



Better medicines for **children** in India

Report on Informal Consultation
WHO-SEARO, New Delhi, India, 2-3 February 2010



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Printed in India

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Acronyms and abbreviations

CBO	community-based organization
CME	continuing medical education
DANIDA	Danish International Development Agency
DFID	Department for International Development
DPCO	Drug Price Control Order
DRA	Drug Regulatory Authority
DSPRUD	Delhi Society for the Promotion of Rational Use of Drugs
EAG	Empowered Action Group
EML	Essential Medicines List
EMLc	Essential Medicines List for children
FDA	Food and Drug Administration
FDC	fixed-dose combination
FOGSI	Federation of Obstetric and Gynaecological Societies of India
GMP	Good Manufacturing Practices
GOI	Government of India
IAP	Indian Academy of Pediatrics
IFPMA	International Federation of Pharmaceutical Manufacturers & Associations
IMA	Indian Medical Association
IPS	Indian Pharmacological Society
MDG	Millennium Development Goal
MoHFW	Ministry of Health & Family Welfare
MRP	maximum retail price
NEML	national Essential Medicines List

NGO	nongovernmental organization
NPPA	National Pharmaceutical Pricing Authority
NRHM	National Rural Health Mission
ORS	oral rehydration solution
RCH	Reproductive and Child Health
SEAR	South-East Asia Region
SEARO	Regional Office for South-East Asia (of WHO)
STG	standard treatment guideline
UNICEF	United Nations Children’s Fund
VAT	value added tax
WHA	World Health Assembly
WHO	World Health Organization

Executive summary

Following the adoption of the World Health Assembly Resolution WHA60.20 in May 2007, WHO launched the “make medicines child size” project on 6 December 2007. This project is a global campaign to raise awareness and accelerate action to address the need for improved availability of and access to safe, child-specific medicines for all children. With the United Nations Children’s Fund (UNICEF), WHO will work to promote scientific studies of medicines for children leading to specific formulations tailored for use in children, and making these medicines available. By improving access to children’s medicines, the project seeks to directly support and address some of the major issues in Millennium Development Goal 4 (MDG 4).

A WHO Subcommittee on Selection and Use of Essential Medicines developed the first-ever Model Essential Medicines List for children (EMLc) in 2007 and revised it in 2008. The process also identified “missing” essential medicines for children, based on the best available evidence. Advocacy for the project was started by promoting the cause of “better medicines for children” to policy- and decision-makers, clinicians and other professionals, representatives of professional associations and drug supply managers. The project now has many country activities flowing from these initial global activities.

An Informal consultation on better medicines for children in India was held on 2–3 February 2010 at the WHO Regional Office for South-East Asia (SEARO). The objectives were to explore the feasibility of implementing the project in a few states of India and to discuss a broad outline of the activities to be carried out under the project at the national and state levels. Prior to the India meeting, the Essential Drug Lists of five Empowered Action Group (EAG) States from central India, namely, Chhattisgarh, Jharkhand, Madhya Pradesh, Orissa and Uttar Pradesh were compared with the WHO Model EMLc in order to document areas of discordance and identify gaps in implementing the lists with special reference to children’s formulations.

Representatives from the state health departments, representatives of the Indian Academy of Paediatrics (IAP) from the five states, executive committee members of the IAP, professors of paediatrics and pharmacology from various

institutes, experts from WHO Headquarters (HQ), WHO-SEARO, the WHO Country Office, and the Bill and Melinda Gates Foundation came together and discussed the road map for the project in India. The report on the EMLs served as a starting point for the country activity in India, and was extensively discussed during the meeting, because it showed a lack of inclusion of child-friendly formulations for almost every childhood disease.

After deliberations, the broad objectives and outline of the project in India were formulated. It was agreed that the activities would be as follows:

- Development of a national EMLc by the IAP for inclusion in the national essential medicines list (NEML) of India currently being formulated by the Government of India (GOI) with the All India Institute of Medical Sciences (AIIMS) as the lead agency;
- Activities in two EAG states (Chhattisgarh and Orissa) that include (1) development of an EMLc with updating of the EML and facilitation of activities to ensure that procurement follows the EML, and (2) undertaking availability and affordability surveys of children's medicines in these states before and after updating the State EMLc and EML, with at least one procurement cycle using the revised EML.

1. Background

The global “make medicines child size” project of WHO began on 6 December 2007 and focuses on encouraging the development, procurement and use of better medicines for children globally. Studies have revealed that, in many cases, the medicines available for adults are speculatively extrapolated for use in children. This is a serious anomaly as scientific and clinical evidence shows that the absorption, distribution, metabolism and excretion of medicines in children are markedly different from that in adults. Therefore, increasing the number of scientific studies leading to the development of specific formulations tailored for use in children, and the final step of making such medicines available and used, are the ultimate objectives of the “make medicines child size” project.

The project focused initially on global activities, such as developing an Essential Medicines List for children (EMLc), identifying formulations that are “child-friendly”, and engaging policy- and decision-makers, clinicians and other professionals, representatives of professional associations and drug supply managers in promoting the cause of “better medicines for children”. The project has country activities flowing from these global activities.

Under the “better medicines for children” initiative, an Informal consultation on better medicines for children in India was held on 2–3 February at the World Health Organization Regional Office for South-East Asia (WHO-SEARO), New Delhi. Participants at the meeting included practising paediatricians, office bearers and members of the Indian Academy of Paediatrics (IAP), professors of paediatrics and pharmacology from various institutes and pharmacists. Representatives of the Government of India and the Delhi Society for the Promotion of Rational Use of Drugs (DSPRUD). Experts from WHO-HQ, WHO-SEARO, WHO India Country Office, and the Bill and Melinda Gates Foundation were also present.

2. Objectives of the meeting

The objectives of the meeting were:

- (1) To explore the feasibility of implementing the better medicines for children project in a few states in India.
- (2) To identify gaps in implementing the EMLc and improving access, and exploring options and strategies to overcome them.
- (3) To discuss the outline of activities to be undertaken at the state level by the respective state governments and at the national level by the IAP.
- (4) To sensitize the participants on the need to prepare an EMLc and conduct pricing and availability studies in order to have baseline information on the availability of children's medicines.

On Day 1, the discussion focused on the global and regional status with regard to EMLs and the status in India. A report on the comparison of the EMLs of five states in India with the WHO Model EMLc 2009 was presented and a discussion followed. On Day 2, technical, advocacy and access issues were discussed, and the road map for country- and state-level activities in India was formulated.

3. Day 1

The meeting started with a welcome by Dr Krisantha Weerasuriya and Dr Suzanne Hill. Following self-introductions by all the participants, Dr Suzanne Hill outlined the "concept of essential medicines, what they are and why we should have an EML". A summary of her talk is given below.

4. Essential medicines: what they are

Worldwide, many countries have developed EMLs for their use. The concept of an EML is to have a limited range of carefully selected core essential medicines that lead to better health care, better drug management and lower costs. These essential medicines should satisfy the priority healthcare needs of the population of the target country/state. They are selected with due regard to disease prevalence, evidence on efficacy and

safety, and comparative cost-effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times, in adequate amounts, in the appropriate dosage forms, with assured quality, and at a price the individual and the community can afford. Implementation of the concept of essential medicines is intended to be flexible and adaptable to many different situations; exactly which medicines are regarded as essential remains a national responsibility.

Ideally, the WHO Model EML should be aligned with WHO treatment guidelines and the list should be updated regularly to reflect this. However, while essential medicines are the responsibility of the Essential Medicines Department, treatment guidelines are the responsibility of individual departments. More treatment guidelines for chronic diseases need to be developed. Country lists are now being collected and activities mapped to link EMLs to procurement.

Among the strengths of a national EML (NEML) the most important one is that it can contribute to making medicines affordable. However, there is weakness in its implementation. Often, this is because only middle-level people such as those in medical colleges are consulted for its preparation. People at other levels should be included in the development of an NEML. Political sensitization is crucial for building a successful list. Policy- and decision-makers must be told how best they can use the EML. Once a draft list is ready, its applicability needs to be discussed with all stakeholders. The final list should be widely disseminated. A national or state EML may be based on the WHO Model List and then adapted according to the country's/state's needs. Clinical evidence on comparative efficacy and safety of drugs should be used for its creation.

Dr Krisantha Weerasuriya then gave a brief overview of the NEMLs in the South-East Asia Region.

5. National Essential Medicines Lists in the South-East Asia Region

Most countries have a national EML or a selective state/provincial list. In the South-East Asia Region (SEAR), a selected list of drugs was a long-felt need even before the WHO Model EML came into being. The WHO Essential Medicines Concept (1975) and the first EML in 1977 were a result of

country requests to WHO. Two of the members of the first Expert Committee in 1977 were from SEAR countries (Indonesia and Sri Lanka). The 11 Member States of SEAR all have an EML in some form. However, the situation regarding medicines varies widely across countries; while some are totally self-sufficient (e.g. India), others are wholly dependent on imports (e.g. Bhutan, Timor-Leste).

Some countries in SEAR have formularies and standard treatment guidelines (STGs) in association with the NEML. However, in most countries, activities in the area of essential medicines are limited only to the public sector.

Bhutan has had an EML in some form since 1978, but the earlier lists were not comprehensive and the drug selection process was not systematic. In 2007, Bhutan published the fourth edition of its NEML and National Formulary. Since there is no private sector in Bhutan, the NEML applies to the whole population. The cost of medicine supply is US\$ 2/person/year, which has been made possible by the fact that affordable medicines are available from India. A good quality control system is also in place. However, this model is not replicable in other countries.

Thailand's first list became available in 1972, and is updated regularly. The first NEML according to WHO criteria was developed in 1981 and the current list was developed in 2004. The list is being revised at present. However, the country has three lists for different categories of the population in the state health-care sector, thus creating differences in access. The 30-baht health insurance scheme was a strong impetus in incorporating essential medicines into the public health-care system.

Sri Lanka developed its first formulary as early as 1959, which included unbiased drug information. Its NEML is fully compatible with the WHO List since 1985, and is updated regularly; the last revision was in 2009. However, the list is applicable to the public health-care sector only.

In **India**, at the central level, three ministries are responsible for regulation of the health and pharmaceutical sectors – the Ministry of Health and Family Welfare (MoHFW), Ministry of Commerce and Industry, and the Ministry of Chemicals and Fertilizers (through the Department of Pharmaceuticals and its attached office of the National Pharmaceutical Pricing Authority [NPPA]).

Professor Y K Gupta, Professor Gitanjali Batmanabane, Professor Usha Gupta and Professor Santanu Tripathi then gave some inputs as to what has been done in India regarding essential medicines. The summary of their presentations as well as the gist of the discussion that followed is given below.

6. Essential medicines in India

The Hathi Committee in 1975 identified major problems with the pharmaceutical industry and provided recommendations, some of which have been achieved, such as self-sufficiency in medicines. The first EML was developed in 1996, but was not implemented for procuring drugs and no STGs were drawn up. The list was revised in 2003 and the next update is scheduled for 2010. The changing pattern of the burden of disease calls for an urgent revision of the list. The NEML has been useful in advancing medicines in the health sector. It has also helped to prevent irrational combination drugs and ineffective ones. EMLs are accepted in government health-care systems but it remains a challenge to get the private health-care sector to accept them due to opposing forces.

In India, health is the individual responsibility of each state. Many states have developed their EMLs. The NEML serves as a model list and is adapted to reflect the health status, morbidity patterns, financial and other logistic requirements for procuring and transporting medicines within the state. The Tamil Nadu Medical Supplies Corporation used the EML to develop the most successful state medicines procurement system. States have their own budget and system of procurement, and are also funded by outside agencies such as the Danish International Development Agency (DANIDA), Department for International Development (DFID) and the World Bank. Vertical programmes such as the National Malaria Programme, National Tuberculosis Programme, National Rural Health Mission (NRHM) and others are implemented centrally and receive drugs from the central government. However, states also have their own programmes for these and often supplies of the same drugs are duplicated. Coordination between the central and state governments for the same programmes is less than optimal.

Implementation of the EML is weak in most states. The reasons for non-implementation of EMLs in states include frequent changes in the

political set-up, lack of sensitization of administrators and prescribers, faulty procurement and distribution systems, prescribers' unhappiness at being restricted to the list, lack of expertise to update the EML in many states and the influence of the pharmaceutical industry on prescribers.

Delhi was the first state to formulate a drug policy and implement an essential medicines programme in 1993. The Delhi Society for Promotion of Rational Use of Drugs (DSPRUD) is an NGO which works with the Delhi Government. The first list was developed by DSPRUD in 1994. The latest list is that of 2009 and a 2010 revision is being undertaken.

In 1996, 30% of the health budget was saved by procuring drugs through the use of an EML. The Government of Delhi allows the medical superintendent of a hospital 10–20% flexibility in the essential medicines budget for drugs that are not on the list. In 1997, WHO's Essential Medicines Programme provided technical assistance to DSPRUD in implementing the drug policy as well as in procuring drugs. Following the example of Delhi State, many other states in India approached Delhi for help with their EMLs. The State has also made an effort to increase access by providing free essential medicines to all. To bring practising doctors on board, a prescription audit was conducted for doctors to show them that they were already prescribing most of the drugs on the list. STGs are also being revitalized.

The corporate and private sectors have also realized the need to have a separate list which they call a formulary list to manage their own hospitals. There are no separate EMLs for children, but Delhi State has included a few children's medicines in their EML.

West Bengal has a population of 90 million. Of the doctors, only 50 000 practise the modern system of medicine and 200 000 are unregistered rural medical practitioners. The health needs of 25 million people are looked after by the 50 000 registered doctors, while 65 million are looked after by the unregistered practitioners. For these rural doctors, the role-models are the professors of medical colleges whose prescriptions they study and follow. Overall in India, 50%–70% of the population is managed by unqualified practitioners.

The public sector has a list for procurement of drugs, but practitioners do not know what the choices are for a particular condition in the list. Many prescribe brand names, though the generic forms are in the list. In

the private sector, there are commercial and NGO hospitals. These have their own lists which are followed by their pharmacies.

Dr Suzanne Hill in her presentation gave a brief update on the 16th WHO Model List of Essential Medicines and the 2nd EMLc.

WHO developed the first EML in 1977 and updates the list every two years after deliberations by an Expert Committee. For each update, a new Expert Committee is appointed. Since 2002, revised procedures were adopted and an added requirement for updating the Model EML was the availability of evidence on the efficacy of the drug. In the 2009 list, there are approximately 350 drugs, of which about 50% are supported by a relevant Cochrane review. Conversely, some drugs for which there is no evidence for efficacy are considered for deletion (e.g. antacids, allopurinol). The inclusion of new drugs in an EML has a direct impact on pricing and import policies.

7. Essential Medicines List for children (EMLc)

The EMLc is a recent development and the first list developed by WHO became available in 2007. The 15th Model List was reviewed and an initial draft list of medicines for children developed. A number of liquid formulations were added. For the second EMLc in 2009, the first list was reviewed, medicines for neonates were added, and two other new sections included. Some sections were deleted. It was decided to maintain a separate list of essential medicines for children, add formulations such as fixed-dose combinations (FDCs), provide prescribing information and promote marketing incentives for appropriate drug development, while ensuring that the medicines conform to international regulatory and safety standards. Hospital-based treatment guidelines are taken into consideration while developing the EMLc.

Some of the issues in paediatric formulations include the technical difficulties associated with the manufacture and storage of liquid preparations for children, the impact of climate on transportation and storage, and the palatability of the medications. Local factors and practices also make a difference. The preferred dosage form would be a form that can be turned into liquid at the point of administration, e.g. dispersible tablets or granules.

Ten priority medicines for children based on the morbidity patterns are: oral rehydration solution (ORS), zinc (for diarrhoea), amoxicillin (for pneumonia), ampicillin injection and gentamicin injection (for neonatal sepsis), ceftriaxone (for meningitis), artemether–lumefantrine (for malaria), quinine or artesunate injection (for complicated forms of malaria), morphine (for pain relief) and vitamin A (to prevent blindness). These drugs have been selected on the basis of the survival benefit they offer. If these 10 drugs are available in a health system, in child-friendly formulations, at least the priority conditions in children under 5 years of age can be managed.

Only about two thirds of the drugs included in the EMLc have adequate evidence for clinical effectiveness and safety in children. This is due to the lack of clinical trials in children, lack of appropriate formulations, lack of prescribing information and of licensed medicines. Other gaps include a lack of market incentives for appropriate drug development, a lack of international regulatory standards for formulations, and paucity of international safety monitoring and post-marketing surveillance studies. The plan is to work on a global project to make paediatric medicines a priority and overcome these gaps.

Dr Krisantha Weerasuriya and Dr Suzanne Hill then gave a general overview of the better medicines for children initiative.

8. Better medicines for children initiative

An estimated nine million children worldwide die each year from preventable and treatable causes. More than half of these deaths are caused by diseases which could be treated with safe, essential, child-specific medicines: acute respiratory infections – pneumonia (17%), diarrhoeal diseases (17%), neonatal severe infections (9%), malaria (7%) and HIV/AIDS (2%). Studies have revealed that, in many cases, the medicines available for adults are speculatively extrapolated for use in children without studies in children. This is a serious anomaly as scientific and clinical evidence shows that the absorption, distribution, metabolism and excretion of medicines in children are markedly different from that in adults.

Launched on 6 December 2007, “make medicines child size” is a global campaign spearheaded by WHO to raise awareness and accelerate action to address the need for improved availability and access to safe, child-specific medicines for all children. This has been endorsed by the

industry through the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA); civil society through Médicines sans Frontières, Caritas Internationalis and others; professional organizations as well as agencies such as the National Institutes of Health, European Medicines Evaluation Agency and UNICEF. By improving access to children's medicines, the project seeks to directly support and address some of the major issues in Millennium Development Goal 4 (MDG 4).

Professor Gitanjali Batmanabane gave a presentation entitled "Comparison of the EMLs of five states in India – preliminary findings: challenges and opportunities". A summary of the presentation is given below.

9. Comparison of the EMLs of five states in India

A comparison of the EMLs of the states of Chhattisgarh, Jharkhand, Madhya Pradesh, Orissa and Uttar Pradesh with the WHO EMLc 2009 was undertaken in order to identify the main areas of discordance.

9.1 General observations

- Comparison of the EMLs of the five states showed that while the principle of essential medicines has been followed, implementation has been very irregular and flawed. None of the states have separate lists for children's medicines. However, the effort taken to prepare a list should be commended. A comparison of the EMLs with the WHO EMLc 2009 showed that the number of medicines and the categories were much more in the state lists.
- Definite discordance exists in many areas, especially in those which account for large morbidity and mortality in children such as diarrhoea.
- There is very poor representation of child-friendly dosage formulations and of medicines in smaller strengths suitable for children. Formulations such as scored tablets or dispersible tablets are very rarely listed. The few that are available are in the form of syrups or suspensions, which are not very stable at the extreme temperatures seen in various parts of India.

- Irrational drug combinations and some of the newer more expensive medicines, for which not enough evidence is available at this point in time, have been included, as have some obsolete medicines.
- Pharmacopoeial standards as well as pack sizes have not been stated in three of the lists. Details of formulations and strengths are not given consistently.
- Some drugs which are in the STGs have not been included in the list, e.g. zinc for use in diarrhoea.

9.2 State-specific observations

- The EML of Chhattisgarh was published in 2002 and has not been updated since. Jharkhand adopted the same list in 2004 without any changes. Orissa has the most updated list (2009).
- The EMLs of Chhattisgarh and Jharkhand closely follow the WHO model list. However, some of the formulations listed may not be available in India. In preparing the list, the availability of the formulations and cost do not seem to have been considered.
- The list of Madhya Pradesh seems to be a “copy and paste” from other sources. The format of entry for medicines under the same category varies and there are duplications and deletions within a category. The deleted rows have not been removed. This list needs careful scrutiny and editing.
- Apart from the EMLs of Chhattisgarh and Jharkhand, the EMLs of the other three states do not seem to have had critical input and do not conform to the general conditions of listing in an EML. The lists from Orissa, Madhya Pradesh and Uttar Pradesh have two or three medicines from the same class, contain irrational FDCs and medicines of doubtful efficacy and safety for the listed conditions, or those that are no longer considered the best choices.

9.3 Discussion

The discussion which followed the presentation focused on the fact that the EMLs were most often not used as a basis for procurement. Issues such as the need to update the list regularly, transparency in procedures, quality of

medicines procured and storage in extremes of temperature were discussed. A few of the issues which were deliberated upon in detail on which a general consensus was reached are given below:

- (1) The review highlights the need to focus on including child-friendly formulations in these EMLs. This would require the support of the government, paediatricians, professional bodies and civil society.
- (2) Advocacy efforts should aimed at state health officials to convince them that medicines for children should be a priority.
- (3) Health policy-makers should be made aware of the need for sustained commitment to the cause of better medicines for children, and a team of committed professionals convened to update/prepare the list.
- (4) The issue of including age-appropriate formulations needs to be addressed.
- (5) Procurement and supporting services such as warehousing, computerization, inventory control and additional staff/training should be improved, and operational research promoted.
- (6) People at the periphery must be educated on dosage forms, schedules, types of preparations available and drugs that are contraindicated in children.
- (7) Drugs that should not be used by pregnant and lactating women should be listed.
- (8) Drugs for treatment of diabetes in children should be available as it is increasing in incidence. Anti-HIV drugs for children must be listed, including liquid formulations.
- (9) Children's medicines are often not palatable and this is a very important issue for adherence. Efforts should be made to make children's medicines more palatable.

10. Day 2

On the second day, the previous day's proceedings were reviewed and a preview of the day's schedule presented. The first group discussion was on

technical issues. The session was facilitated by Dr Suzanne Hill, Dr Lisa Bero and Dr Gitanjali Batmanabane, and the following points were brought out.

11. Group discussion: technical issues

- (1) Joint national advocacy through the IAP is needed to arrive at a national consensus on better medicines for children. Regulators and national-level policy-makers need to be involved. How will this be done?
- (2) At the professional level, there is a public–private sector divide, though both are working for the health of children. What would be the differences between the top ten drugs in the public and private sectors?
- (3) What are the state lists for? Who uses them and for what? Are they used only for procurement? What should be done to these lists to optimize medicines for children? Who can influence the updating of these lists?
- (4) Could pharmaceutical manufacturers be induced to make the drugs that are needed (including the required formulations) and promote these?

Dr Tanmay Amladi and Dr Panna Choudhury from the IAP explained the activities of the IAP and its role in advocacy.

12. Paediatricians and their role in advocacy: role of the Indian Academy of Paediatrics

The IAP has 18 000 members and 306 state and local branches. It has about 20 subspecialty chapters nationwide. It holds regular seminars and conferences, and has wide communication networks such as three websites, two journals and a newsletter. The IAP has its own formulary, which is evidence-based and includes cost considerations; each subspecialty contributes its own list. About 625 paediatric drugs are listed in the formulary, which is updated every three months. The role of IAP is in advocacy and endorsement. Considering the large membership and pivotal

role played by IAP in continuing medical education (CME) programmes, this professional body is ideally suited for advocacy and training.

Dr Kathleen Holloway moderated the discussion on access issues. Dr Anita Kotwani, Professor Santanu Tripathi and Professor Vijay Thawani made brief presentations on the issue. Some of the discussion points are given below.

13. Group discussion: access issues

- (1) Health is not treated as a fundamental right in India. Thus, individuals are not empowered to demand health. Poor literacy levels and attitudes are also a barrier.
- (2) There is a lack of efficiency and transparency in the health system. There is no coordination between the demand and supply for medicines, price controls are ineffective, and pharmacoeconomics is not considered.
- (3) Health is a state subject, and there is duplication and multiplicity of organizations at the state and central levels. For example, there are two regulatory bodies – the central Food and Drug Administration (FDA) and the state FDA.
- (4) EMLs are not always available in the states and, if available, are infrequently updated.
- (5) In rural areas, health facilities are located far away from where people live and there is a paucity of health-care providers. This also restricts access.

13.1 Issues in the supply chain

- (1) Procurement lists in which the rates are fixed and usually chosen by selecting the supplier quoting the lowest price (also known as rate contract lists) are not the same as EMLs. Competitive rates must be fixed for a reasonable period of time.
- (2) Supplies should not have a short expiry date, and should be regular. Cold chain maintenance and transportation under refrigeration must be ensured. The stability of medicines and their shelf-life must be considered.

- (3) Staff managing drugs should receive appropriate training in materials and crisis management.

13.2 Pricing issues in access to medicines

- (1) Only 20% of the population access health care through the public sector and <4% of the population have any kind of insurance. Expenditure on medicines constitutes 79% of health-care expenditure (OPD setting). Out-of-pocket payments by patients and their families account for 80% of the expenses in the Indian health-care system.
- (2) A six-state survey of medicine prices conducted in 2003–2004 revealed that the median availability of essential medicines varied from 0% to 30%. Generic equivalents that are available in retail pharmacies have almost the same MRP as the most sold generic equivalents; thus, affordability is a big challenge for the majority of the population.
- (3) Seventy-four medicines are listed in the Drug Price Control Order (DPCO) and are known as “scheduled bulk drugs”. Of the 74 drugs, only 38 are in the EML.
- (4) The responsibility for medicine pricing and access to essential medicines is fragmented and distributed across different ministries. Taxes are levied on medicines both during manufacture and distribution (value added tax [VAT], excise, education cess [which is a type of tax]). The NPPA fixes the price of scheduled drugs according to a standard formula, with a 100% margin. This formula has not been revised. The rest of the drugs are not under government control and the manufacturer sets the price known as the maximum retail price (MRP). The MRP printed on the products locks the price at the highest possible level in the market. Thus, there is poor correlation between manufacturing costs and the MRP set by manufacturers of branded medicines.
- (5) Low prices are also a cause for poor access, as pharmacies do not want to stock these drugs.

14. Group discussion: road map for improving access

14.1 At the national level

- (1) There should be political will for improving access to essential medicines and medicines for children. Advocacy efforts aimed at national and state health officials should be conducted for this.
- (2) To improve the EMLc, the EML must first be improved.
- (3) A position paper should be prepared on the access situation. There must be a year-wise time plan, and at the end of each year, the successes/failures of the plan must be examined. The targets should be the Central and State Governments, the Panchayats (people's governance at block/village level) and hospitals/health facilities at the most peripheral levels. Rogi Kalyan Samities or people's committees, which are attached to these hospitals, should also be targeted. Action at each of these levels will vary.
- (4) There is a need for convergence and congruence of professional bodies. A common forum can be established, and journals and newsletters used for awareness generation.
- (5) Medical, nursing and pharmacy schools can be targeted and access to essential medicines included in the curriculum. At the school level, informal means of education on health can be included.
- (6) Awareness of the population must be enhanced and they should be told that they have a right to information. Parliamentary questions can also be raised.
- (7) Unregistered medical practitioners need to be tapped, as well as nongovernmental organizations (NGOs)/community-based organizations (CBOs) working in this area.
- (8) There should be a process of continuous monitoring and operational research. For this, trained manpower and funding are required.
- (9) In the public sector, there should be an EMLc, an annual procurement policy, and timely replacement of drugs with a staggered supply to prevent stock-outs.

- (10) Drug quality must be addressed through strict quality control and licensing. There is a policy in place for quality control but the laboratories can be influenced.
- (11) Warehousing should be improved as paediatric liquid preparations are not as stable as tablets.
- (12) Insurance schemes for patients can be started, as in Kerala.
- (13) The top 10 drugs on the EMLc should have a national price control policy so that children from both the public and private sectors are able to access them.
- (14) Tax exemption for essential medicines should be introduced.
- (15) A certain percentage of the budget can be reserved for children's medicines. Purchase and reimbursement should be done for essential medicines only. Only drug donations of essential medicines should be accepted.
- (16) The concept of having generic stores should be promoted. Some civil society groups and doctors' groups pass on 15%–40% of the profit margin to users, e.g. Jan Seva Project in Trichur. Red Cross stores also provide medicines at low cost.

14.2 At the state level

- (1) States have a greater empathy for their population and can establish better monitoring and evaluation, control and administration procedures, and allocate and optimally utilize economic resources. They have procurement and communication systems in place, and can improve the generic policy.
- (2) States should provide Good Manufacturing Practices (GMP) certification through their Drug Regulatory Authorities (DRAs) and conduct pharmacovigilance studies. They should also train health personnel to provide better health-care delivery.
- (3) As a part of the project working in five states, a common list of medicines for children should be drawn up and one each for the individual states. Data on disease burden in children are available and must be considered for this. These lists can be used for procurement and to change prescribing practices, as well as for teaching. Some parts can be replicated in other states as well.

- (4) Concessions should be given for the local production of essential medicines. Upgradation of technology and support should also be provided for the manufacture of essential medicines only.

15. Group discussion: Advocacy and strategies

After lunch, Dr Panna Choudhury, Dr Jeeson C Unni and Dr Tanmay Amladi from the Indian Academy of Paediatrics moderated the session on Advocacy and Strategies.

- (1) Advocacy and policy initiatives have to be taken at the central level. The Central Government has constituted a committee to formulate a national EML. If the government can be sensitized at this stage to constitute two separate committees, it will be of help. A subcommittee for paediatrics can be formed to develop a national EMLc. This could include paediatricians from the public sector. However, having a separate list for children may cause problems at the level of procurement.
- (2) A core list of drugs should be constituted for all health facilities so that health workers at the peripheral level can identify with it. Alternatively, three core lists could be made according to the level of health-care facility (primary, secondary and tertiary) by consultation with general practitioners and even nurses and midwives so that they "own" the list and use it.

Dr Tanmay Amladi presented the IAP's road map for advocacy.

15.1 Road map for advocacy: Proposal by the Indian Academy of Paediatrics

The IAP's road map for developing a suitable EMLc for India comprises communication with its administrative members about an EML and feedback through its state and local chapters by the end of 2010. The list will be compiled by early March 2010 and finalized at its office bearers' meeting in mid-March. Discrepancies between this list and the WHO EMLc will be examined. This would be done in the first stage.

In the second stage, the IAP proposes to hold a national consultative meeting involving a wide range of stakeholders, including IAP experts, WHO members, representatives from the government and professional bodies (Indian Medical Association [IMA], Federation of Obstetric and Gynaecological Societies of India [FOGSI], etc.), regulatory bodies, the Indian Pharmacology Society (IPS), pharmacists, members from industry, among others. A national EMLc will be developed by consensus and an agenda prepared for training IAP members in various state and local branches, depending on the availability of funding. In May–June 2010, it plans to identify priority areas that need to be covered.

In the third stage, IAP plans to sensitize its members nationwide, hold a national training programme, or a training of trainers' workshop. High-level members from the states and local branches as well as those of other professional bodies such as the IMA, FOGSI, nurses and midwives' associations, WHO and others will be included. At this meeting, small groups would be formed to develop a specific roll-out plan and decide how it would be implemented. The updated EMLc would be made available through the quarterly IAP web updates, *Academy Today* and its journals.

In the fourth stage, all members of the IAP will be asked to use the list, following which a drug-use audit would be conducted through a software developed by IAP. Areas where the EMLc is not being used could be identified. The group could meet after one year to review the situation and identify problems and ways of overcoming these. However, the IAP cannot ensure the availability of medicines on the list.

15.2 Specific targets

During the informal consultation, participants highlighted problems related to getting lists approved/amended by key policy-makers such as the Commissioner of Health, Director and Health Secretary of each state. Participants felt that the IAP could develop a model list. WHO could have a sensitization meeting in all the states. The role of the IAP lies in educating paediatricians and moving from them to involve the general community. It can educate people who will prescribe, and those who will make these drugs available in the correct places.

The group cited examples of key medicines for children that needed to be on the lists of all the states. The use of zinc for paediatric diarrhoea and gentamicin for neonatal sepsis were discussed as suitable examples.

Zinc

- (1) There is a regulatory barrier to the widespread use of zinc. Though zinc is supplied in the Reproductive and Child Health (RCH) Programme, it is not on the EMLs of all states and is a scheduled drug. Scheduled drugs cannot be advertised and hence awareness generation becomes a problem.
- (2) There is a policy barrier as zinc is not on all the state EMLs. However, participants felt it would be relatively easy to make sure that it is included in all state EMLs and at the procurement level.
- (3) The major challenge identified was the practice barrier. People do not use zinc because it is not freely available and also because of lack of awareness. It may not be used even where it is available because of perverse incentives through price, preferences (palatability), etc.

It was felt that widespread community uptake of the use of zinc needs to be addressed with the national regulatory authority to turn it into an over-the-counter (OTC) medicine from its present status of a scheduled drug and make it freely available. The first two targets could be achieved in a year or so but practices would take longer to change.

Gentamicin

Dr K.R. Antony, Director of the State Health Resource Centre, Raipur, Chhattisgarh raised the issue regarding the use of gentamicin for neonatal sepsis.

- (1) The regulatory/administrative barrier involved is focused on who can give the injection. Even the most peripheral health worker (the auxiliary nurse midwife [ANM]) should be authorized to use it as she is the first person to come in contact with a sick child. This issue could be worked on at the state and national levels.
- (2) The lowest strength of injection designed for use in neonates should be worked out. Is once/day dosing possible? Could manufacturers be induced to manufacture child-size doses (5 mg/ml) of gentamicin? The availability of child-size doses may help in overcoming the practice barrier, since the drug, in appropriate dosage formulation will be easily available and perhaps even the regulatory barrier would be

overcome as it would be possible to convince the administrators that gentamicin can be safely administered by the ANMs.

- (3) It was felt that if this issue is resolved and gentamicin injection could be given by ANMs, it would go a long way in reducing neonatal mortality due to neonatal sepsis.

16. Conclusions

The participants discussed the role of WHO and concluded as follows.

16.1 Role of WHO

WHO should:

- (1) Play a role in developing a national EMLC along with the local and central government and all stakeholders involved in child health care (e.g. physicians, perinatologists, neonatologists, obstetricians, midwives).
- (2) Collaborate with the IAP in advocacy and educational activities (e.g. information on EMLs, participation in meetings) over the next two years.
- (3) Work with those involved in state insurance schemes and manufacturers to promote child-friendly formulations (WHO country office and health-care financing).
- (4) Investigate mechanisms for an EMLC subcommittee of the EML committee.
- (5) Support those wishing to publish journal articles on essential medicines by providing data and related articles, e.g. *Journal of the Indian Medical Association* (special issue on medicines for children), *Indian Journal of Paediatrics*, *Your Health* (for the general public). It could help in writing an editorial on the EMLC in a prominent peer-reviewed journal.
- (6) Develop a tool to provide guidance on storage needs for EML products.

- (7) Conduct advocacy with the national programme officer for Reproductive and Child Health (RCH). The Joint Secretary RCH and State Directors RCH in each state should also be involved. The subcommittee on EMLc should include members of the RCH.

16.2 Outline of activities in India

The meeting concluded with participants agreeing to the following activities as a part of the better medicines for children project in India.

16.3 Major activities at the state level

- (1) Prepare an EMLc for the states and facilitate activities to ensure that procurement follows the EML.
- (2) Conduct pricing and availability surveys, both pre- and post-intervention, with at least one procurement cycle using the revised EML.
- (3) Make efforts to try and include children's medicines formulations into the procurement lists of the states.

16.4 Major activity at the national level

Develop a national EMLc by the IAP for inclusion in the national essential medicines list (NEML) of India. The activity should include inputs from all stakeholders. This EMLc can be later endorsed as the national EMLc (if agreed to by the Ministry of Health and Family Welfare, Government of India). The NEML is currently being updated by the Government of India with the All India Institute of Medical Sciences (AIIMS) as the lead agency.

17. Statement by participants

Through WHO, participants request the Government of India to constitute a single, technically competent and administratively empowered body to ensure the adequate production and provision of an uninterrupted supply of essential drugs. This would help to overcome the administrative problems caused by poor collaboration between the Ministry of Petroleum and Chemicals and the Ministry of Health and Family Welfare.

Annex 1

Programme

Tuesday, 2 February

0830–0900 **Registration**

0900–1300 ➤ **Introduction and welcome**

Dr Krisantha Weerasuriya, WHO-SEARO

Dr Suzanne Hill, WHO-Geneva

➤ Meeting objectives

➤ **Essential Medicines – What are they and why should we have an EML**

Dr Suzanne Hill, WHO-Geneva

➤ **National Essential Medicines Lists in SEAR**

Dr Krisantha Weerasuriya, WHO-SEARO

➤ **Essential Medicines Programme – What has been done in India**

Professor Y K Gupta

Professor Gitanjali Batmanabane

Professor Usha Gupta

Professor Santanu Tripathi

1400–1730 ➤ Review from WHO-HQ: update on 16th WHO Model List of Essential Medicines and 2nd EMLc

Dr Suzanne Hill, WHO-Geneva

➤ **General Overview of Better Medicines for Children initiative**

Dr Krisantha Weerasuriya, WHO-SEARO

Dr Suzanne Hill, WHO-Geneva

➤ **Comparison of the EMLs of the five states in India – preliminary findings: Challenges and Opportunities**

Professor Gitanjali Batmanabane

➤ **Comments from Paediatricians from the five States (Chattisgarh, Jharkhand, Madhya Pradesh, Orissa and Uttar Pradesh)**

➤ **Discussion – on the review of the EMLs of the five states**

Wednesday, 3 February 2010

0830–0900 **Review of Tuesday, key issues**

Discussion Sessions

0900–1030 **Technical Issues** (Moderators/Facilitators – Dr Suzanne Hill, Dr Lisa Bero and Professor Gitanjali Batmanabane)

1. Review of EMLs/formulation requirements
2. Fixed-dose combinations
3. Child-friendly formulations
4. Paediatricians and advocacy for children's medicines

1045–1300 **Access Issues** (Moderators/Facilitators – Dr Anita Kotwani, Professor Santanu Tripathi, Professor Vijay Thawani and Dr Kathleen Holloway)

1. Main barriers to access
2. Role of State Essential Medicines Lists in improving general access
3. Role of State Essential Medicines Lists in improving access to Children's medicines
4. Implementing an Essential Medicines List in a State – How can a road map be created?
5. Pricing studies
6. Better access and better use?
7. Supply chain issues

1400–1600 **Advocacy and Strategies** (Moderators/Facilitators – Dr Panna Choudhury, Dr Jeesson C Unni, Dr Tanmay Amladi)

1. Role of policy-makers, opinion leaders, clinicians, medical and pharmacy school teachers and drug supply managers
2. Children's medicines – role of Indian Academy of Pediatrics
3. Teaching about Children's Medicine in undergraduate education
4. Research priorities in Children's Medicines

1630–1730 **Focusing on the five States (General Discussion)**

1. What is common and what is different?
2. What can be learnt from other states in their implementation
3. Road map

Final Discussions and Conclusions

Annex 2

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The “Make Medicines Child Size” initiative of the World Health Organization is a global campaign launched in December 2007 to raise awareness about and accelerate action towards addressing the need for improved availability of and access to safe, child-specific medicines for all children. This informal consultation on “Better Medicines for Children in India” was held to explore the feasibility of implementing the 'Better Medicines for Children’ project in a few states of India. It updated participants about the objectives of the project, the achievements so far and ongoing activities. It also gave the participants an opportunity to identify the objectives for this project in India and discuss a road map for its implementation. This report titled Informal Consultation on Better Medicines for Children in India, 2-3 February 2010, outlines the discussions held at the consultation and the recommendations that emerged from it.



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