Workshop on Essential Medicines Lists and Better Medicines for Children
Meeting Report

Accra, Ghana
2-4 August 2009

This publication contains the collective views of an international group of experts, and does not necessarily represent the decisions or policies of the World Health Organization.
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**Executive summary**

The objectives of the workshop in Accra meeting were to review work in eight African countries on updating national essential medicines lists and treatment guidelines, and to consider possible activities in relation to work on essential medicines for children, taking into account the WHA resolution, 60.20 Better Medicines for Children, from May 2007 and including consideration of the Essential Medicines List for Children (first edition 2008; second edition 2009). Access to essential medicines is a key component of any effort to meet MDGs 4, 5 and 6.

Following the adoption of the WHA Resolution 60.20, WHO has worked closely with partner organizations, pharmacologists, pharmacists, and pediatricians internationally to identify tangible projects that will advance the goal of improved therapy for children. A grant from the Bill and Melinda Gates Foundation to support this work was received in October 2008 and reports on progress on the project are published at [http://www.who.int/childmedicines/progress/Progress/en/index.html](http://www.who.int/childmedicines/progress/Progress/en/index.html). The most recent meeting in Geneva (June 15-16, 2009) focused on potential activities in countries in Africa and in India and considered interventions that would improve use of medicines in children.

Following consultation with AFRO and initial expressions of interest from countries, eight countries (Eritrea, Ethiopia, Ghana, Kenya, Nigeria, Tanzania, Uganda, and Zambia) were invited to send delegations to Accra, including WHO national programme officers, leaders in pediatric pharmacy and pediatrics as well as individuals familiar with drug procurement and supply. In addition, SEARO nominated two participants from India to attend meeting and to provide a link between African projects and future work in India on the project.

At the meeting, each country group updated the participants on their national essential medicines lists and related activities. Potential activities in relation to essential medicines for children were discussed and a framework for these activities was presented. Participant also attended the 10th CPA meeting including the symposium on Better Medicines for Children, on August 5th 2009. Draft workplans will be developed for 2010-2011 based on these discussions; this report provide summaries of suggestions made by participants at the meeting, to be confirmed.
**Background**

In April 2009 it was decided that a meeting of African countries could be effectively coupled to the meeting of the Ghana Pharmaceutical Society and the 10th Commonwealth Pharmacy Association Congress meeting scheduled for Accra in August 2009. Initial expressions of interest were sought via AFRO, through circulation of a survey on country-specific approaches to better medicines for children. Several countries expressed interest in greater involvement, and it was decided to hold two meetings, one for anglophone countries in Accra and a second for francophone countries to be scheduled later in 2009.

In planning the meeting it was agreed that, in addition to country teams, it would be desirable to have additional input from pharmacists, pharmacologists, and pediatricians with an interest pediatric medicines and direct experience in Africa, including the design of practical interventions aimed at improving use of medicines for children.

The University of British Columbia Centre for International Child Health agreed to coordinate the attendance of facilitators and to work closely with WHO Geneva in planning the meeting agenda. The University of Ghana took responsibility for all other invitees and for local meeting arrangements.

**Meeting objectives**

The objectives of the meeting were to:

1. to review progress on national medicines lists and treatment guidelines and related activities;
2. to consider activities related to improving access to essential medicines of children and how they might be implemented in countries (including the essential medicines list for children);
3. to discuss potential activities for country workplans for 2010-2011.

The discussion was structured to bring together representatives of the clinical community, academia, government, and WHO at a country level. On day 1, the discussion was on general issues and there were short reports from countries; for day 2, the discussion was in small groups and is reported according to the group summaries.
General discussion

Key issues discussed included:

– A review of the currency of national medicines lists and standard treatment guidelines - most recent revision for each country:

<table>
<thead>
<tr>
<th>Country</th>
<th>Year</th>
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<tbody>
<tr>
<td>Eritrea</td>
<td>2009</td>
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<td>Ethiopia</td>
<td>2007</td>
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<td>Ghana</td>
<td>2004</td>
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<td>Kenya</td>
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<td>Nigeria</td>
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<td>Tanzania</td>
<td>2007</td>
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<td>Uganda</td>
<td>2007</td>
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<td>Zambia</td>
<td>2007</td>
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</table>

– All countries indicated that they have challenges in keeping their national EMLs up-to-date. Efforts to make EMLs relevant to children have been variable but are limited by a shortage of individuals with pediatric expertise. The ideal of revision of EML every 2 years and close linkage to STGs and procurement procedures is hard to achieve.

– All countries expressed difficulty in achieving STGs particularly with relevance to children. There are usually multiple inputs and sometimes conflicting advice is provided from different quarters. Even when STGs exist, achieving adherence in problematic. The importance of congruence between EMLc and IMCI guidelines was noted. In some countries the process of adoption of STGs seems to be undermined by the non-evidence-based approach of senior consultants. There is a need for a better knowledge transfer/communication strategy. Dissemination of STGs in the form of paper copies is probably not achievable. Countries reported a variable state of preparedness to use electronic distribution.

– Human resource limitations were noted for most countries for the development of EML/STGs, for knowledge transfer activities, and for participation in active interventions.

– The achievement of a sound EML/EMLc policy will require a commitment to evidence-based practice and institution of a committee able to evaluate evidence relevant to specific countries. There is a need for improved tools to help countries in developing a national EMLc and for continuing professional development that would support any EMLc initiative.
The challenges in achieving better availability and use of medicines for children were discussed. The need to identify interventions that will make a difference was emphasized.

Local supplies and procurement procedures. How best to establish connectivity between local needs and availability, including taking into consideration manufacturing capacity.

Development of standardized approaches to compounding and extemporaneous preparation, including development of toolkits that would support standardized methods.

Development of a virtual global warehouse for products and information, including shared reviews.

Addressing procurement issues and avoiding overlap and inconsistencies among multiple lists.

Expanded use of prequalification programme (WHO).

Inventory regarding the adequacy of in-country manufacturing capacity and exploration of national procurement policies favouring local producers (how prevalent are these and are they an impediment to rationalization of drug supply?).

Advocacy issues

It was agreed that there was a need for a concerted effort to support advocacy for better medicines for children. The necessary programme would include:

- Appropriate messages from ministries of government.
- Appropriate messages the pharmaceutical industry and local manufacturers.
- A programme to improve awareness of EML and EMLc at various levels of health care delivery.
- Informational material for medical stores and others within the medicines supply chain.
- Materials to encourage a sense of ownership of EML and EMLc by drug and therapeutics committees.

All of the above should constitute an advocacy and communications package and appropriate tools should be brought together to support advocacy initiatives.
Data needs

Overall, a number of gaps in the necessary data/information base were identified. These gaps must be rectified if an effective better medicines for children programme is to be instituted. Data is required in the following areas:

- Current expenditure on medicines for children.
- Availability of a ‘basket’ of essential medicines for children on the shelf at various levels within the health system.
- Information on supply bottlenecks and stockout situations.
- Prices of various formulations for children, including liquids and dispersibles.
- Costs for transportation component of liquid preparations prepared at source.
- Availability of pediatric dosage forms. Source of supply? Monitoring of use patterns?
- Drug adverse reaction patterns; drug interactions commonly encountered.
- Local antibiotic resistance patterns.

For each country a baseline study is required to identify the burden of illness for common childhood conditions. Ideally this should be broken down by region so that intervention programs can target high priority conditions and address local realities.

Country reports

Eritrea

The EML is up to date. A workshop was held in 2009 with 115 participants leading to 16 alterations in EML including 15 additions. The process included input from three pediatricians and there was a particular focus on the needs of neonates. The current plan is to have pediatric solutions premade for pediatric use. A need has been identified for improved availability of pediatric supplies for drug delivery. At present, no specific pediatric guidelines or policies are known to be in place.

Ethiopia

The national medicines list was reviewed in 2007 and is modified to meet needs at three delivery levels. While there is a national list there is room for revision at an individual hospital level. The national aim is to review the EML on a five-year cycle and to include STGs, particularly for important target diseases. Pediatricians are included in the national committee and the national drug list does include pediatric
dosage forms. The national EML is not well distributed because of lack of finances. It is posted on the web but many areas do not have access and most clinicians do not have a copy.

**Ghana**

Current EML is 2004, although a 2009 revision will be available. A standing committee exists for review of STGs and this includes three pediatricians. Other pediatric inputs are also obtained and each peer review group has pediatricians who deal with issues that couldn’t be handled by the standing committee. Reviewers are screened to avoid conflict of interest. The published STGs give an evaluation of quality of evidence. Timely renewal is constrained by lack of fiscal and human resources. There is a depot in Kumasi responsible for the production of pediatric formulations. A 2006 study showed that many available medicines are not used.

**Kenya**

The current EML is the 2003-2004 version. Revision was started in 2007 and will be completed in 2009. WHO has been critical of slow progress. The committee comprises mostly academic clinicians and starts with clinical guidelines provided by specialists. There are six levels of defined care and there are discrepancies between public and private procurement. There are three different versions of the EML available. Kenya is beginning to look at the needs of children and has examined the EMLc. Existing guidelines come primarily from the private sector although abbreviated guidelines for pediatric treatment have been circulated for some key conditions based on the WHO pocketbook.

**Nigeria**

Nigeria was not present on day of reporting; appropriate information has been requested.

**Tanzania**

The last medicines list review was in 2007 and the list includes diagnostics. Zanzibar has a separate list that has undergone revision this year. There are harmonized guidelines for treatment of key target diseases and the EML. A single government agency in Tanzania is responsible for procurement of drugs for public, private, and NGO use, using an EM catalogue which goes beyond the recommendations of the national EML committee. There are concerns that the Tanzanian list is not comprehensive for pediatric use. There is currently a movement to consolidate guidelines used by pediatricians and to make a single guideline available but the review process for treatment guidelines is slow. The MOH tends to emphasize
preventive medicine whereas clinicians are more interested in treatment. There is a challenge with Zanzibar because of guidelines that differ from Tanzania. However, Zanzibar is perceived as dealing with the private sector effectively.

**Uganda**

The last Uganda EML was produced in 2007 and revision is underway. Specialists are heavily involved in the development of therapeutic protocols. Not all listed drugs are available at all levels in the system and concern was expressed that some key consultants do not follow recommendations or procedures. Uganda does not have a standing committee and it is hard to link the national EML with procurement and availability. This discourages participation in the process.

**Zambia**

The EML is up to date. The EML process consults with specialists, including pediatricians, and recommended pediatric doses are included. Detailed STGs have been developed and these include children. There are current plans to develop a revised formulary with a new formulary committee. Zambia is experiencing difficulty in meeting the requirement for a two-year review cycle and maintaining synchronization with WHO. Financial and human resources are a problem across four levels of health care delivery.

**Summary of Day 2 - small group discussions**

**Group 1: Formulations**

**ACTION POINTS**

1. **What formulations?**

   a. Identify a list of 10 priority medicines based on priority diseases. For example, pneumonia, diarrhoea, malaria, TB.

   **Suggested starting list of medicines:**

   - Amoxicillin
   - Cotrimoxazole
   - Artemether + lumefantrine
   - Artesunate + amodiaquine
   - Quinine
   - Paracetamol
   - Zinc sulfate
b. Have an assessment of what is the most suitable/feasible formulation in each country for each drug.

c. Do a cost/benefit analysis and knowledge translation package for decision makers and policy makers in countries.

d. Develop a business case for industry (local and global) for these drugs and a communication strategy for each.

**ACTION PERSONS:**

1. World Health Organization to take the lead, together with UNICEF.

2. In country-MOH to drive the process and work with NDRA, Schools of pharmacy, Schools of Paediatrics, Pharmacy and paediatric professional associations.

3. MOH to identify a Champion on medicines for children in the Ministry of Health.

2. **Manufacturing capacity**

   a. Local compounding/extemporaneous preparations:

   - Need for a package that comprises standards, methods, technical skills, equipment required.
   - WHO to collate all info that is available on compounding (David Woods, PPAG, et al) and make it accessible to developing countries.
   - Countries to identify priority products for compounding and generate local package from the collection above.

   b. In depth assessment of local (and global) Pharmaceutical industry manufacturing capacity:

   - WHO to develop tools for assessment of existing and potential manufacturing capacity for medicines for children-technical, production capacity, etc.
   - NDRAs in countries to take the lead to carry out assessments-consider regional collaboration in doing assessment.
3. **Set up a global virtual warehouse of quality sources (and prices?) of medicines for children**

   a. Donors to be approached to support funding for the platform and technical expertise to set this up, based on the ongoing work in UNICEF on Sources and prices of medicines for children. Noted that less than 10% of Africa has access to internet.

   Lead persons: Tony Nunn, David Knoppert, Atieno Ojoo.

**Group 2: Improved access/EMLc adoption**

**Facilitators:** Andy Gray, Kopano Mukelabai

The discussion focused on finding answers to four questions:

1. What should be the priority actions?
2. How should these actions be undertaken?
3. Who should be involved and responsible?
4. What support is needed?

**Introduction:**

Action should be taken at all levels of the health care system, including government, hospital therapeutics committees, professional training institutions, clinical facilities, and individual caregivers. Once resources are in place, a workplan should be developed that targets every level throughout the national health system.

1. **A starting point should be review of the national EML to determine whether needs of children are included.** Consideration should be given to developing an EMLc that meets the needs of each country, using all tools available: the WHO EMLc, pocketbook, IMCI, STGs, MDGs

   - Ensure that needs for neonates to puberty are addressed.
   - Decisions should be based on careful assessment of disease burden.
   - Identify gaps and barriers to effective treatment of children.
At the MOH level:

- Secure a dedicated budget for children. A focused and funded programme would give the MOH a sense of ownership of the process of improving access.
- Use MDG information and progress reports to advocate for resources.
- Understand the procurement process (in countries where this is a MOH responsibility).
- Policies should be open and transparent.

At the therapeutic drug committee level:

- Ensure that training of individuals on committees includes information about the special needs of children.
- Supply supporting materials.
- Link medicines list to the procurement process to determine availability.

At the professional training institution level:

- Identify effective advocates.
- Review training programs for medicine and pharmacy from undergraduate to specialization and including continuing education to ensure that the EMLc is part of the curriculum.
- Ensure that trainers at every level have the right information.
- Approach all professional associations.

2. The importance of rational procurement to improving access:

- Governments should consider having national pricing policies (in India the regulatory authority sets the maximum allowable prices).
- An understanding of burden of disease and previous purchase quantities is necessary.
- Buying should be based on a process of tendering and medicines should be purchased in bulk to reduce cost.
- Use of generics should be tempered by careful investigation of quality.
- WHO should expand the prequalification process.
- GMP should be rigorously enforced in local manufacturing facilities.
- There should be a postmarketing followup process with QA component.
Reciprocity: Harmonization of regulatory requirements among countries should be discussed, using ICH as a model.

3. The importance of advocacy as a tool was clearly evident at every step, the MOH, hospital therapeutic committees, professional education institutions and donors

Tools such as fact sheets should be developed to present information about the state of medicines for children to help with recruitment of advocates. At all levels it is important that there is clear evidence of what is feasible so that resources will be spent based on agreed plans that are completely transparent.

**Group 3: Guideline development and implementation**

**Priority actions identified**

- Any participating country must have an up to date compendium of practical STGs that include pediatric conditions.
- The STGs must, as far as possible, be evidence-based and accepted on consensus following comprehensive review.
- Each participating country should have an inventory of human resources able to support the guideline process and implementation studies.
- The inventory should identify methodologists such as epidemiologists who can participate.
- Responsibility for the updating of guidelines should be taken by the WHO and MOH working together, using the EMLc and basing the updated guidelines on existing materials such as the WHO pocketbook.
- A mechanism must be determined for efficient dissemination of guidelines.
- Strategies should be improved for assuring adherence to STGs.

**Process issues**

- Any study should be based on the identification of feasible (practical) interventions at district and community levels.
- The support of the pediatric association should be enlisted to facilitate dissemination.
- A marketing and advocacy programme should be developed.
- A peer review process overseeing compliance with STGs would be desirable.
- The support of key opinion leaders in academic centres should be encouraged.
Levels of engagement required

– WHO Geneva should provide technical support and should assist with dissemination of guidelines.
– WHO country offices should take responsibility for raising awareness at a political level.
– The MOH should disseminate guidelines to facilities where they will be used.
– Guideline compliance should be monitored through the drug and therapeutics committee and district health offices.
– Awareness must be raised with civil society. The public should be encouraged to demand better medicines availability and use for children.
– The MOH must assure that the correct medicines in the correct dosage forms are procured. The tendering process must be efficient and explicit quality assurance programs are required.

Support

– Political support will be needed to make interventions sustainable.
– All partners must collaborate to raise political awareness.
– Resources (dollars) will be required to mount convincing demonstration projects.
– The professional associations should play a major advocacy role and encourage integration of involvement by multiple stakeholders.
– International partners (governments, foundations, professional organizations, etc) should provide technical and logistical support.
– Technical assistance from WHO Geneva and from country offices will be required.
– Collaboration of donors with multiple stakeholders is critically important to the design and testing of promising interventions.
Country workplans - proposals

**Eritrea**

A task team will be instituted as soon as possible and will strive to make the drug and therapeutics committee more responsive to the EMLc and therapeutic needs of children. Pediatricians and other child care professionals will be involved in the DTC process. Meetings will be arranged with key decision makers in the Ministry of Health.

Local manufacturing capacity for EMLc drugs will be evaluated.

Dissemination efforts will include a review of STGs and the inclusion of guidelines for the treatment of key pediatric conditions.

**Ethiopia**

The formation of a national task force with representation from government, health care professionals, and relevant content experts will be a priority. The task force will institute a dialogue with the Ministry of Education aimed at improving training and skills development relevant to optimal pediatric therapy.

Outreach activities will include strategies for improving adherence with STGs.

**Ghana**

Ghana will focus on priority health problems around better medicines for children with concentration on community training in optimal drug therapy and an examination of national health insurance benefits. The intent is to develop a specific child health programme that will review formulations, availability and pricing.

There will be an effort to develop tools for assessment and to conduct an inventory of local manufacturing capacity.

The process will begin with a facilitated meeting that will include all stakeholders, including representation from the procurement and distribution sectors. An effort will be made to identify champions who will lead task-specific teams and institute an advocacy programme.
Kenya

The Kenyan national effort will centre on a core decision making group of individuals who are already sensitized to the needs of children. A standing committee with specific pediatric responsibilities will be formed and charged with the responsibility to assess current gaps in the Kenyan national list relevant to EMLc. Careful tracking will identify problems with drug supply and stockouts at district and local levels to determine whether or not EMLc products are adequately available at all levels of care in Kenya. A survey will be conducted to determine whether or not essential medicines for children are sold at an appropriate price when available.

A review of STGs is currently underway and this review will be extended to include children.

An advocacy programme will target the development of political support for a pediatric program.

Nigeria

A process of advocacy will be instituted with the national EML committee aimed at increasing the awareness of the needs of children. An inventory will be conducted to determine the current availability of products listed in the EMLc. Manufacturing capacity will be reviewed and discussions with industry will take place concerning their ability to manufacture EMLc products.

A Nigerian programme will focus on the use of the WHO pocketbook for acute care of children and will emphasize adaptation of the pocketbook to needs of Nigerian children.

Every effort will be made to influence the undergraduate medical and pharmacy schools to encourage an expanded role in securing better drug treatment for children.

Tanzania

A national task force will be instituted that will attempt to reach out to communities and to hospitals. It will align itself as much as possible with IMCI guidelines. Pharmaceutical supply chain issues will be reviewed and the stock situation will be inventoried.

The task force will identify all child relevant guidelines and will make recommendations for training programs at all levels. Advocacy will include an effort to influence undergraduate education of health professionals. Outreach will be
directed to the three medical schools and the School of Pharmacy at the University of Dar es Salaam.

**Uganda**

Uganda will assemble a national child health team that will work closely with the child health office at the Ministry of Health. A task force will be instituted that will concentrate on an inventory of availability of EMLc products, review of STGs from a pediatric perspective, assessment of manufacturing capacity, and assessment of prices.

The national team will conduct stakeholder meetings to increase sensitivity to child health issues and will develop a programme of advocacy activities.

**Zambia**

A commitment will be made to improve access to EMLc products and to update the treatment of priority conditions as reflected in current STGs. The representation from child care specialists and pediatricians in decision making bodies will be reviewed and encouraged. A survey will be conducted in a cross section of health facilities concerning the availability of products suitable for treatment of infants and children.

A process will be initiated for advocacy and dialogue with policy makers and key opinion makers. It will be a priority to secure public sector involvement in this process.
Next steps 2009-2011

1. Finalization of country plans including improvement of pediatric treatment guidelines and alignment of EML with EMLc.

2. Planning and implementation of a workshop on better medicines for children targeting francophone countries in Africa.

3. Further consideration of intervention protocols to examine the impact of consensus-driven, evidence-based pediatric prescribing guidelines in target countries on outcomes of high impact conditions.

4. Exploration of potential funding sources for comprehensive intervention studies.

5. Completion of a pediatric therapeutics capability survey among countries participating in the Accra workshop.

6. Development of capacity enhancement tools to help participating countries in the development of EMLc and pediatric treatment guidelines, drawing on available international expertise.
# Activity framework

**Children's medicines work**

**2010-2012**

<table>
<thead>
<tr>
<th>Activity</th>
<th>What</th>
<th>How</th>
<th>Possible partners</th>
<th>Budget needed</th>
<th>Funding source</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MANAGEMENT</strong></td>
<td><strong>Formation of 'country task team' on medicines for children</strong></td>
<td>Get support from MOH. Facilitate links through NPO. Support from UBC to hold meeting.</td>
<td>NPO, MOH, UBC</td>
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<tr>
<td><strong>POLICY activities</strong></td>
<td><strong>Adaptation and adoption of EMLc</strong></td>
<td>Workshop/meeting with travel requests from HQ as needed; regional, subregional, francophone Support to national pediatric committees Document production (EML, treatment guidelines</td>
<td>All countries who express interest HQ(MAR), AFRO, NPOs Academic partners</td>
<td>Workshop support Country technical assistance Document production</td>
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<td></td>
<td><strong>Assessment of child friendliness of national EML versus Model EMLc</strong></td>
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<td></td>
<td><strong>Assessment of relevant treatment guidelines</strong></td>
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<td></td>
<td><strong>Support for evidence based update of national EML to include medicines for children</strong></td>
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<tr>
<td><strong>POLICY activities</strong></td>
<td><strong>Medicines regulation</strong></td>
<td>Contract with Susan Walters to prepare background document Global network meeting supported by WHO Development of training material and workshops with EMEA?</td>
<td>All countries who express interest HQ, all regions, regulatory partners Possible academic partners (Bradford, Purdue, others)</td>
<td>Global meeting (target February 2010) Support for network</td>
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<td></td>
<td><strong>Assessment of existing regulatory frameworks</strong></td>
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<td><strong>Participation in PEDMEDREG NET</strong></td>
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<td><strong>Training &amp; capacity development for evaluation of pediatric dosage forms.</strong></td>
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<tr>
<td><strong>Data collection</strong></td>
<td><strong>Burden of disease</strong></td>
<td>National task team to review MOH data</td>
<td>MOH, NPO</td>
<td>Possibly analysis/report?</td>
<td></td>
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<td></td>
<td><strong>Evaluate current survey data on burden of disease, check against EML</strong></td>
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<tr>
<td><strong>Data collection</strong></td>
<td><strong>Availability/price</strong></td>
<td>NPO, task team to coordinate - consultant possible for data collection</td>
<td>NPO, technical support from HQ, task team, MOH</td>
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<tr>
<td></td>
<td><strong>Baseline survey of availability and price of children's medicines</strong></td>
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<tr>
<td>Data collection</td>
<td>What</td>
<td>How</td>
<td>Possible partners</td>
<td>Budget needed</td>
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<td><strong>Financing/expenditure</strong></td>
<td>Analysis of national public sector expenditure on paediatric medicines</td>
<td>Use supply/procurement data and identify key medicines for children based on Model EMLc, evaluate to assess relative expenditures</td>
<td>NPO, technical support from HQ, task team, MOH.</td>
<td>Technical support, ? consultant.</td>
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<tr>
<td><strong>Suitability of dosage forms</strong></td>
<td>Assessment of health professional, patient and carer preference and beliefs about dosage forms of medicines for children</td>
<td>Survey as per Dartmouth</td>
<td>Tanzania - academic partners Muhimbili, Dartmouth (plus possibly 2 other countries).</td>
<td>Survey and analysis</td>
<td></td>
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<tr>
<td><strong>Local manufacturing capacity</strong></td>
<td>Assessment of local capacity for manufacturing dosage forms of medicines for children +/- quality</td>
<td>Adaptation of existing instruments?</td>
<td>6 countries initially-Ghana, Kenya, Ethiopia, Tanzania, Nigeria, Cameroun. Possibly with Clinton Foundation?</td>
<td>Survey and analysis</td>
<td></td>
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<tr>
<td><strong>Baseline measurement of indicators of rational use of medicines in children</strong></td>
<td></td>
<td>Review and adaptation of existing indicators for facilities to develop assessment instrument</td>
<td>? UBC + Lisa Bero to develop instrument NPOs, MOH, health professionals and academic groups in countries</td>
<td>Instrument development Data collection and analysis</td>
<td></td>
</tr>
<tr>
<td><strong>ADvocacy &amp; information provision</strong></td>
<td><strong>Adaptation/adoption of WHO model formulary for children</strong></td>
<td>Contract for content development. Editorial review Document production</td>
<td>RCH, Melbourne + editorial review reviewers. writer</td>
<td>Content production Guideline group meeting, document production</td>
<td></td>
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<tr>
<td></td>
<td><strong>Dissemination of updated pocket book</strong></td>
<td>Content development Document production</td>
<td>CAH, reviewers, writer/editor MOH</td>
<td>For document production</td>
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<tr>
<td></td>
<td><strong>Development of advocacy package</strong></td>
<td>Definition of content Production Dissemination</td>
<td>TBD</td>
<td>????</td>
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</tr>
<tr>
<td><strong>PROCUREMENT and Supply</strong></td>
<td>'Bottle neck analysis' for supply/procurement of core medicines for children based on burden of disease data (e.g. zinc, vitamin K, salbutamol inhalers etc)</td>
<td>????</td>
<td>With MSH?</td>
<td>???</td>
<td></td>
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<tr>
<td>Improving use interventions</td>
<td>What</td>
<td>How</td>
<td>Possible partners</td>
<td>Budget needed</td>
<td>Funding source</td>
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<tr>
<td>DTC training on selection of paediatric medicines</td>
<td>Review and update training material to include children's medicines Technical support for training workshops</td>
<td>? HQ plus RCH??</td>
<td>Material update</td>
<td>Technical support</td>
<td></td>
</tr>
<tr>
<td>Implementation of pocket book in selected district hospitals using ETAT 1 approach with supervision feedback and facilitation (full protocol to be developed)</td>
<td>Consolidation of existing experience and training material Selection of district hospitals Baseline assessment of quality of care and medicines supply/availability</td>
<td>(Initially 2 countries) RCH Melbourne MOH, NPO, CAH CAH, MOH, NPO</td>
<td></td>
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<tr>
<td>Implementation of computerized prescribing</td>
<td>Protocol to be developed.</td>
<td></td>
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<tr>
<td>Implementation of dispersible amoxicillin study</td>
<td>Protocol to be developed.</td>
<td></td>
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<tr>
<td>Commence monitoring safety of children's medicines</td>
<td>Protocol and plan to be developed.</td>
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</tbody>
</table>
Abbreviations:

AFRO: WHO Regional Office for Africa
CAH: Child & Adolescent Health, WHO
CPA: Commonwealth Pharmacists Association
DTC: Drugs and Therapeutic Committee(s)
EMEA: European Medicines Agency
EML: Essential Medicines List
EMLc: Essential Medicines List for Children
EMP: Medicine Access and Rational Use
GMP: Good manufacturing practices
HQ: WHO Headquarters
ICH: International Conference on Harmonisation
IMCI: Integrated Management of Childhood Illness
MAR: Medicine Access and Rational Use, EMP, WHO
MDGs: Millennium Development Goals
MOH: Ministry of Health
MSH: Management Sciences for Health
NDRA: National Drug Regulatory Authority
NPO: National Professional Officer
PPAG: Pediatric Pharmacy Advocacy Group
QA: Quality assurance
PEDMEDREG: Pediatric medicines regulation
RCH: Royal Children’s Hospital, Melbourne
SEARO: WHO Regional Office for South-East Asia
STGs: Standard Treatment Guidelines
TB: Tuberculosis
TBD: To be determined
UBC: University of British Columbia
UNICEF: United Nations Children’s Fund
WHA: World Health Assembly
WHO: World Health Organization
## Agenda

**Chairs:** Alex Dodoo, Suzanne Hill, Stuart MacLeod

### Sunday, 2 August 2009

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
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<tbody>
<tr>
<td>1800 – 2100</td>
<td>Registration and informal meetings (Welcoming Reception)</td>
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</table>

### Monday, 3 August 2009

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
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</table>
| 0900 – 1200 | • **Introduction and welcome:**
<p>|           |   Prof David Ofori-Adjei, Prof Alex Dodoo, Prof Stuart MacLeod, WHO   |
|           | • <strong>Meeting objectives</strong>                                                 |
|           | • <strong>Progress review of essential medicines programmes:</strong>                 |
|           |   • Update from MOH/NPOs                                                 |
|           |   • Review from WHO-HQ: update on 16th WHO Model List of Essential Medicines and 2nd EMLc |
|           |   • Progress re WHO Formulary for Children                                |
|           |   • Discussion                                                            |
|           | • <strong>Identification of next steps:</strong>                                       |
|           |   • Use of evidence in revisions                                          |
|           |   • Process for EML committees                                            |
|           |   • Linkage with procurement programmes                                   |
|           |   • Linkage with rational/optimal use programmes                          |
|           |   • Any other issues                                                      |
| 1200 – 1300 | Lunch                                                                    |
| 1300 – 1700 | • <strong>General overview of Better Medicines for Children project:</strong>          |
|           |   • Project plan – WHO                                                   |
|           |   • Challenges and opportunities                                          |
|           | • <strong>Discussion</strong>                                                          |
|           | • <strong>Potential areas of work:</strong>                                            |
|           |   • Policy: adoption of EMLc, regulatory                                  |
|           |   • What’s working and what isn’t                                         |
|           |   • Research: research on essential medicines; development of new formulations |
|           |   • Health professionals                                                  |
|           |   • Access                                                                |
| 1700 – 1800 | Break                                                                    |
| 1800 – 1900 | • <strong>Challenge in Closing the Know-Do Gap in Pediatric Therapeutics</strong>     |</p>
<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
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</thead>
<tbody>
<tr>
<td>1900</td>
<td>Social event</td>
</tr>
<tr>
<td><strong>Tuesday, 4 August 2009</strong></td>
<td></td>
</tr>
<tr>
<td>0830 – 0900</td>
<td>• <strong>Review of Monday - key issues</strong></td>
</tr>
<tr>
<td>0900 – 1030</td>
<td>• <strong>Potential areas of work</strong> (continued)</td>
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<tr>
<td>0900 – 1030</td>
<td>• <strong>Measures to foster improved use:</strong></td>
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<tr>
<td>0900 – 1030</td>
<td>• Guideline development (handbooks/pocket book) and validation</td>
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<tr>
<td>0900 – 1030</td>
<td>• Better use of information/communication technology, including e-prescribing</td>
</tr>
<tr>
<td>0900 – 1030</td>
<td>• Other strategies</td>
</tr>
<tr>
<td>0900 – 1030</td>
<td>• <strong>Opportunities for synergy with other African initiatives</strong></td>
</tr>
<tr>
<td>1030 – 1100</td>
<td>Break</td>
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<tr>
<td>1100 – 1230</td>
<td><strong>Breakout discussions</strong> (3 groups with balanced country/discipline membership) with emphasis on researchable questions:</td>
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<tr>
<td>1100 – 1230</td>
<td>• Research/formulation requirements</td>
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<tr>
<td>1100 – 1230</td>
<td>• Improved access/EMLc adoption</td>
</tr>
<tr>
<td>1100 – 1230</td>
<td>• Guideline development and validation, knowledge transfer/scaling up</td>
</tr>
<tr>
<td><strong>Breakout 1:</strong></td>
<td>Research on formulations and pharmaceutical issues</td>
</tr>
<tr>
<td><strong>Facilitators:</strong></td>
<td>Tony Nunn, Dave Knoppert, Atieno Ojoo</td>
</tr>
<tr>
<td>1.</td>
<td>Priority needs for African settings</td>
</tr>
<tr>
<td>2.</td>
<td>Adjustable age-related dosing</td>
</tr>
<tr>
<td>3.</td>
<td>Foundation for dosing guidelines</td>
</tr>
<tr>
<td>4.</td>
<td>Alternative routes of administration</td>
</tr>
<tr>
<td>5.</td>
<td>Attitudes to medication use – children and families</td>
</tr>
<tr>
<td>6.</td>
<td>Impediments to adherence</td>
</tr>
<tr>
<td>7.</td>
<td>Fixed-dose combinations or flexible combinations</td>
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<tr>
<td><strong>Breakout 2:</strong></td>
<td>Improved access/EMLc adoption</td>
</tr>
<tr>
<td><strong>Facilitators:</strong></td>
<td>Andy Gray, Kopano Mukelabai</td>
</tr>
<tr>
<td>1.</td>
<td>Better access or better use?</td>
</tr>
<tr>
<td>2.</td>
<td>Main barriers to access</td>
</tr>
<tr>
<td>3.</td>
<td>Initial reactions to EMLc introduction</td>
</tr>
<tr>
<td>4.</td>
<td>Strategies to enhance impact of EMLc</td>
</tr>
<tr>
<td>5.</td>
<td>Supply chain issues and stock-outs</td>
</tr>
<tr>
<td>6.</td>
<td>Drug pricing studies</td>
</tr>
<tr>
<td>7.</td>
<td>What has worked in various jurisdictions</td>
</tr>
</tbody>
</table>
### Breakout 3: Validated Guidelines

**Facilitators:** David Ofori-Adjei, Mike English

1. Process for guideline development and validation
2. Incorporation of best evidence
3. Optimal dissemination strategies
4. Role of opinion leaders
5. Most advantageous locus of intervention
6. General handbooks versus targeted guidelines
7. Use of computers and wireless technologies
8. Research priorities

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
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<tbody>
<tr>
<td>1230 – 1330</td>
<td>Lunch</td>
</tr>
<tr>
<td>1330 – 1500</td>
<td>Continuation of breakout discussions with rotation of group membership; each participant will have opportunity to join two breakout discussions.</td>
</tr>
<tr>
<td>1500 – 1530</td>
<td>Break</td>
</tr>
<tr>
<td>1530 – 1600</td>
<td>Reports from breakout groups and general discussion</td>
</tr>
<tr>
<td>1630 – 1730</td>
<td>Facilitated discussion and agreement on priority actions</td>
</tr>
<tr>
<td>1730</td>
<td>Future directions</td>
</tr>
</tbody>
</table>

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List of participants

Participants

Mr Yakob Seman **Ahmed**, Federal Ministry of Health, P.O. Box 1234, Addis Ababa, Ethiopia

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**Management for Sciences for Health**

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**Host organization**

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Mr Abdul Malik Sulley, Assistant to Dr A. Dodoo, University of Ghana Medical School, Accra, Ghana

**WHO**

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