

WHO to launch first essential medicines list for children

WHO's list of essential medicines turns 30 this year and will finally have an offspring: a parallel list of essential medicines for children that specifies proper dosages and formulations for their smaller, constantly-changing bodies.

A list of essential paediatric medicines is sorely needed. The WHO essential medicines list, first launched in 1977, is predominantly for adults. It includes some dosages for children, but in most cases formulations for children simply do not exist.

Children cannot be treated as “little adults” when it comes to medicines. “Children differ in the way they ingest, absorb, metabolize and excrete drugs, and behavioural and developmental issues complicate their treatment,” said the United Nations Children’s Fund (UNICEF) and the World Health Organization (WHO) in a report last year.

The report concluded: “These factors are not constant but vary as the child grows. The majority of medications worldwide are not formulated for easy or accurate administration to children.”

An estimated 10 million children die every year, many from diarrhoea, malaria, respiratory tract infection, pneumonia or HIV/AIDS. Medicines for these illnesses exist, but paediatric formulations and knowledge on how best to use them in children are often lacking. To remedy this, WHO, UNICEF and others proposed a paediatric essential medicines list at a meeting in August 2006 in Geneva.

WHO has since developed a draft list of medicines and distributed it, setting a 30 April deadline for feedback. A committee of experts will finalize the list at a meeting to be held from 9 to 13 July.

The list will be made available to countries by September or October and will undergo revision as more children’s medicines become available.

It would not be the first list of its kind – Canada, the United Kingdom, the United States of America and other developed countries have their own versions – but it would be the first to address diseases of children in developing countries.

The project is timely given a number of factors. The changing nature of childhood diseases is one. Children today need more chronic treatment than in the past, when health systems mainly had to manage children with acute diseases for which some medicines exist.

Secondly, the world’s health systems and public health organizations are making a concerted effort to deal with malaria – which accounts for one in five of childhood deaths in Africa alone – and other major infections, such as HIV, in children. But there are few age-appropriate formulations for antimalarials or antiretrovirals.

Thirdly, the USA and the European Union have acknowledged the lack of children’s medicines in developed countries and are seeking ways to address it from a regulatory perspective.

At the August 2006 meeting, experts from WHO, UNICEF and other organizations took stock of existing children’s medicines and their availability. The meeting’s report found that of 284 medicines on the adults’ list, 119

required an approved indication for use in children. While 52 of the 119 had a paediatric formulation listed, the remaining 59 did not. There were eight duplicate listings.

Certain diseases are common in childhood, such as meningitis, pneumonia, ear and respiratory infections, and gastrointestinal infections. “You might



Child is vaccinated against measles in Pakistan just after the earthquake struck in October 2005.

WHO/C Black

need additional drugs that you wouldn’t use in adults,” said Dr Suzanne Hill, a scientist from WHO’s Policy, Access and Rational Use team.

“What we’ve not had is a separate list that covers comprehensively all the diseases of childhood,” Hill told the *Bulletin*. “And we certainly haven’t looked in detail at medicines for neonates.”

HIV infection and malaria are diseases in adults too, but the dosage for the medicines used to treat them is different for children. On the existing essential medicines list for HIV, there are 12 antiretrovirals with syrup formulation, which can be used in children. But dosage forms that combine antiretrovirals in one tablet would be more appropriate, as children usually need to take three or four drugs at a time.

Research is just beginning into many paediatric medicine formulations and it’s no small task. “Several hundred medicines need to be evaluated as to whether they should be on the children’s essential medicines list,” said Dr Howard Zucker, assistant director-general of WHO’s Health Technology and Pharmaceuticals cluster of departments.

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Report by the United Nations Children’s Fund and the World Health Organization.



WHO/J. Gubb

There are few medicines formulated specifically for neonates, such as these babies at an AIDS clinic in Ethiopia.

Dr Jane Schaller, executive director of the International Paediatric Association in British Columbia, Canada, said that drugs on the list need to be affordable, and take into consideration distribution and storage. Many existing formulations need to be refrigerated, which is difficult in places with unreliable electricity supplies, Schaller said.

Not all adult medicines are palatable to children. For example, zinc is an effective treatment for diarrhoea in children, but children don't like the existing tablet formulation and refuse to take it. Kids often dislike syrups too.

What's needed is solid-dose formulations that a child can swallow, Hill said. "We know they work, they're on the essential medicines list, but we need to have a dose and a formulation that is palatable to children," she said. "And we need a manufacturer who will make that

and do so at a reasonable price. So that's the sort of process we'll be going through for all the different diseases."

Developing medicines for children requires clinical trials. An important part of researching adult medicines to enable their use in children will involve looking at side-effects. Currently there is very little information on adverse drug reactions in children. Trials involving children – who can be more vulnerable than adults – need to be done according to the highest possible standards with close monitoring.

Several companies and research organizations are doing clinical trials in children.

GlaxoSmithKline is studying chewable asthma tablets, ointment against impetigo in children aged 1 month to 1 year, and drugs to combat HIV/AIDS. Other trials include a study of the use of lithium in treating paediatric mania by the National

Institute of Child Health and Human Development at Case Western Reserve University in the USA, and Pfizer's comparison of adults' versus children's doses of a drug for ear infections.

The big question is how to encourage pharmaceutical companies to start costly and often challenging trials for a whole new series of children's medicines, when the markets for these medicines are mainly in developing countries with small health budgets.

UNICEF has proposed an advocacy plan to promote the development of such medicines. WHO has a prequalification programme: a list of medicines it recommends for purchase by United Nations agencies for developing countries, which also serves as a market incentive, Hill said. She added that this system had successfully encouraged generic manufacturers to produce high-quality, affordable medicines for adults.

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Theresa Braine, *Mexico City*

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