Meeting report


Executive summary

WHO and UNICEF convened an expert consultation to consider ways of tackling the problem of lack of essential medicines for children. The need for affordable and appropriate child-friendly formulations of medicines for priority diseases including HIV, malaria and TB as well as respiratory and diarrhoeal diseases has been well described.

The specific objectives of the meeting were to:

- review bottlenecks for availability of paediatric medicines and short-term and long-term priority interventions to address them
- identify the priority medicines for children for potential addition to the WHO Model List of Essential Medicines in March 2007
- review a proposal for monitoring safety of use of medicines in children
- identify priority treatment guidelines for medicines for children for review or development
- define objectives for an international project on improving access to essential medicines for children, including priorities and strategies for project development, implementation and fund-raising.

The meeting produced a list of recommended actions for WHO and UNICEF to undertake to improve access to essential medicines for children. The key recommendations were to:

- update the WHO Model List of Essential Medicines to include essential medicines for children, based on their clinical needs and the burden of disease
- take steps to identify the appropriate formulations of medicines for children, and encourage their manufacture and licensing by drug regulatory authorities
- work with countries to promote rapid licensing of appropriate, high-quality and affordable medicines for children, including developing innovative methods for monitoring the safety of medicines
- provide up-to-date and evidence-based clinical guidelines and prescribing information about medicines for children
- collaborate with health care professionals and other organizations to promote better use of medicines in children.
Introduction

Improving child survival is an urgent priority. Much has been done to define the causes of mortality and morbidity in children and the interventions that are known to be effective. Many programmes and partnerships have been set up to work on these problems, including those with a particular focus on HIV, TB and malaria, and access to effective and safe medicines.

The inequity of access to medications for children has been recognized for many years but has been emphasized recently in relation to access to appropriate formulations of medicines for HIV and AIDS treatment and care, especially in resource-limited settings. The scarcity of age-appropriate formulations, first of all for life-saving antiretrovirals and artemisinin combination therapies for malaria, has highlighted many other problems related to medicines for children. These include inadequate prescribing and dosing information as well as the absence of basic evidence about efficacy and safety. The differences between children and adults in relation to medicines have been well described. Children, and particularly newborns, suffer from different diseases than adults and may require different medicines. Children differ in the way they ingest, absorb, metabolize and excrete drugs, and behavioural and developmental issues complicate their treatment. These factors are not constant but vary as the child grows. Age-related differences also mean that many medications have different therapeutic effects and adverse reactions in children compared with those in adults.

The need for child-specific medicines, references and formularies has been recognized by several countries over the last decade. In the mid-1990s, in the USA a series of strategies was initiated to encourage manufacturers to develop medicines specifically for children. The EU has developed a similar package of legislative and regulatory measures that will officially commence in 2007. A number of developed countries have produced prescribing information about the use of medicines in children, for example the British National Formulary for Children (formerly Medicines for Children). However, these approaches, although important, do not address many problems of improving access to child-appropriate formulations of essential medicines in developing countries, where medicines for children may not be available or affordable, if they exist.

What is special about medicines for children?

Adults are generally able to swallow medications presented as tablets or capsules. Doses for adults tend to be fairly uniform, without large differences between individuals, so usually a limited number of tablet or capsule formulations and strengths of a medicine is sufficient to provide the appropriate dose. Children, on the other hand, vary greatly in their ability to handle various medication formulations, due to their age, physical development, ability to coordinate swallowing and psychological development. Also, the required dose of a medicine varies continuously throughout childhood. This is due to change in body size due to growth, usually accounted for by using doses of medications for children according to the child’s weight or body surface area. Importantly, dosing in children, even if based on weight or surface area, also varies in different age groups due to developmental differences in drug disposition. Thus for medications to be used for children effectively and safely they must be presented in
formulations that are easily amenable to dose adjustments, easy for children to ingest and palatable and easy for carers to administer. The majority of medications worldwide are not formulated for easy or accurate administration to children. The lack of appropriate formulations and appropriate dosing data means the administration of many medications to children is less precise and less safe than it is in adults. The younger the child the less likely it is that there will be an appropriate formulation and data on safety and efficacy.

Liquid formulations, such as syrups, suspensions and emulsions, allow considerable scope for dose variation and may be the most appropriate oral formulation for younger children (birth to 8 years). However, liquid formulations have some significant problems: they tend to be less stable than solid preparations, and thus have a shorter shelf-life; they may require refrigeration; their volume makes transport and storage an issue; and masking the taste of bitter drugs in a liquid can be difficult. Furthermore, dose adjustments in relation to management of chronic disease are not easy to implement, especially when a child is taking several liquid medicines simultaneously.

WHO has had an action programme on essential medicines for over 20 years, to improve access to safe, effective, high quality and affordable essential medicines. UNICEF has been working with countries on supply and access to these medicine, as well as with the pharmaceutical industry to advocate improved access to required products e.g., for HIV and AIDS. Given the increasing importance of access to essential medicines for children, WHO and UNICEF arranged for an “Expert Consultation on Paediatric Essential Medicines” in August 2006. The list of participants is in Annex A and the meeting agenda is in Annex B.

### Meeting objectives

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- identify the priority medicines for children for potential addition to the WHO Model List of Essential Medicines in March 2007
- review a proposal for monitoring safety of use of medicines in children
- identify priority treatment guidelines for medicines for children for review or development
- define objectives for an international project on improving access to essential medicines for children, including priorities and strategies for project development, implementation and for fund-raising.

### What medicines for children are on the current Essential Medicines List and what are the gaps?

A review of paediatric formulations on the 14th WHO Model List of Essential Medicines (EML), 2005, was commissioned by WHO in January 2006. The review was conducted by Sean Beggs and Noel Cranswick of the Royal Children's Hospital, Melbourne, Australia. Only the status of orally administered medicines was considered in the review. Parenteral and
inhalational formulations of medicines were excluded from the analysis. Medicines were assessed for their applicability for use in children, including the existence of a registered indication. It was then determined whether an appropriate formulation was currently available on the Model List. For medicines for which an appropriate formulation was not included in the Model List, the formularies of three countries (Australia, the UK and USA) were checked to see whether an appropriate formulation was marketed. The availability of appropriate prescribing information to support safe and effective use in children of these medicines was also assessed.

The medicines were divided into the following groups:

<table>
<thead>
<tr>
<th>List</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>Green List</td>
<td>An appropriate formulation for children is on the 14th Model List</td>
</tr>
<tr>
<td>Yellow List</td>
<td>The medicine is licensed for use in children, but an appropriate formulation for children is not on the Model List AND an appropriate formulation is available in a reference country</td>
</tr>
<tr>
<td>Orange List</td>
<td>The medicine is licensed for use in children, an appropriate formulation is not on the list AND an appropriate formulation has NOT been identified in a reference country</td>
</tr>
<tr>
<td>Red List</td>
<td>The medicine is on the Model List, is indicated but not licensed for use in children, and there is no formulation in a reference country.</td>
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Current Core Model List
Of the 284 medicines listed on the EML core list, 119 medicines were judged as requiring an oral paediatric formulation. Of these 119 medicines, 52 were listed with a paediatric formulation, leaving 59 medicines on the EML without paediatric formulations (there were 8 duplicate listings). Of these 59 medicines, 29 medicines had an appropriate formulation and licensed indication available in one of the reference countries while 30 medicines did not have an appropriate paediatric formulation identified in these countries.

Current Complementary Model List
Of the 84 medicines in the EML complementary list, 28 were judged as requiring a formulation for children. Of these 28 medicines, 3 had paediatric formulations, leaving 23 medicines without paediatric formulations (there were 2 duplicate listings). Of these 23 medicines, 2 medicines had an appropriate formulation available in one of the reference countries while 21 medicines did not have an appropriate paediatric formulation identified.

The meeting noted the following:
- the appropriate formulations for children at different ages/developmental stages need to be considered
- appropriate dosing devices need to be available (e.g.: measuring cups)
- there are many gaps in information about efficacy and safety of possible essential medicines for children
- parenteral formulations and pack sizes and volumes appropriate for children need to be considered
• rectal formulations need specific consideration
• medicines for use in neonates need special consideration
• dispersible tablet/fast-melt tablet/melt granulation development would be useful if product suitability is not compromised in tropical environments
• destruction of "out-of-date" syrup formulations of medicines needs to be considered.

The meeting recommended that WHO and UNICEF:
• prioritize the addition of medicines and formulations to the EML based on the clinical needs of children. As the current List is based on adult medicines, procedures to define these needs should be developed urgently
• prioritize the addition of paediatric and paediatric pharmacological experts to the WHO Expert Panel on Drug Evaluation. In this way appropriate experts can be included on the Expert Committee on the Selection and Use of Essential Medicines, to enable it to properly assess and decide on medicines/formulations for children
• establish a formal sub-committee of the Expert Committee on Selection and Use of Medicines to oversee the comprehensive update of the Model List of Essential Medicines to meet the needs of children
• further characterize formulations according to clinical evidence and formulation criteria (see below for criteria)
• identify the clinical research gaps regarding safety and efficacy of essential medicines, for children, in order to improve sub-optimal prescribing and dosing, and also to facilitate regulatory approval of paediatric formulations
• prioritize formulations on the 'yellow list' for submission to the next Expert Committee on the Selection and Use of Essential Medicines, including particular consideration of medicines for infection, pain management and epilepsy
• review the formulations on the 'orange list' to determine whether they should be considered as priorities for formulation development, based on children’s needs
• obtain additional feedback on the EML review, identifying additional existing formulations in reference countries to identify medicines that could be moved from the orange to the yellow list
• commission a review of parenteral products on the EML (with particular consideration of use in neonates)
• review the feasibility of manufacturing appropriate formulations for those priority medicines for which currently none exist, specifically considering requirements for use in resource-limited settings and availability of data on efficacy and safety in the appropriate age groups.

What are the appropriate formulations of medicines for children?

Tony Nunn of the Royal Liverpool Children’s Hospital, UK, presented his work on the development of paediatric HIV dosing information and the development of paediatric formulation of fixed-dose combinations of antituberculosis medicines. He raised the following points:
• formulations need to address dosing needs over the size and developmental range in children as well as considering co-existing conditions such as malnutrition
using an Excel spread sheet and agreed weight bands, the deviation from desired dose can be illustrated when different formulations and doses are used. This has enabled an expert group to advise on the 'best fit' given the constraints in resource-limited countries.

dosing by body surface area should be taken into account when devising weight-related doses.

in primary care settings, height can sometimes be used to estimate weight and determine dosing in children. However, this may underestimate the needs of some children who increase their weight quickly after treatment has begun.

fixed-dose combinations require careful consideration for appropriate active drug ratios in the formulation designed for children, in specific sub age groups linked to the development of the child, which may differ from those in adult formulations.

publications such as the BNF-C and USP have begun to address issues of extemporaneous formulations.

The meeting noted that:

there is a need for guidelines for simple, validated extemporaneous formulations for children, especially for medicines currently only available in an adult dose form.

'minitablets', fast-melt tablets and granulations and dispersible tablets may be among the “best” suitable formulations for children, specifically in resource-limited settings.

'suitability' criteria for paediatric formulations should be developed. The following were suggested:

- taste
- appropriate concentrations
- bioavailability / pharmacokinetic data available
- efficacy data available
- formulation covers the range of age groups needing the medicine
- stability in a variety of climates
- formulation is cost-effective within its class
- excipients are “child-friendly”
- formulation is easy to handle and adjust for the care-giver.

The meeting recommended that WHO and UNICEF:

- establish a 'formulation working group' to develop, review and consolidate guidelines for regulators and manufacturers on appropriate formulations for children (including consideration of cost-effective formulations)
- develop guidelines for extemporaneous formulations for children in the environment/setting of the developing world
- develop suitability criteria for paediatric formulation development with particular reference to the developing world.

What are the main issues in relation to regulating medicines for children?

The EMEA representative provided a brief overview and update of the new EU legislation on paediatric medicines, which has been developed over several years. The new legislation
includes a series of incentives and requirements aiming to improve the health of children by stimulating the research, development and authorization of medicines in Europe to treat children without subjecting them to unnecessary clinical trials and without delaying the authorization of medicinal products for other population.

The meeting noted that:

- there is need for expertise in paediatrics for regulating paediatric medicines, and the lack of this capacity in many countries, in both the developed and developing world
- the challenges in conducting clinical trials in children for drug development, including the need for appropriate ethical review and guidelines for conducting clinical trials
- if the same standards for registering medicines for adults are required for registering medicines for children, it may preclude approval of necessary indications, and lead to widespread off-label use.
- the potential for using some of the legal and funding provisions being introduced in the EU for facilitating development and regulatory assessment of children's medicines relevant to developing countries
- the need to provide appropriate guidance and incentives for the pharmaceutical industry to encourage development of adequate markets for children's medicines;
- the cost of encouraging development of children's medicines was also considered, based on the USA's experience of providing funding for clinical trials in children.

The following actions were recommended. WHO and UNICEF should:

- develop a policy to advise countries on the drug regulatory needs for licensing children's medicines, recognizing the essential role of paediatric expertise and capacity, and the complexity of developing this capacity
- establish processes for working with developed country regulatory authorities to facilitate licensing of products for children in developing countries. In order to establish effective collaboration, it is recommended that an inventory of current regulatory activities related to medicines for children should be published
- establish processes that encourage mutual recognition of registration of paediatric medicines by competent drug regulatory authorities
- encourage regional collaboration on registration of medicines for children, where appropriate
- prepare a list of essential medicines products for children that already have approved paediatric indications, to support generic manufacture
- work with appropriate partners to improve understanding of the need for and value of high quality clinical trials in children
- review existing clinical trial guidelines for children to ensure they meet developing country needs
- review possibilities for making key medicines for children that are available in some national markets available on the global market, e.g., through collaboration with UNICEF Supply Division.
What should be done to monitor the safety of medicines in children?

Adverse drug reaction (ADR) information is essential to support safe use of medicines. Regrettably, safety information from children is very limited. A draft proposal prepared by Anders Rane and Hannsjörg Seyberth for monitoring safety of medicines in children was considered. Among risk factors that predispose children to develop an ADR are young age, continuous changes of medicine, dispositional parameters during maturation in all age classes, polypharmacy, length of hospital stay due to congenital and chronic diseases, being critically ill, and the use of unlicensed and off-label medicines, e.g., in orphan diseases. In many resource-limited settings, children's poor nutritional status contributes to the development of ADRs. In addition, medication error is another potential problem of medicine use in children due to inaccurate dosages and extemporaneous formulations and dispensing.

The meeting noted that in order to support safer paediatric medicine use, there is an urgent need to develop a system for enhancing safety monitoring of medicines in children, e.g., developing multiple strategies for ADR and adverse event surveillance, focusing on bottlenecks where ADR information could be useful, and revising ADR reports with attention to paediatric patients. Missing paediatric formulations and lack of advice on proper dosing of essential medicines are some of the potential causes of incorrect doses. Considering the seriousness of medication error among paediatric patients, the participants of the meeting also propose to separate surveillance of medication error from ADR surveillance.

The meeting therefore recommended that:

- the draft proposal on safety monitoring should be circulated for comment
- a system for enhancing safety monitoring of medicines in children should be developed, including improving ADR reporting systems and enhancing awareness of safety of medicines for children among all health care professionals
- innovative methods for long-term assessment of safety of medicines in children should be developed that are practical and do not delay registration of important medicines
- methods for surveillance of medication error should be developed separately from ADR surveillance
- consideration is given to the 'medication error potential' of medicines purchased through national contracts.

What are the priorities for clinical guidelines for children?

Clinical guidelines to support the appropriate use of medicines for children are essential. Currently there is no comprehensive list of available management guidelines relevant for children, and the known guidelines do not completely cover the range of important paediatric diseases. There is a standard process for guideline development within WHO. Several treatment guidelines for neonatal and childhood illnesses have been developed by specific WHO departments, principally the Department of Childhood and Adolescent Health and Development, Making Pregnancy Safer and the Global Malaria Programme.

In order to support the addition of relevant paediatric medicines to the Model List of Essential Medicines, there is a need for a full compilation of paediatric guidelines and identifying those that are outdated. Guidelines that should definitely be included in this process are 'Hospital Care for Children', 'Integrated Management for Childhood Illnesses' and the disease-specific
guidelines for HIV, malaria and TB, but it is likely that there are others. It was noted that there may not be guidelines that are appropriate and current for palliative care in children, and paediatric oncology.

The meeting therefore recommended that WHO and UNICEF ensure that:

- a comprehensive review of the existing clinical guidelines for childhood illnesses is done to harmonize the medicines mentioned in guidelines with those on the EML; where discrepancies exist, either the medicine is added to the EML or the guidelines are modified
- WHO guidelines are updated where necessary
- once the EML is completed, a formulary for paediatric essential medicines should be developed.

**Preliminary survey on availability of quality paediatric formulations in low- and middle-income countries**

WHO's Department of Technical Cooperation for Essential Drugs and Traditional Medicine conducted a preliminary survey in countries in Africa and the South Pacific. A questionnaire was developed to collect information on paediatric medicines policy in countries, including the selection and use (availability of EML with or without paediatric list; with or without paediatric formulations; covering HIV/malaria/TB, availability of treatment guidelines, and standard methods for advising on doses); quality and safety of medicines (registration of paediatric formulations and medicines for priority diseases, registration of generics, ADR monitoring systems); and access to those medicines (pricing, affordability, procurement and supply, and management bottlenecks).

Fifteen out of 40 countries have so far responded to the questionnaire. Preliminary results indicated that all country respondents had national essential medicines lists, all without separate medicines lists for children. Eight countries reported having formulations of some medicines for children (range between 11 and 52 formulations), eight countries had formulations for children of medicines for HIV, malaria and TB on the list. Eleven countries reported that clinical guidelines were available based on integrated management for childhood illnesses', nine countries had clinical guidelines for HIV, and eight countries had clinical guidelines for TB.

The numbers of registered paediatric formulations varied widely. Reports from four countries indicated that the percentage of registered paediatric formulations to total varied from 3 to 40%. Three countries applied the EU or US regulatory framework. ADR monitoring was in place in five countries. Eight countries reported that paediatric medicines were available in the public sector, free of charge. However, the price of medicines for children varied widely, as illustrated by cotrimoxazole syrup (200/40 mg, 5 ml) that costs 4 to 125% of daily wages.

It was also reported that paediatric dosage forms for the following conditions were not available: artemisinin combination therapy (ACTs), antiretrovirals, TB (including fixed-dose combinations), other chronic disease medicines and parenteral formulations with appropriate dosage strength. Only seven countries reported the availability of dosing tools or dosing
instructions to modify adult medicine formulations. In addition, the results indicated storage and stability problems with the modified formulations.

The meeting therefore recommended that at country level WHO and UNICEF should:

- in collaboration with partners, provide support to countries for enhancing availability and affordability of medicines for children through advocacy and policy interventions
- assist countries in updating their national essential medicines list, formularies and clinical guidelines that take into consideration pharmacotherapy for children, in line with WHO recommendations
- assist countries in strengthening capacity and mechanisms for ensuring quality and safety of medicines for children
- provide guidance for needs assessment, quantification, procurement, storage and distribution of medicines for children
- contribute to the establishment of mechanisms to ensure sustainable financing and affordable medicines prices - including undertaking surveys of prices of medicines used for children
- include medicines for children in applications for funding to organizations such as the Global Fund and the World Bank
- include medicines for children in national medicines budgets
- enhance programmes to promote rational use of children's medicines.

The meeting therefore recommended that at global level WHO and UNICEF should:

- develop an advocacy plan to encourage continued availability of important medicines for children that otherwise might be discontinued
- develop procurement planning guidelines for paediatric medicines, including policy briefs
- examine mechanisms to provide incentives to industry to produce medicines for children for a global market
- develop methods for drug regulatory support in relation to medicines for children
- finalize country surveys and analysis of paediatric medicines with the addition of age-group stratified data and publish the results
- add medicines for children to the WHO/HAI pricing survey tool.

What should the components of an action programme on essential medicines for children be?

The meeting reviewed a preliminary draft of a proposal for an action programme on essential medicines for children. The following suggestions were made:

- the proposal should be revised to highlight the whole spectrum of problems of children’s medicines: lack of age-appropriate formulations and the data on efficacy and safety needed for proper dosing, in addition to the broader aspect of access to medicines in developing countries
- the proposal should be revised to highlight partnerships with appropriate groups and to define respective roles and responsibilities of the various partners
activities should be prioritized into short-term acute response activities (such as adding the requirement to discuss the need for paediatric use, availability of a paediatric formulation and paediatric data on efficacy and safety when submitting proposals for all medicines to be considered for addition to the EML and adding appropriate and available formulations to the current EML) and longer-term activities (such as developing appropriate regulatory capacity) - including for country support activities.

- that although the priority disease areas of malaria, HIV and TB are clearly important, there should be appropriate recognition of the main causes of childhood mortality, including respiratory tract infections and diarrhoea.

- additional components that need to be added included:
  - capacity development for conducting clinical trials in children
  - establishing guidelines for advising on product development, such as fixed-dose combination products specifically for children
  - creating an inventory or database of products that have approved indications for use in children, to facilitate generic manufacture
  - encouraging the development of appropriate educational strategies for health care professionals
  - developing education strategies for carers of children, especially regarding overuse of medicines and inappropriate doses
  - developing guidelines on appropriate extemporaneous dispensing using either adult formulations or the active ingredient in an unfinished form.

Identification of partners and funders

The meeting was asked to identify potential partners for WHO and UNICEF and funders for the proposal. It was noted that some partners might be involved in some but not all components of the project. Potential partners or funders identified included:

- Interested governments
- Health professional associations in paediatrics, including paediatric pharmacology and pharmacy, nursing and carers (e.g. IPA, FIP, IUPHAR and the International Alliance for Better Medicines for Children) researcher networks and organizations (e.g. Cochrane, NIH, INRUD)
- Pharmaceutical manufacturers' associations
- Drug regulatory authorities and regional regulatory harmonization initiatives (e.g. SADC, ASEAN)
- Patient and consumer organizations
- NGOs (e.g. MSF)
- WHO Collaborating Centres
- Health care funders, including reimbursement and health insurance authorities
- Foundations and charities e.g. Gates Foundation, Wellcome Trust.

The following actions were recommended:

- the funding proposal presented during the meeting should be revised and circulated for comment
- individual components of the proposal should be costed in detail, where possible early consultation with potential funders should be undertaken.
JOINT WHO-UNICEF EXPERT CONSULTATION
ON PAEDIATRIC ESSENTIAL MEDICINES
M.505, WHO headquarters, Geneva
9 - 10 August 2006

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DRAFT AGENDA

Wednesday, 9 August 2006

08.30 - 08.45 Welcome from Director
Dr Hans V. Hogerzeil

08.45 - 09.00 Introductions
All

09.00 - 09.30 Review of objectives of meeting
Dr Sue Hill and
Ms Hanne Bak Pedersen

09.30 - 09.45 The imperfect onion
Dr Hans V. Hogerzeil

09.45 - 10.15 Presentation of review of EML: identification of paediatric gaps
Prof. Noel Cranswick

10.15 - 10.45 Presentation of information about formulations
Dr Tony Nunn

10.45 - 11.00 Coffee/Tea

11.00 - 12.45 Discussion and agreement on criteria for prioritizing applications and
position on development of formulations
All

12.45 - 13.45 Lunch

13.45 - 14.45 Presentation of draft proposal on safety monitoring
Dr Anders Rane and
Prof. Hannsjörg Seyberth

14.45 - 15.45 Discussion and recommendations on consultation and next steps
All

15.45 - 16.00 Tea/Coffee

16.00 - 16.30 Review of regulatory activities for paediatrics
Dr Nathalie Seigneuret
EMEA

16.30 - 17.30 Discussions on possible activities
All

17.30 End of meeting
**Thursday, 10 August 2006**

<table>
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<tr>
<th>Time</th>
<th>Activity</th>
<th>Speaker</th>
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<tbody>
<tr>
<td>08.30 - 10.30</td>
<td>Review of paediatric prescribing information needs - guidelines, formulary, dosing information. Discussion and identification of key areas for activities</td>
<td>Dr Sue Hill</td>
</tr>
<tr>
<td>10.30 - 10.45</td>
<td>Coffee/Tea</td>
<td></td>
</tr>
<tr>
<td>10.45 - 11.15</td>
<td>Preliminary results of country surveys</td>
<td>Dr Gilles Forte</td>
</tr>
<tr>
<td>11.15 - 12.30</td>
<td>Discussion and identification of key topics for activities</td>
<td>All</td>
</tr>
<tr>
<td>12.30 - 13.30</td>
<td>Lunch</td>
<td></td>
</tr>
<tr>
<td>13.30 - 16.00</td>
<td>Review of overall project objectives an fundraising plans</td>
<td></td>
</tr>
<tr>
<td>16.00 - 16.15</td>
<td>Tea/Coffee</td>
<td></td>
</tr>
<tr>
<td>16.15 - 17.30</td>
<td>Next steps and follow up actions, meeting close</td>
<td>All</td>
</tr>
</tbody>
</table>