Update on Essential Medicines for Children

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Copenhagen
Causes of death in under 5s

- Injuries: 26
- AIDS: 10
- Measles: 8
- Malaria: 17
- Other neonatal causes: 11
- Diarrhoeal diseases: 3
- Other infections: 3
- Neonatal severe infections: 3

World Health Statistics 2007
WHO-UNICEF joint plan

- Work on a global project to make paediatric medicines a priority:
  - Add missing essential formulations to the Model list in 2007; advise on doses
  - Develop EML for children (2007-8)
  - Update treatment guidelines (2007-9)
  - Develop paediatric prescribing information – a formulary
  - Develop effective methods for provision of information at the point of care
  - Collaborate with regulatory authorities to encourage appropriate drug development and approval processes in all regulatory authorities
  - Develop quality standards for paediatric medicines
  - Advocate for the development of paediatric medicines by the industry
  - Develop a system for enhancing safety monitoring of medicines in children
  - Provide guidance on procurement and supply of paediatric medicines
Progress

- August 2006: WHO- UNICEF consultation on essential medicines for children
- January 2007 – Executive Board Resolution – Better Medicines for Children
- March 2007 – Expert Committee recommendation for sub committee
- May 2007 – WHA resolution, EB resolution
- July 2007 – Expert Subcommittee meeting
- October 2007- Expert Committee meeting
- December 2007 – Make medicines child size
- 2008……..
Model Essential Medicines List for Children
Terms of reference for Subcommittee

(1) To prepare a list of medicines for children, based on their clinical needs and the burden of disease, that the WHO Expert Committee on the Selection and Use of Essential Medicines can use to revise and regularly update the WHO Model List of Essential Medicines to include missing essential medicines for children:

(2) To determine suitability criteria for dosage forms of medicines for children, with particular attention to conditions prevailing in the developing countries:

(3) To review the feasibility of manufacturing appropriate formulations for those priority medicines for which no dosage form for children currently exists, specifically considering requirements for use in resource limited settings and availability of data on efficacy and safety in the appropriate age groups:

(4) To identify the clinical research gaps regarding safety and efficacy of essential medicines for children in order to improve suboptimal prescribing and dosing, and to facilitate regulatory approval of paediatric formulations:

THE SELECTION AND USE OF ESSENTIAL MEDICINES

Report of the WHO Expert Committee, October 2007
(including the Model List of Essential Medicines for Children)
EMLc - Priority areas – July 2007

- Medicines for HIV, TB
  - New applications for new FDCS
  - Work in progress for TB

- Medicines for malaria
  - Treatment guidelines under review
  - Review of doses in children
  - Potential new FDC for March 2009?

- Medicine for pain
  - Proposal for palliative care

- Anti-infectives
  - Several proposals

- Medicines for neonates
  - New proposal
EMLc - Priority areas – July 2007 (2)

- Medicines for ENT
  - New proposal

- Medicines for behavioural disorders in children
  - Preliminary review

- Vitamins and minerals
  - Vitamin A review
  - Multivitamins?
Selection of essential medicines

The Second Meeting of the Subcommittee of the Expert Committee on the Selection and Use of Essential Medicines took place in Geneva from 29 September to 3 October 2008.

- Application form [pdf 69kb]
- Revised procedure for updating WHO's Model List of Essential Drugs -- Executive Board document EB109/S.7 December 2001 [pdf 170kb]
- All applications
- Applications by section
- Draft agenda for the open session [pdf 154kb]
- (French version) [pdf 158kb]
- Draft agenda for the closed session [pdf 157kb]
- (French version) [pdf 144kb]
- Expert reviews
- Comments from WHO departments

For more information, please contact:
The Secretary of the Second Meeting of the Subcommittee of the Expert Committee on the Selection and Use of Essential Medicines

USEFUL DOCUMENTS

- WHO Technical Report Series 950
  - Read more... [pdf 844kb]
- First WHO Model List of Essential Medicines for Children
  - WHO Technical Report Series 946
  - Read more... [pdf 129kb]
Dosage forms
Progress

- Standards for development of paediatric dosage forms
  - Points to consider
- Collaborative working group – review of manufacturing experience
- Preliminary studies on 'suitability' to commence
- Consultation December 2008
Priority products

- Based on major causes of morbidity and mortality:
  - Diarrhoea – palatable, age appropriate zinc salts
  - Infections
    - antibiotics (various)
    - topical preparations
  - TB – new FDC proposals in development
  - Malaria – FDCs based on treatment guidelines update
  - HIV – FDCs based on treatment guidelines, ideal doses
WHO-UNICEF joint plan

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Pre-Conference to the 13th ICDRA
14 and 15 September 2008, Berne, Switzerland

Better Medicines for Children – The Way Forward
stock outs

Uhjin Kim,
Nauru 2008
S&P for selected children’s medicines (WHO, UNICEF, MSF)

- 77 Medicines selected from LEMC
  - Undernutrition
  - Malaria
  - Diarrhea
  - Pneumonia
  - Sepsis in newborn
  - HIV/AIDS
  - Opportunistic infections and palliative care
  - Anti tuberculosis

- Publication
  - Background Information
  - Indicative price info
  - Manufacturers and contact info
  - Registration info

- Sources
  - Open market survey
  - UNICEF suppliers
  - WHO suppliers

- Sent questionnaire
  - To over 400 manufacturers worldwide
  - Over 80 replies meeting criteria

Sources:
- South America 5%
- Africa 1%
- Asia 30%
- Europe 53%
- Middle East 4%
- North America 7%

To be posted on http://www.unicef.org/supply/
30 Years of Essential Medicines

Where is my essential medicine?

¿Donde está mi medicamento esencial?

Et moi?