Essential Medicines: update on policies and standards

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Pharmaceutical sector is complex

- R&D and clinical trials
- Patent
- Manufacturing
- Registration
- Inspection
- Selection
- Procurement & import
- Distribution
- Pricing
- Prescription
- Dispensing
- Pharmacovigilance
Where do Essential Medicines fit?

- R&D and clinical trials
- Patent
- Manufacturing
- Registration
- Inspection
- Selection
- Procurement & import
- Distribution
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- Prescription
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However the influence of essential medicines is potentially much greater.
Access to quality assured medicines as part of health services coverage

1. Rational Selection and use
2. Affordable prices & Sustainable financing
3. Assured quality
4. Reliable & efficient supply chain

Policy & Governance of systems
Access to medicines matters
SDG 3: Ensure healthy lives and promote well-being for all at all ages

3.8 achieve universal health coverage (UHC), including financial risk protection, access to quality essential health care services, and access to safe, effective, quality, and affordable essential medicines and vaccines for all

3.b support research and development of vaccines and medicines for communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration which affirms the right of developing countries to use to the full the provisions in the TRIPS agreement regarding flexibilities to protect public health and, in particular, provide access to medicines for all
Access to medicines matters
Recent WHA Resolutions

- A67.22 (2014) Access to essential medicines
- A69.25 (2016) Shortages medicines & vaccines
- A67.20 (2014) Regulatory system strengthening for medical products
- A67.25 (2014) Combating antimicrobial resistance
Regulatory system strengthening (A67.20)

- Recognizes WHO global role in medicines regulation
  - establishing necessary norms and standards, supporting regulatory capacity-building, enhancing collaboration and networking among regulators, and strengthening safety monitoring programmes.

- Endorses NRA assessment and PQ programme for medicines/vaccines/devices for selected priority essential medicines, diagnostics and vaccines

- Endorses the future progressive transition of prequalification to networks of strengthened NRAs
Medicine shortages (A69.42)
A global issue

- Problems with manufacturing
  - Limited number of manufacturers; poor forecasting; cost of regulations; (too) low price may drive manufacturers out

- Problems with supply chain
  - Lack of visibility on needs; timing of procurement; inefficiencies

- Measures to mitigate
  - Fair/minimum pricing & incentives; financing and reimbursement; early warning, information sharing with DRAs on substances at risk; strengthening supply chain; global information system

- Manufacturers, wholesalers, global & regional procurement agencies asked to participate in notification systems
Medicines for children (A69.20)
Promoting innovation and access

- Analysis of pharmaceutical supply systems
  - Identify inefficiencies in cost and pricing structures, sources of mark-ups with a view to reducing prices of children’s medicines

- Strengthen R&D on appropriate medicines for children
  - Support innovative research, formulation and timely regulatory approval, provision of adequate information on use in children

- Facilitate clinical trials of medicines for children

- Strengthen pharmacovigilance, post-market surveillance

- Enhance education, training in rational use of medicines
Combating AMR (A67.25)

- Global Action Plan endorsed WHA in 2015
  - Multi-sectoral approach; tripartite with FAO and OIE; One Health
- Responsible use of antimicrobials
  - surveillance of consumption (and resistance)
  - regulation aspects on products approval [concern SSFFCs]
  - controls (and enforcement) on prescribing and dispensing
  - use of antibiotics in veterinary medicines
  - new business models for antibiotic innovation
Strengthening palliative care (A67.19)
Component of comprehensive care

- Assess palliative care needs, ensure adequate supply of essential medicines in palliative care avoiding shortages
- Review national and local legislation and policies for controlled medicines; country-level barriers to access
- Update national EMLs in light of changes to Model List
- Need balanced policies; better quantification of medicine needs particularly in Africa and Asia
- WHO is developing pain guidelines (exist for children)
Essential Medicines (A67.22)

- WHO Model Essential Medicines Lists
  - recognized as a valuable evidence-based tools that enable countries to identify a core set of medicines which need to be accessible to provide quality medical care – with special mention of children.

- Essential Medicines
  - satisfy priority health needs, should be available at all times in appropriate dosage forms, of assured quality at an affordable price
Selection of essential medicines based on scientific evidence

**Guiding principle:** Identify a limited range of carefully selected essential medicines leads to better health care, better medicines management, and lower costs

**Definition:** Essential medicines are those that satisfy the priority health care needs of the population

**Selection:** Selected with due regard to disease prevalence, evidence on efficacy and safety, and comparative cost-effectiveness.
Revisions to the WHO Model List

• Lists updated every 2 years (40 years in 2017)
• Evidence-based selection
• Guide for national lists (NEML, reimbursement)
• Separate Model Lists adults, children
• Essential medicines are not ‘cheap generic medicines for poor people’
• May have role in advocacy
• UNICEF, UNHCR, IDA, MSH catalogues
• Interagency Emergency Health Kit
Updates to WHO Model Lists: 2015

• 36 added to EML (15 core list, 21 complementary list)
  – 16 new cancer treatments; endorsed 30 existing medicines
  – new medicines for TB (bedaquiline, delamanid, linezolid)
  – 6 oral direct-acting antivirals for hepatitis C (daclatasvir, dasabuvir, ledipasvir + sofosbuvir, ombitasvir + paritaprevir + ritonavir, simeprevir, and sofosbuvir)
  – Added low molecular weight heparins but not newer novel oral anticoagulants (NOACs) [dabigatran, rivaroxaban, apixaban]

• 16 medicines added to EMLc
• Alignment of medicines with WHO HIV guidelines
• Did not recommend inclusion of ‘polypill’ for CVD
High cost medicines are listed

- Cancer medicines [imatinib, trastuzumab and rituximab]
  - Inclusion based on magnitude of absolute benefit
- Hepatitis C medicines
  - Calls for expressions of interest UN/WHO prequalification of medicines for hepatitis C and B [sofosbuvir tablet 400mg; simeprevir capsule 150mg; entecavir tablet (0.5mg, 1mg); daclatasvir]
  - Guidance for sofosbuvir bioequivalence studies (March 2015)
- *Price itself is not an exclusion criterion for WHO EML*
Inclusion of high price medicines in EML

- Focus attention on clinical value and may help mobilise international commitment and resources
- Advocacy role for lower prices; may stimulate licensing and access arrangements for LMICs
- However, may put benign pressure on countries to procure these medicines with consequences on health budgets and access to medicines for other patients
- Legal processes may favour access to medicines deemed essential by WHO
Anticipated revisions in 2017

Revision of Section 6.2 (antibacterials)

- For adults
  - syndromic approach for applications (hospital, community)
  - Systematic reviews and guidelines on antibiotic choices for most common infectious diseases
- For children – 5 disease-based applications
  - Neonatal sepsis; community-acquired pneumonia (CAP); diarrhoea; cholera; severe malnutrition
- Developing priority list of antibiotic resistant bacteria to guide R&D for new antibiotics
Implementation of NEMLS

• EML part of broader series of activities for optimal use and best use of scarce healthcare resources
• Priority procurement in public sector
• Basis of health insurance/reimbursement medicines list
• Aligned to clinical guideline recommendations for priority clinical conditions and programs
• Dissemination and implementation strategy for clinicians and other HCPs – aware of and use essential medicines
Interagency Emergency Health Kit 2011

- Designed to meet the first primary health-care needs of a displaced population without medical facilities
- Medicines & medical devices for 10,000 people for 3 months
- *Basic unit*: used by primary health-care workers with limited training; oral and topical medicines, none injectable
- *Supplementary unit*: used only by professional health workers or physicians; not contain any medicines or devices from the basic unit; used when basic units are available; modules for malaria & patient post-exposure prophylaxis (patient PEP)
Interagency Emergency Health Kit 2011
2015 Addendum

• 2015 addendum to malaria and PEP modules
• Response to changes in treatment guidelines
• Recognition that manufacture of certain medicines would likely be phased out and medicines would be unavailable

http://www.who.int/medicines/publications/Addendum_2015_InteragencyHealthKit2011_april2016_PEP.pdf?ua=1

**Agencies:** World Health Organization; International Committee of the Red Cross; International Federation of Red Cross and Red Crescent Societies; Médecins Sans Frontières; United Nations Children's Fund; United Nations Population Fund; United Nations High Commissioner for Refugees
EML 2017: Submitting an application

- The 21st Expert Committee meeting will take place at WHO Headquarters, Geneva, in April 2017.

- Applications for inclusion of new medicines, changes or deletion of currently listed medicines should be emailed to the WHO Essential Medicines List Secretariat at emlsecretariat@who.int in both PDF and Word formats between 15 February and 2 December 2016.

- Information to be included in an application on website [http://www.who.int/selection_medicines/committees/expert/expcom21_information_for_applicants.pdf?ua=1](http://www.who.int/selection_medicines/committees/expert/expcom21_information_for_applicants.pdf?ua=1)
Access to essential medicines: an unfinished agenda

• Despite some improvements towards MDGs, problems with access to key essential medicines remain
• Patients with HIV, TB, malaria untreated or sub-optimally treated
• MDR-TB poses significant threats to management of TB
• Unmet needs of mothers and children for essential medicines and reproductive health commodities
• Global challenges of non-communicable diseases; poorest countries are dealing with double burden of communicable and NCDs
• Providing access to cancer therapies and other high cost medicines
• Managing responsible use of antimicrobials to deal with AMR
Thank you for your attention