines particularly in Africa.

The following issues were noted in discussion:

1. the challenge of measuring the impact of a programme that is 'horizontal' compared to focusing on disease specific interventions; 'Better Medicines for Children' can be described as a health systems project, although it starts by working in disease specific areas, and therefore evaluation measures need to be designed accordingly;
2. the persistent problems of stock outs of medicines, limited numbers of medicines available for treatment of children, inappropriate dosage forms and related lack of consumables and equipment in healthcare facilities;
3. the impact of failure of demand (from health care professionals, and from carers/consumers) on supply and availability of appropriate medicines for children (e.g. zinc for use in acute diarrhoeal disease), and therefore the need to work simultaneously on improving supply and demand, to improve availability;
4. communication gaps between healthcare implementers, providers, and researchers, and policy makers resulting in sub-optimal quality of prescribing and referral;
5. deficiencies in skilled human resources and the need for improved strategies to develop and retain appropriate skilled workers;

6. the paucity of high quality research in children, especially in settings associated with highest mortality;
7. the long periods between expression of need of medicines for children and eventual availability;
8. the limited number of GMP certified manufacturers, as well as limited capacity for pharmaceutical product innovation existing in Africa; and
9. the challenges of incentivizing product development for children in an environment of limited resources, slow licensing, and uncertain markets.

Participants comments

Participants provided the following comments (slide presentations are available on request):

1. Collaboration between professional bodies from various parts of the world as initiated by the International Paediatric Association, International Union of Basic and Clinical Pharmacology and the International Pharmaceutical Federation to create a multi-disciplinary approach for country actions on paediatric medicines has received a positive response from national professional organizations in Africa.
2. Work is currently in various stages of progress at Purdue University to increase manufacturing efficiency for tenofovir, reduce API needed in some dosage forms, develop newer methods to generate PK/PD data and taste masking and a training and capacity development partnership with the Kilimanjaro School of Pharmacy in Tanzania. Purdue has already enrolled 12 students in 2008 and 15 in 2009.
3. DNDi presented its model of development of medicines for neglected diseases, highlighting the challenges of catering to rare diseases in remote and poor parts of the world. Highlighted was the role of early consultation between researchers, regulators, manufacturers and national authorities, as well as the need for affordability of medicines to be assured.
4. Medicines for Malaria Venture plays an important facilitator role in developing artemisin-based combination therapy by enabling dialogue between manufacturers, malaria control programmes and regulators. A hallmark of this has been the development and registration of a fixed dose paediatric formulation of artemether and lumefantrine. There are new challenges for completion of development of the paediatric formulation of dihydroartemisinin-piperaquine; expediting licensing initially by avoiding paediatric trials, later resulted in delays due to Paediatric Investigation Plan requirements of the European Paediatric regulation (EMA). This has resulted



in the commitment to develop a paediatric formulation of dihydroartemisinin-piperaquine for children and infants with body weights below 5 kg, The question is how to find the most efficient way to develop this product.

5. IFPMA's review of collaboration with regulators and Private Public Partnerships to streamline the research and development of newer medicines and to generate acceptable data on medicines licensed for adults but needed by children, highlighted the challenge of a large number of medicines clogging up regulators, unclear standards of research in children and the unresolved issue of prioritizing the needs of children in terms of medicines.
6. A Paediatric Committee (PDCO) was established at EMEA to oversee regulation and development of medicines for children, deciding on the content of Paediatric Investigation Plans, which cover the timing and measures such as clinical trials in children with an age-appropriate formulation in all paediatric age groups affected by the condition. Further measures include the creation of an European network of paediatric research, an inventory of paediatric needs, improved communication and transparency of paediatric information (product information, publishing PIP decisions and results of clinical trials in- and outside of the EU (European Database of Clinical Trials (EUDRA-CT)), and priority for the development of off-patent medicines for which EU funding is available. Currently areas of priority are neonatology and paediatric oncology.
7. EPN shared the results of a survey of faith-based health facilities in Africa with emphasis on medicines that showed that human resources and formal centralized procurement structures are significantly below needs. The EPN is considering two interventions: (1) recruiting part time pharmacists for supervision and measuring the impact of this on the supply chain and (2) dispensing of medicines in Faith-Based Facilities.
8. The Clinton Foundation shared market research findings that illustrated the importance of supporting needs agendas with incentives to manufacturers to invest in product innovation, suggesting provision of a ready committed market and streamlining research and regulatory issues as ethically appropriate to create a viable business model.
9. Médecins Sans Frontières provided an overview of the status of antiretroviral therapies available for children, highlighting the limited number of medicines licensed, and the very small number with child friendly formulations. They provided a list of missing antiretroviral needs for children, and emphasized the need for financial and technical support for developing more options, the need for expediting trials to accelerate availability of children's medicines and



the potential usefulness of a medicines patent pool for making fixed dose combination products. They also noted that medicines made for use in the community must be able to withstand climatic conditions, and be relatively easy to administer.

10. Health Action International shared their initiative to develop a manual and training materials to help students in medical and pharmacy schools to understand and respond to pharmaceutical promotion and to help governments to regulate promotion in an effort to support optimal prescribing. They also emphasized the need for establishing innovative mechanisms for pricing of essential medicines for children; for independent funding mechanisms to support clinical trials that assess public health relevant outcomes, including comparative effectiveness studies; as well as ensuring the highest possible standards of transparency and management of conflicts of interest in the Better Medicines for Children initiative.
11. STaR Child Health shared their initiatives to develop research standards to meet the demands for good quality research in children's medicines, by creating a world wide collaboration of researchers, publishers, regulators and the WHO. They highlighted consideration of the challenges of ethical review capacity , adequate technical support, and infrastructure need to conduct good quality clinical trials.
12. OXFAM noted the NGO campaign to draw attention of policy makers in Africa to medicines shortages, called 'Stop the Stockouts', to raise awareness among policy makers of the problems of supply of medicines. Also specially highlighted was the concomitant need to supply consumables (e.g. laboratory reagents)and equipment (e.g. weighing scales) to enable medicines to be used optimally.
13. The Ecumenical Advocacy Alliance and Caritas Internationalis shared their work in the area of advocacy for various aspects of comprehensive care of people with HIV/AIDS. The EAA highlighted the need to recognize the contribution of community health workers, and to work on strategies to use them as effectively as possible (tailored training, clear roles).

Key discussion points

Research

- The need to ensure adequate assessment of impact of new interventions in relation to the work on medicines for children, including survival (where appropriate) or other measures to evaluate 'quality of life'. An appropriate outcome measure may need to be developed that capture domains such as impact on a community (for example, relevant to African trypanosomiasis/



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- sleeping sickness), impact on continuity of education and capacity for development (e.g. relevant to epilepsy), reduction in complications of 'minor' disease (e.g. relevant to scabies) and associated costs and cost-savings.
 - The need to obtain evaluation and impact data from implementation of public health interventions e.g. the impact of a 'public health' approach to providing antibiotics as solid oral flexible dosage forms rather than liquids for community acquired pneumonia.
 - The need to develop a comprehensive list of priority medicines for research and development, taking account of existing lists (US, EU and WHO among others).
 - The need for global standards for the ethical conduct of trials in children, including research guidance applicable across the world, including capacity development for research ethics approval/review committees.

Product development and regulation

- Increasing the availability of quality products requires various approaches, including enhancing capacity for GMP.
- Further developments of 'platform technology' may improve efficiency of manufacturing, as an eventual means of improving the quality and reducing the cost of medicines.
- Determining the relative importance of taste masking and palatability, as well as suitability of different dosing forms for different settings.
- Regulatory authorities prioritizing the licensing of medicines for children, taking account of other priorities and workloads.
- Acceptable approaches to speeding up development of key medicines for children (e.g. efavirenz), including recommendations for the size of appropriate observational trials needed to demonstrate pharmacokinetics, pharmaco-dynamics, efficacy and safety, that consider the course and characteristics of the conditions being managed with respect to outcome.

Improving use of medicines in children

- The delivery of optimal healthcare to children is limited by the scarcity of skilled human resources in all areas. This could be addressed through developing tailored training, designed to update and improve skills as close to the field as possible.
- Useful ways of achieving focused training involve development of tools such as clinical practice guidelines and algorithms for case management. Such training should be focused, consistent and be reinforced by supervision and



- follow up, including maintenance and availability of appropriate independent information tools.
- Communication and record keeping of healthcare workers was identified as a problem, with implications for optimal decision making, and quality data collection. Tools like checklist forms were suggested as useful in all areas of service delivery.
 - Neglected subgroups such as newborns were identified.
 - Strategies to enhance adherence and compliance in relation to medicines use in children need to be defined in relation to both short-term and chronic illnesses.
 - The potential value of alternate routes for administration of medicines (e.g. rectal gels or solutions, transdermal, transmucosal films), as a strategy to enhance adherence or acceptability, need to be further investigated.

Supply

- Stockouts and availability are a major issue; understanding the causes in any given situation may require further research.
- The need to build human resource capacity to audit existing systems and to run the supply chain.
- The importance of transparency in strengthening the supply chain, such as ensuring transparency of medicines selection and tender processes.
- The link between failure of demand and lack of supply, and the importance of providing accurate market signals to manufacturers, promoting competition and quality.
- Private and public sector supply and demand can have variable effects on availability and supply, that may need to be mapped for different disease and situations.

Next steps

1. WHO will continue to facilitate communications between the various groups, aimed at developing a global community of interested partners and reducing duplication of effort. Opportunities this year include professional society scientific meetings (e.g. Commonwealth Pharmacy Association, August 4-8, Ghana), the research summit scheduled for Amsterdam in October and other meetings to be identified. The next partners' meeting should be scheduled for May 2010.



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