Access to Essential Medicines and Universal Health Coverage

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Director, Essential Medicines and Health Products
World Health Organization

- UN specialized agency for health (1948)
- The directing and coordinating authority on international health work
- 194 Member States
- Director-General: Dr Margaret Chan
WHO six regional offices and 147 country offices
Essential Medicines and Health Products Department (EMP)

Office of the Director
Kees de Joncheere

Public Health, Innovation and Intellectual Property (PHI)
Zafar Mirza
- Management of intellectual Property for Public Health
- Financing and Coordination for health research & development
- Local production for improvement in access
- Transfer of technology for vaccine & biotherapeutics production
- Health technology innovation
- Global Platform for Innovation & Access

Policy, Access and Use (PAU)
Gilles Forte
- National policies on medicines & on technologies; regional & country support
- Indicators & tools for pharmaceutical sector monitoring & assessment
- Transparency & good governance in medicines
- Supply management systems
- Medicines pricing policies
- Selection of essential medicines
- International control of psychotropic and narcotic substances: evaluation of abuse liability (of dependence-producing drugs)
- Access to controlled medicines
- Rational use and anti-microbial resistance

Regulation of Medicines and other Health Technologies (RHT)
Lembit Rägo
- Regulatory systems strengthening (including blood products)
- Norms/standards (including nomenclature)
- Quality assurance of products
- Safety/pharmacovigilance
- Prequalification of medicines, vaccines, diagnostics & medical devices

Technologies Standards and Norms (TSN)
David Wood
- Global standards/nomenclature
  - Biological Standardization
  - Pharmaceutical Preparations
  - International Pharmacopeia
  - International Nonproprietary Names (INNs)
- Global measurement standards
  - Biotherapeutics; blood products; in vitro diagnostic devices; vaccines

Regulatory Systems Strengthening (RSS)
Mike Ward
- Regulatory networks
- NRA assessment
- Capacity building
- Harmonization initiatives
- ICDRA support

Prequalification Team (PQT)
Mark Mc Donald
Prequalification of medicines, vaccines, diagnostics & medical devices:
- Dossier assessments
- Inspection
- PQ of medicines QC laboratories
- Laboratory testing
- Scientific advice
- Technical assistance

Safety and Vigilance (SAV)
Clive Ondari
- Medicines classification & assignment of daily doses (ATC/DDD)
- Surveillance/monitoring, including for SSFFC medical products
- Capacity building & coordination of global response to health/safety events
- Technical assistance
Overview

- SDGs and Universal Health Coverage (WHR 2010)
- Access to essential medicines
  - Policies, regulation, selection and rational use, prices, financing and supply systems
- Challenges and future steps
- WHA Recent Resolutions (2014/2015)
Historic crossroads: NCDs included in the 2030 Agenda for Sustainable Development

3. Good Health and Well-being
3.4 By 2030, reduce by one third premature mortality from non-communicable diseases through prevention and treatment and promote mental health and well-being

3.8 Achieve universal health coverage, 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 the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all
WHO medicines & technologies 2014-2019
strategic lines of action

- GPW : 6 leadership priorities
  - Access to essential, quality-assured, affordable medical products

- Three axis :
  - UHC : selection/HTA – financing/pricing – right supply mix – use
  - MDGs => SDGs
  - NCDs

- Underpinned by regulation to assure quality

- Partnership

- How : Standards + evidence/guidance + information/networking +
country policy dialogue and support
“Universal health coverage is the single most powerful concept that public health has to offer”

Dr Margaret Chan, Director-General of WHO, Address to the Sixty-fifth World Health Assembly, May 2012
What is Universal Health Coverage?

1. All people obtain the health services they need (including prevention, promotion, treatment, rehabilitation, and palliation), of sufficient quality to be effective;

2. The use of these services does not expose the user to financial hardship
A direction, not a destination

- No country fully achieves all the coverage objectives
  - And harder for poorer countries

- But all countries want to
  - Reduce the gap between need and utilization
  - Improve quality
  - Improve financial protection

- Thus, moving “towards Universal Health Coverage” is something that every country can do
Three Dimensions to Consider When Moving Towards Universal Coverage

There is no standard package of HSS actions to progress towards UHC

- Every country already has a health system
  - This is the starting point for any reform

- Solutions need to be tailored to context
  - Key contextual factors (e.g. fiscal, public administration, political, cultural, etc.) condition both what can be achieved and what can be implemented

- Country level analytic capacity is essential
  - Policy analysis linked to the specific reform agenda (hypotheses)
  - Much more than tracking standard indicators
  - Supporting this capacity and strengthening links to decision making is key role for us at country level
Conventional wisdom and standard policy prescriptions

- Starting with the formal sector / civil servants
- Identify the poor for subsidies
- Contributory, voluntary, CBHI for the identified “non-poor” in the informal sector
- Many emerging countries are doing this, or want to do it
  - The bad news is that it does not work very well, and tends to create new equity and efficiency problems

Re-think : the good news is that there are other pathways
Out-of-pocket spending (OOPS) as a critical problem

- Widespread reliance on patient payments is contrary to Universal Coverage objectives
  - Compromises equity of access, because service use depends on ability to pay rather than medical need
  - Health care costs pose risk of impoverishment ("your money or your life")
  - When payment is informal, there are problems of transparency, and it is also difficult to organize incentives for providers
Universal health coverage and medicines
Why a focus on medicines?

- Between 20% and 60% of the health budget in LMIC goes to medicines expenditures.
- In LMIC countries, up to 80 to 90% of medicines are purchased out-of-pocket as opposed to being paid for by health insurance schemes.
- In many LMIC out-of-pocket expenditures for health account for more than 50 per cent of total health spending.
- Average availability of selected generic medicines in LMICs:
  - public sector less than 42%.
  - private sector almost 72%.
**Ten leading sources of inefficiency in health systems**

Ref: World Health Report 2010, Chapter 4

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<tr>
<th>Medicines: under-use of generics and higher than necessary prices</th>
<th>Medicines: use of sub-standard and counterfeit medicines</th>
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<tr>
<td>Medicines: inappropriate and ineffective use</td>
<td>Services: inappropriate hospital size (low use of infrastructure)</td>
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<tr>
<td>Services: medical errors and sub-optimal quality of care</td>
<td>Services: inappropriate hospital admissions and length of stay</td>
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<td>Services &amp; products: oversupply and overuse of equipment, investigations and procedures</td>
<td>Health workers: inappropriate or costly staff mix, unmotivated workers</td>
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<tr>
<td>Interventions: inefficient mix / inappropriate level of strategies</td>
<td>Leakages: waste, corruption, fraud</td>
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Considerations in priority setting for UHC

- In moving towards UHC, questions focus on:
  - The population covered by the package of interventions: Who?
  - The services that can be provided: Which services?
  - The proportion of service costs that can be covered: How much?

- Health technology assessment (HTA) provides a decision-making framework for different types of decisions and can be applied in all health care systems
  - In fragile health systems: to identify basic essential care packages
  - In middle-income countries with limited coverage: to decide how to extend the package of health care services provided
  - In systems with established UHC: to inform decisions ‘at the margin’: what extra services to provide and at what cost
The continuum of H(I)TA activities

Health Systems

Continuum of HTA Activities

- Fragile states: Essential services
- Emergency kits
- Disaster planning
- Low income countries with low coverage, Primary health care packages
- Middle income countries with low coverage, Guaranteed packages of care
- Strong health system, Marginal analysis for additions to packages
Access to essential medicines and UHC

1. Rational selection
2. Affordable prices
3. Sustainable financing
4. Reliable health and supply systems
Medicines regulation: Quality, Efficacy, Safety

- Norms and standards
- Licensing of manufacturers, wholesalers, pharmacies
- Regular inspection, GMP
- Registration of products
- Regulate and control medicines promotion
- Pharmacovigilance...
- A regulatory system
Regulatory collaboration

- Global and Regional initiatives
  - ASEAN, EU, APEC, AMRH, PANDRH, … ICDRA

- Common standards

- Mutual recognition / fast track procedures

- Pharmacovigilance collaboration (WHO CC Uppsala)

- SSFFC

- Exchange information
Selection

- First edition 1977
- Revised every two years
- Now contains 462 medicines including children's medicines
- Patent status NOT considered in selection
- Over time has contained app. 5% patent protected medicines
Median availability of lowest-priced generic medicines

**Fig. 9.1** Median availability of selected lowest-priced generic medicines, in the public and private sector, by World Bank income group, 2007–2012


n = number of countries. Baskets of survey medicines differ between countries.
### Mean availability of medicines used for Acute and Chronic diseases

**Table 9.1** Mean availability of medicines used for acute and chronic conditions in 40 low- and middle-income countries

<table>
<thead>
<tr>
<th>Sector and product type (number of countries)</th>
<th>Mean availability (%) of medicines</th>
<th>Difference (%) in mean availability (95% CI)</th>
<th>p</th>
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</thead>
<tbody>
<tr>
<td><strong>Public sector</strong></td>
<td></td>
<td></td>
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<tr>
<td>Generic products (n = 35)</td>
<td>53.5 (46.2–60.8)</td>
<td>17.5 (6.5–28.6)</td>
<td>0.001</td>
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<tr>
<td><strong>Private sector</strong></td>
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<tr>
<td>Generic products (n = 40)</td>
<td>66.2 (60.4–72.1)</td>
<td>11.5 (2.4–20.6)</td>
<td>0.007</td>
</tr>
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CI: confidence interval.
Source: see reference (9).

*(Cameron et al, 2011)*
Low public sector availability leads patients to the private sector, where medicines are unaffordable.

Affordability of treatment for diabetes (days’ worth of wages)

Source: World Health Organization, using WHO/HLI standard methodology and data from surveys of medicine prices and availability (see http://www.halweb.org/medicinesprices/).

Note: Results from individual surveys have been averaged without weighting where multiple state or provincial surveys have been conducted (China, India, Sudan).

a Number of days’ wages required for the lowest-paid government worker to buy a 30-day supply of lowest-priced generic medicines from the private sector.
Medicines prices differ enormously.
Medicines pricing policies

» Pricing policies and procedures
  – Pricing policies and procedures
  – Distribution remuneration
  – Taxes

» Reimbursement
  – Reimbursement lists and rates
  – Reference price systems
  – Co-payments
  – Patient access schemes

» Generics policies
  » Use of TRIPS flexibilities, generic competition

» Trends in pricing and reimbursement : HTA, VBP, GPG, …
Advocacy, corporate responsiveness, & market forces have reduced antiretroviral prices 95% in 2 years

Annual cost per person for triple therapy (US $)
Medicines supply systems in TANZANIA. 2007
Many Factors Influence Use of Medicines

Treatment Choices

Intrinsic
- Scientific Information
- Prior Knowledge
- Habits

Societal
- Influence of Drug Industry
- Workload & Staffing
- Social & Cultural Factors
- Economic & Legal Factors

Workgroup
- Infrastructure
- Relationships With Peers
- Authority & Supervision

Information
- Workplace

World Health Organization
Responsible use of medicines

- Need to understand what doctors prescribe and what medicines patients take to treat illnesses (requires in-country studies)

- Assess whether prescribing is in line with best-practice treatment guidelines (WHO supports development of treatment guidelines)

- Health care professionals and patients/consumers need accurate information about medicines (WHO Essential Medicines and Health Products Information Portal is one source)

- Promotional practices of pharmaceutical industry need to be monitored (WHO has developed criteria for ethical promotion)

- Concerns about antimicrobial resistance have given a renewed focus to the responsible use of medicines
Not all health systems are well designed to deal with NCDs, mental -, geriatric -, rare diseases ……

- Many infectious conditions can be effectively treated in an episodic, ’clinic’ based system
- However such settings are not well designed to deal with many NCDs, mental, geriatric & rare diseases
  - They lack the continuity of care needed for chronic conditions including for medicines treatment
  - Providers lack the specialized skills needed to deal with complex conditions
  - Appropriate use of medicines – becomes far more challenging and impact may not be seen unless specific efforts are made
Future issues

- Access to essential medicines within UHC framework
- Growing internationalization of medicines regulation
  - Regional harmonization/convergence initiatives
- Innovation, targeting new product development, how to price innovation for global access? – global public goods
- SDGs: UHC, including priority diseases and NCDs
- Medicines pricing: R&D + access/affordability + competition
- Need for promoting the appropriate use of medicines
Follow-up of the Report of the Consultative Expert Working Group on Research and Development: Financing and Coordination - Health R&D demonstration projects (DP) :

- Firm go-ahead on the implementation of innovative health R&D DP selected in the run-up to the WHA. Through this decision the MS endorsed the indicators for measuring the success in implementing DP

- WHO will take steps to establish at the Special Programme for Research and Training in Tropical Diseases (TDR) a pooled fund for voluntary contributions towards R&D for diseases of the poor. To be continued
Resolutions at the WHA 67th

Resolution A67.22 Access to Essential Medicines:

- Originally sponsored by China, adopted with small amendments.

- WHO Essential Medicines List recognized as a valuable tool that enables countries to identify a core set of medicines which need to be accessible to provide quality medical care – with special mention of children.

- This resolution provides us with a renewed mandate to continue to support MS in improving access in line with UHC, but also in connection with the MDGs and the NCD global action plan. It also provides us with the political umbrella to complete our strategic action plan for 2014-19
Resolution A67.23 Health Intervention and Technology Assessment in support of Universal Health Coverage:

- Broad support for the Resolution (originally sponsored by Maldives and Myanmar): WHO will support capacity-building for Health Technology Assessment in countries.

- WHO will provide tools and guidance to prioritize health technologies and intensify networking and information exchange among countries to support priority setting.
Resolution A67.20 on Regulatory System Strengthening for medical products:

- Originally sponsored by USA, Mexico and Nigeria, and finally backed by EU, India, Brazil and other MS after a large range of amendments.

- WHO important role globally in medicines regulation through 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/Dx for selected priority essential medicines, diagnostics and vaccines.

- Endorses the future progressive transition of prequalification to networks of strengthened NRA
Resolutions at the WHA 67th

- Resolution A67.21 on Access to biotherapeutic products and ensuring quality, safety and efficacy:

  - Resolution (originally put forward by Argentina and UNASUL) to improve access to biotherapeutic products, including similar biotherapeutic products, was approved.

  - Many issues to be discussed still on the technical regulatory aspects but it was noted that pre-ICDRA meeting in August on biotherapeutics would help to shed light on this evolving area.

  - Resolution calls for developing the necessary scientific expertise to facilitate development of scientifically-based regulatory frameworks that would promote the access to biotherapeutic products that are affordable, safe, efficacious and of quality. WHO has been requested through the Expert Committee on Biological standardization to update the 2009 guidelines on similar biotherapeutic products.
Resolutions at the WHA 67th

- Resolution A67.25 on Combating Antimicrobial resistance, including antibiotic resistance:
  - Originally submitted by UK and Sweden. Set to create the momentum to tackle the growing threat of AMR. WHO will develop a global action plan to combat antimicrobial resistance for approval in WHA 2015.
  - Global action plan: multisectoral approach - MS and multilateral stakeholders.
  - Responsible use of antibiotics, surveillance of consumption, regulation aspects on products approval and on prescribing and dispensing, use of antibiotics in veterinary medicines, and new models for antibiotic innovation will all need to be covered in the global action plan.
Resolutions at the WHA 67th

- Resolution A67.6 on Hepatitis:
  - Resolution (originally put forward by Brazil) approved to improve the prevention, diagnosis and treatment of viral hepatitis.
  - Importance of implementing appropriate measures to protect groups such as people who inject drugs from infection and to improve their access to diagnostics and treatment, whilst addressing intellectual property rights issues related to those products.
  - The Resolution mandates WHO to lead a discussion on access to new therapies, very timely as the new Hep C drugs are prohibitively expensive even for High income countries, and tiered pricing arrangements are too restrictive.
Resolution A67.19 on Strengthening of palliative care as a component of integrated treatment within the continuum of care:

- First ever Resolution on palliative care, originally sponsored by Panama and Chile, emphasizes the importance of palliative care services, as a component of UHC and integrated treatment and service delivery, as well as in connection with NCDs and TB and HIV/AIDS;

- The resolution has specific paragraphs on improving access to controlled medicines for pain and palliative care, including for the children, and as such provides impetus to this specific area of the "access" agenda.
SSFFC Mechanism (counterfeiting):

- The WHA noted the report of the MS mechanism meeting in November 2013 and stressed the importance of SSFFC;

- Concern was expressed over the continued lack of funds. In line with the MS Mechanism decision on rotation of the Chair, it was announced that Argentina will assume the Chair of the Steering Committee of the MSM, with immediate effect.
Resolution A67.14 on Health in the post-2015 development agenda:

- The Resolution has been approved and calls for a health goal that includes UHC and a continued focus on priority disease areas (the unfinished work of the health Millennium Development Goals), a focus on non-communicable diseases (NCD), mental health.

- The resolution stresses the importance of universal health coverage (UHC) and the need to strengthen health systems. This is very much in line with the approaches WHO/EMP has taken in drafting the Strategic action plan for 2014-2019.