Access to quality Medicines
Priority Needs, Priority Actions for Today and Tomorrow

EPN Forum
21st - 22nd MARCH 2012 Addis Ababa, Ethiopia
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<th>Abbreviation</th>
<th>Description</th>
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<tr>
<td>ACHAP</td>
<td>Africa Christian Health Associations Platform</td>
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<tr>
<td>ADDO</td>
<td>Accredited Drug Dispensing Outlets</td>
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<td>ADF</td>
<td>Asthma Drug Facility</td>
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<td>AIDS</td>
<td>Acquired Immune Deficiency Syndrome</td>
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<td>ARV</td>
<td>Antiretroviral</td>
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<td>AU</td>
<td>African Union</td>
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<td>BE</td>
<td>Bioequivalence</td>
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<td>CBC</td>
<td>Cameroon Baptist Convention</td>
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<td>CHAK</td>
<td>Christian Health Association of Kenya</td>
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<td>CHAN</td>
<td>Christian Health Association of Nigeria</td>
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<td>CHAZ</td>
<td>Churches Health Association of Zambia</td>
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<td>CHD</td>
<td>Coronary Heart Disease</td>
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<td>CHI</td>
<td>Church Health Institution</td>
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<td>DEQM</td>
<td>Direction Européenne de Qualité du Médicament</td>
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<td>DSO</td>
<td>Drug Supply Organization</td>
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<td>EAC</td>
<td>East African Community</td>
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<td>EECMY/DASSC</td>
<td>Ethiopian Evangelical Church-Development and Social Services Commission</td>
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<td>EMA</td>
<td>European Medicines Agency</td>
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<td>EPN</td>
<td>Ecumenical Pharmaceutical Network</td>
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<td>EU</td>
<td>European Union</td>
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<tr>
<td>EudraGMP</td>
<td>A European Community database on manufacturing and import authorisations and Good Manufacturing Practice (GMP) certificates</td>
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<td>FBO</td>
<td>Faith-based organization</td>
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<td>GFATM</td>
<td>Global Fund to Fight AIDS, TB and Malaria</td>
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<td>FEAPM</td>
<td>Federation of East African Pharmaceutical Manufacturers</td>
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<td>GIZ</td>
<td>Gesellschaft für Internationale Zusammenarbeit (Society for International Cooperation)</td>
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<td>GLP</td>
<td>Good Laboratory Practice</td>
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<td>GMP</td>
<td>Good Manufacturing Practice</td>
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<td>HAI</td>
<td>Health Action International</td>
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<td>HIV</td>
<td>Human Immunodeficiency Virus</td>
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<td>HPLC</td>
<td>High-Performance Liquid Chromatography</td>
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<td>HSS</td>
<td>Health System Strengthening</td>
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<td>ICH</td>
<td>International Conference on Harmonisation</td>
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<td>KEC</td>
<td>Kenya Episcopal Conference</td>
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<tr>
<td>LMIS</td>
<td>Logistics management and information system</td>
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<td>MDG</td>
<td>Millennium Development Goal</td>
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<td>MEDS</td>
<td>Mission for Essential Drugs and Supplies</td>
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<td>MEMS</td>
<td>Mission for Essential Medical Supplies</td>
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<td>MOH</td>
<td>Ministry of Health</td>
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<td>MSF</td>
<td>Management Sciences for Health</td>
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<td>NCD</td>
<td>Non-communicable disease</td>
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<td>NGO</td>
<td>Non-governmental organization</td>
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<td>NTD</td>
<td>Neglected Tropical Diseases</td>
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<td>OHA</td>
<td>Oral hypoglycaemic agent</td>
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<tr>
<td>ORS</td>
<td>Oral Rehydration Salt</td>
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<td>PEPFAR</td>
<td>President’s Emergency Plan for AIDS Relief</td>
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<td>PMPA</td>
<td>Pharmaceutical Manufacturing Plan for Africa</td>
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<td>PPP</td>
<td>Public-Private Partnership</td>
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<td>PSM</td>
<td>Pharmaceutical supply management</td>
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<td>QA</td>
<td>Quality Assurance</td>
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<tr>
<td>R&amp;D</td>
<td>Research and Development</td>
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<tr>
<td>REC</td>
<td>Regional Economic Communities</td>
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<td>SEAM</td>
<td>Strategies for Enhancing Access to Medicines</td>
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<td>SOP</td>
<td>Standard Operating Procedure</td>
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<td>TRIPS</td>
<td>Trade-related aspects of intellectual property rights</td>
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<td>TWG</td>
<td>Technical working group</td>
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<tr>
<td>UNCTAD</td>
<td>United Nations Conference on Trade and Development</td>
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<tr>
<td>UNFPA</td>
<td>United Nations Population Fund</td>
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<tr>
<td>UNICEF</td>
<td>The United Nations Children’s Fund</td>
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<tr>
<td>UNIDO</td>
<td>United Nations Industry Development Organization</td>
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<tr>
<td>UNITAID</td>
<td>Not an acronym. Organization cooperating with WHO and others on the WHO Millennium goals</td>
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<tr>
<td>UNRWA</td>
<td>United Nations Relief and Works Agency for Palestine Refugees</td>
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<td>US FDA</td>
<td>United States Food and Drug Administration</td>
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<tr>
<td>WCC</td>
<td>World Council of Churches</td>
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<td>WHO</td>
<td>World Health Organization</td>
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<tr>
<td>WHOPAR</td>
<td>World Health Organization Public Assessment Report</td>
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<tr>
<td>XDR TB</td>
<td>Extensively Drug Resistant Tuberculosis</td>
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Devotion

Dr Sujith Chandy sharing from the book of Romans painted the picture of the EPN network as a body with different organs, or a chain. Its strong members are linked to each other, but without a lock, a chain cannot be fitted to anything. The lock would be useless without a key. Jesus is the key. Our belief strengthens our spirit and helps our body, our network.

Official Opening

Donna Kusemererwa, the Executive Director of EPN, warmly welcomed over 50 Forum participants from about 20 different organizations. She thanked the hosts from Ethiopia for giving the opportunity to meet in Addis Ababa. She apologised for the difficulties some delegates faced during immigration at the airport. The secretariat had worked hard to organise an interesting programme and to facilitate all people with support in travelling details and other issues related. She gratefully thanked all sponsors of the Forum, particularly Bread for the world (Brot für die Welt), EED (Church Development Service), German medical aid organization action medeor e.V., the USAID supported SPS programme of MSH (Management Sciences for Health) and last but not least the EPN members.

Deed Jaldessa Kontoma, Director DASCC, EECMY gave a warm welcome, saying he was happy to host the EPN Forum in Ethiopia. He pointed out his excitement to exchange experiences in the pharmaceutical field. He recalled the history of EECMY founded in 1959.

Welcome by Mengisteab Aregay Teferi, Deputy General Director, Standard & Licensing, on behalf of the Ministry of Health of Ethiopia. Basic health services are a major centre piece of the MDGs. Ethiopia has developed and implemented health and medicines strategies in order to ensure access to quality health services and essential medicines. It has implemented a 20-years health sector development programme for the last 17 years. The targets are one health post for 5,000 inhabitants, one health centre for 25,000, one primary hospital for 100,000, one general hospital for one million, and one specialised hospital for about five million inhabitants. Currently the number of health posts and health centres is achieved, different hospitals are under construction. The number of private and NGO health institutions has also grown. As a result, the health service coverage has reached about 92 – 95%.

Opening remarks by the Chairman of the EPN Board - Albert Petersen

Albert Petersen in his opening remarks highlighted current topics on the health agenda of the world, as reflected by the programme of this 4th edition of the EPN Forum in Addis Ababa. Non-communicable diseases (NCDs), e.g. cancer and diabetes, are in the focus. NCDs often require chronic treatment, some are expensive, a lot have low accessibility. Insulin has to be available in our health facilities. Antibiotics and resistance towards these medicines has been a focus area of EPN. It will be followed up further as problems are not solved and a lot of self medication is still common. The quality of medicines and further measures have to be defined. A curriculum for a 3 months training course was developed by EPN. The target group is personnel with limited training, already working in pharmacies of health facilities within FBO institutions. This will improve the quality of pharmaceutical services. The course is approved by Gulu University of Uganda. Access to children’s medicines is an initiative which will continue. EPN carried out 4 country surveys about the availability of children’s medicines in church hospitals and health facilities. It will identify measures to improve the situation by 2015.

Internal changes in some donor organizations, as well as in WCC, and in the WHO might impair a successful cooperation. EPN with its members has always implemented programmes from these organizations into actions. Furthermore EPN wants to cooperate closer with ACHAP to integrate EPN programmes into the strategies of the Church Health Associations. A memorandum laying the basis is a first step.
Session 1: Perspectives on Essential Medicines

Key Note: The world medicines situation - Dr Richard Laing, WHO

The global situation
The Global Pharmaceutical Market reflects the income situation of the different regions of the world. 20% of the world’s income is spent for medicines by 80% of the world population, while 20% of the population consumes 80% of the available medicines. There is also a clear correlation between income and volumes consumed: the lower the income, the lower the volumes in medicines (fig. 1).

Interesting is the market share of generics. The USA has the highest rate of generics in the market, Japan the lowest, if high regulated markets of industrialized countries are taken into account.

The concept of Essential Medicines
The concept of essential medicines is to have a limited range of carefully selected essential medicines, which leads to better health care, better medicines management, and lower costs. Essential medicines are those that satisfy the priority health care needs of the population. The last revision of the WHO essential medicines list, April 2011, contains 367 active substances. The list is linked strongly to general treatment guidelines. Both are the basis for countries to create their own specific standards.

The correct selection of medicines has a positive impact on the entire medicines management cycle. The WHO recommends 30 medicines as sufficient for health centre level, 130 at hospital level and about 350 for a national essential medicines list. Figure 2 shows that the use of essential medicines lists is widely spread over the world.

Procurement
Generally most procurement agencies procure close to international prices, even UNRWA. There are new opportunities to obtain differentially priced products such as asthma inhalants and insulin. Insulin can be obtained from Novo Nordisk for $3.5 per vial.

Until now, the lowest cost for treating a patient with severe asthma in Benin was 79 euro per year. By ordering through ADF (Asthma Drug Facility), this cost will be reduced to 48 euro; and, in El Salvador, the savings per patient are even more dramatic – the cost reduces from 83 to 35 euro per year. For asthma, information is available from ADF created by The International Union Against Tuberculosis and Lung Disease (The Union). The quality assurance is based on the WHO Model QA System for Procurement Agencies. To ensure sustainability, revolving funds are encouraged if a country does not have a regular budget for asthma medicines.

Mother’s and children’s medicine
The UN Commission on Access to mother’s and children’s medicines and supplies, driven by UNICEF and UNFPA in New York, will launch an initiative in the next few months. It will look for new approaches to bridge key gaps identified in the WHO report on Priority Medicines for Mothers and Children7.

Price and availability information
Surveys continue to be undertaken and posted on HAI web site3, concerning prices and availability of medicines. Surveys have shown that there are huge price differences and making these facts transparent helps drug supply organizations to check on the prices and mark-ups. A recent study in African countries has shown that the situation concerning prices for procurement has improved a lot. In many countries, medicines are free but availability is often very poor. Where patients pay, even the cheapest generics can be expensive, e.g. in the Western Pacific Region the median price was about 12 times international reference prices. Good procurement prices are not always passed on to patients. In some countries, public sector prices are similar to private sector prices, e.g. China, Vietnam, and Sudan. An aspect to look at is the mark-ups. Data show that there are huge differences (fig. 3). Prices may be affected by many factors including:

Fig.1 Distribution of total pharmaceutical expenditures by income level: 2005/06

Fig.2 Number of countries with a national list of essential medicines

Fig.3 Cumulative percentage mark-ups between manufacturer’s selling price and final patient price, private sector
duties & taxes, wholesaler, retailer and dispensing mark-ups.

**Conclusions**
Access to Medicines is determined by financing, prices and prescription practices. Changing one aspect without controlling or addressing others may have no effect. As chronic NCDs become more important, new systems of care and supply systems will be required.

**TAKE HOME MESSAGE**

- 20% of the total expenditures on medicines is done by 80% of the world population, but 20% of the world population is consuming 80% of the medicines.
- The concept of essential medicines «a limited range of carefully selected essential medicines which leads to better health care, better medicines management, and lower costs» is still valid.
- There are chronic diseases, e.g. diabetes, asthma, which need new procurement measures to make the medicines available to the majority of the worlds’ population.

**Access to medicines: perspectives of the African Union Commission - Dr Janet Byaruhanga, African Union Secretariat**

The African Union leadership fully appreciates that access to medicines remains an essential element of delivery of the overall objectives of the Africa Health Strategy. Consequently, the Pharmaceutical Manufacturing Plan for Africa (PMPA) was adopted by the 3rd Conference of AU Ministers of Health in 2007. Access to essential medicines on the continent remains challenged by a host of factors:

- Inadequate local production of generics
- Poor regulation of the pharmaceutical sector and the circulation of counterfeit, substandard, fake, and unregistered medicines
- Inadequate funding of health programmes

The PMPA therefore seeks, through the implementation of the comprehensive business plan in collaboration with a broad range of partners including RECs, to facilitate the production of generics on the continent by guiding governments and other stakeholders to exploit TRIPS Flexibilities, while also facilitating access to information and knowledge that can support the successful challenge of unfair patents. Furthermore, PMPA facilitates the strengthening of medicines regulatory activities in AU member states through a combination of strategies that include institutional strengthening of national regulatory agencies or authorities as well as facilitating regional cooperation to leverage technical and other resources (to enhance regulation). PMPA tries to create linkages for backward/forward integration of research activities from various institutions into the R&D of pharmaceutical manufacturing firms and to motivate governments of AU member states to provide the necessary incentives (and protection) to encourage a commercially driven transfer of technology within its member states.

**Abuja Declaration**

A key message of the Abuja Declaration highlights the importance of health. The AUC continues to encourage and hold African governments accountable to the Abuja Declaration of allocating 15% of the national budget to the health sector.

**Conclusion**

Indeed the AU is aware that access to medicines is a challenge confronted by multiple factors. Progress therefore would require diligent implementation of the PMPA and all other related commitments on health by the leadership of member states and a broad range of partners.

**Comments from the discussion**

The AU does advocacy, and seeks to harmonise among the states what has been endorsed. The AU advocates for what works and shares the experiences with the member countries, as well as monitoring the countries on what has been achieved. The countries stay autonomous. The AU encourages an integrated programme, e.g. integrating the pharmaceutical sector into the health system.

**TAKE HOME MESSAGE**

- FBO’s wishing to link up with the AU should do so through the directorate that deals with linkages with civil society.
- Issues to be brought for advocacy at AU level should be in line with the summit or ministerial meeting themes.
Global programmes and access to medicines—improving access ... sustaining access - Sameh Saleeb, SIAPS

Global Programmes – a decade of Experience. A lot of initiatives contributed to the Millennium Development Goals 4, 5, 6 and 8. Figure 4 gives an overview on funding mechanisms.

Global Programmes – a decade of Experience. A lot of initiatives contributed to the Millennium Development Goals 4, 5, 6 and 8. Figure 4 gives an overview on funding mechanisms.

How can this be sustained? How can this be transferred in our own systems? A systematic and holistic approach to the problems of DLDB (Duka la dawa baridi) was used to develop the Accredited Drug Dispensing Outlets (ADDO) programme during the pilot programme under the Strategies for Enhancing Access to Medicines (SEAM) Program4, funded by the Bill & Melinda Gates Foundation in 2000. The goal of the ADDO programme was to increase access to essential medicines through utilization of the private sector. All aspects of the DLDB enterprise - including the physical premises, stock maintained by the owner, consumer choices, interactions with dispensers, and recommended treatments - had to be improved. In addition, the larger systems in which DLDBs are embedded, which include licensing, supply, training, and inspection, involving ward, district, regional, and national authorities, also had to be changed and strengthened.

In global programmes, there are key strategies for promoting access: standardization of treatment regimens and purchasing economies of scale which comprise pooled demand forecasting, bulk purchasing, volume-based pricing, reduced transaction costs, predictability of funds, leveraging, capacity building, and system strengthening.

Key challenges to sustain access are:
- Economic crisis affecting donors and local governments
- Mismanagement, weak governance and waste
- Increasing demand overwhelming producers
- Gap in innovation and market forces for medicines for MDR and XDR TB; and for ARVs for children
- High cost of second and third line regimens (Intellectual Property)
- Emerging priorities and needs beyond vertical programmes
- Human resource capacity
- System maturity and efficiency - Towards HSS

So far, the big funds continue to fund programmes, e.g. treatment for HIV and AIDS. The impact of malaria could be reduced by the procurement of medicines through funds. Beside the successes, there is still a significant part of the population not yet reached and therefore having no access to the necessary medication.

Possible considerations for planning the access to medicines within a health programme are:
- Prioritization of interventions should address capacity and system gaps most affecting access and/or quality
- Landscaping of the pharmaceutical sector and players is important
- Identification of local “owner” as well as stakeholders buy-in are critical to the success of interventions
- Multifaceted interventions targeting different barriers are more likely to maximize impact rather than single interventions
- System research and innovation
- Oversight and evaluation of impact are essential.

**Take Home Message**

- The four “A” to be looked at in medicines procurement are: accessibility, availability, acceptability, affordability.
- Big funds have had a large impact on the treatment of HIV and AIDS.
- Governance, human resources, information, and finance are the areas which have to be carefully planned and evaluated, if a successful procurement of medicines has to be implemented.
Partnerships with Government to improve access to medicine, a case study from CHAZ - Marlon Banda, CHAZ

How does the cooperation work? Church Engagement with the Government is the key for the cooperation. The highest church leaders interact with the leaders of the government. They use their position within the society to reach a lot of the population. That gives the churches a strong position. Churches serve about 30% of the population with health services, up to 60% in rural areas.

The church health facilities have a high technical competence, which is a reason for the preference of health facilities by the population. The churches are participating in national activities, policy development, forecasting and quantification, SOPs development, etc. There are technical working groups at different levels in the MOH. In a programme to increase the access to HIV treatment, the church sector was allocated more grant money than the government, which reflects the strength of and confidence in the churches and CHAZ. The churches are supporting the medical stores of the government by their capacities in storage and transport. They also work with the pharmaceutical regulatory authority. All of the cooperation of the churches with the government is based on a memorandum of understanding which:

- Defines recognition of place and contribution of Churches to the health sector in the country
- Defines obligations of parties including funding support and partnership roles
- Provides a basis for CHAZ to engage with other cooperating partners and donors
- Provides a basis for advocacy work of CHAZ

The benefits of the memorandum are an increased access to healthcare services, sustained healthcare delivery through extra resource mobilization, increased access to essential health products, and the harmonization of policy & activity implementation. Challenges include funding, inadequate human resources, unplanned expansion of church run health facilities, inadequate PSM systems, including those for QA, LMIS, rational use, pharmacovigilance, among others. The churches have been successful at being heard by government and getting a place on the table for policy and decision making in health because they control a significant proportion of the sector, they have access to the head of state when they don’t make progress at lower levels and they come to discussions with some resources of their own, not just to take from government.

TAKE HOME MESSAGE

- Church Engagement with the Government is the key for the cooperation.
- The good cooperation leads to an improved health of the whole population.
- Good pharmaceutical services can create trust in your capabilities, so that even global aid organizations may cooperate with you.

"I am happy I participated. I’m going back with ideas and I think ideas are better than money."

Dr Ione Bertocchi
Assomesca

"I am so happy I came. I go to a lot of meetings but it has been a long time since I was at such a good meeting."

Dr Richard Laing
WHO
Session 2: Tackling Quality

Keynote: Analysing, understanding and addressing the problem of poor quality medicines in low income markets - Christophe Luyckx, QUAMED

In 2010, the worldwide pharmaceutical market was worth USD 837 Billion. In 1990 it was USD 200 Billion. Sub-Saharan Africa accounts for less than 0.5% of this amount. Up to 90% of the population in poor countries purchase medicines «out of pocket». Medicines account for the second highest expenditure of a poor household, just after food.

Production and QA
In 30 years, the production of pharmaceuticals has changed completely. Now, 80-90% of the active ingredients come from Asia. Today the market share of generics is about 50%. 30 years ago, it was only 10%.

Only 20% of the world’s regulatory agencies have the capacity to do regulatory control. A big number of donors even lack a QA policy compliant to international standards.

A survey from the Global Fund showed that a number of implementers struggle to assure the quality of the medicines. Many have an inadequate understanding of the comprehensive QA concept. As a result of these difficulties, QA is often delegated to procurement agencies. The delegation of the QA to a procurement agency is not necessarily based upon a true technical evaluation (as recommended by the WHO), but rather a decision taken upon operational and/or commercial considerations.

Risks and facts
There is a multiplicity of standards (WHO, ICH, EU,...) and it is difficult to apply them. Quality control and Quality assurance are not the same. Some actors think quality control is sufficient. It is not.

Counterfeit and informal markets hide the growing issue of substandard medicines. Globalization of the market leads to outsourcing, subcontracting, and diversification of the supply chain. This makes traceability an issue. The increasing pressure on price may compromise on quality.

In addition, there is a lack of common references. Different agencies, organizations and purchasers are going to inspect manufacturers. There is a lack of sharing results, harmonisation, which leads to different recommendations. Some organizations publish results and/or certificates on the internet, e.g. WHO, EMA.

For better quality
The prerequisites to develop usable, non-biased information are:

- to improve the technical capacity of organizations involved in the procurement of essential medicines
- to increase the number of qualified persons involved in medicines in the organizations (pharmacists)
- to share the information and the resources
- to build a network of not for profit actors who collect and share reliable information and the related costs with a common approach of quality (same quality standards).

TAKE HOME MESSAGE

- The pharmaceutical production all over the world has changed dramatically in the last 30 years, such that 90% of active ingredients now come from Asia.
- Good cooperation leads to an improved health of the whole population.
- Are you looking for assistance to build up a quality assurance system for your drug supply, identify the right manufacturers, build your own lab? QUAMED is a partner who can help you.

East Africa regional bioequivalence study centre, a case study - Daniel Ayele, GIZ Ethiopia

Malaria, tuberculosis, HIV/AIDS and lately diabetes and cardiovascular diseases are important causes of morbidity and mortality in sub-Saharan Africa. It is estimated that more than 22 million people in sub-Saharan Africa...
Saharan Africa are living with HIV. A significant number of these is estimated to require treatment for HIV, TB and Malaria during their lives. High prices due to patent protections and high costs of imported medical products make their access to the poor population difficult. Looking at these markets, a growing demand and business in sub-Saharan African countries in general and particularly in Eastern Africa can easily be predicted.

Pharmaceutical companies in Africa already produce medicines (finished formulations) for their respective national markets, importing all inputs like APIs mainly from India and China. As most of the patients are not able to pay for the medicines, especially those against HIV/AIDS, malaria and tuberculosis, the medicines are mostly distributed through international funds like the Global Fund to fight HIV/AIDS, Malaria and Tuberculosis (GFATM). For those important essential medicines, the approval from the national regulatory bodies alone is not sufficient. For that reason, the Global Fund and others only accept such medicines that are pre-qualified by WHO.

The need for BE testing
Local production could cover a growing share of this market. But to come to this point, local pharmaceutical manufacturing companies need to improve the quality of the medical product by upgrading their GMP standards and by proving the efficacy and safety of the generic medical products. The latter cannot be established without bioequivalence testing. This has to be proven through clinical trials with a group of healthy patients that get one or the other product and where the decomposition in the blood is tested.

A public-private partnership (PPP) model has been chosen. GIZ is the major public partner and contributes about 50% of the investment and initial running cost of around USD 320,000. Addis Ababa University School of Pharmacy and other share holders such as private companies contributed around USD 320,000. The bioequivalence centre will be officially inaugurated in April 2012. Commercial operations will start in 2014.

Lessons from a decade of quality testing - Dr. Jane Masiga, MEDS
The Mission for Essential Drugs and Supplies (MEDS) is located in Nairobi, Kenya. It is a trust of ecumenical partnership of Christian Churches in Kenya. It serves as a pharmaceutical and medical supply organization, 100% self sustainable, and not-for-profit. MEDS has over 25 years of experience.

MEDS offers the following services:
- A reliable supply of medicines and medical supplies
- Quality, affordable medical products
- Training and Client Support of staff in health facilities
- Sharing of pharmaceutical information through publications, conferences and visits to health facilities
- Collaboration with Ministry of Health in various consultative forums
- Partnerships with other organizations

MEDS covers over 40% of Kenya’s needs (1700 corporate clients), and its service extends beyond Kenya’s borders. The clients are church health facilities in Kenya, other faith-based health facilities, NGOs in Kenya and neighbouring countries, donor-funded healthcare projects, government health facilities, and community-based health care initiatives.

MEDS has a Quality Assurance System in place which covers suppliers/manufacturers inspections, conducts physical inspection of commodities, Good Warehousing Practices, has a customer feedback mechanism in place, and runs analysis in its quality control laboratory. The lab carries out physical/chemical tests on about 1000 samples annually.

TAKE HOME MESSAGE
- Africa has a reasonable number of pharmaceutical manufacturers.
- A key quality element every generic product should have is bioequivalence.
- The launch of a certified bioequivalence research institute in Ethiopia, the first of its kind in Africa, will have a significant impact on the local pharmaceutical industry in East Africa.

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- Quality, affordable medical products
- Training and Client Support of staff in health facilities
- Sharing of pharmaceutical information through publications, conferences and visits to health facilities
- Collaboration with Ministry of Health in various consultative forums
- Partnerships with other organizations

MEDS covers over 40% of Kenya’s needs (1700 corporate clients), and its service extends beyond Kenya’s borders. The clients are church health facilities in Kenya, other faith-based health facilities, NGOs in Kenya and neighbouring countries, donor-funded healthcare projects, government health facilities, and community-based health care initiatives.

MEDS has a Quality Assurance System in place which covers suppliers/manufacturers inspections, conducts physical inspection of commodities, Good Warehousing Practices, has a customer feedback mechanism in place, and runs analysis in its quality control laboratory. The lab carries out physical/chemical tests on about 1000 samples annually.
MEDS’ experiences are:

- A number of incidences of sub-standard quality products are deliberate
- Suppliers target organizations that are not quality-conscious
- A Quality Policy in an organization acts as a deterrent to supply sub-standard products

The laboratory failure rates (1997-2011) were: content 80%, dissolution 15%, and others 5%, e.g. hardness, foreign bodies, impurities. Challenges are:

- Liberalisation of Kenyan market leading to high influx of pharmaceuticals from all over the world
- Inadequate resources by Kenyan Government to regulate quality of pharmaceuticals
- Low levels of awareness of quality of pharmaceuticals in health facilities and general public – cost is top priority in purchase decisions
- Cost of quality assurance
- Inspections, especially overseas
- Cost of running a quality assurance laboratory

Products that do not comply with quality standards are rejected and returned to the supplier because MEDS is not a regulatory body. The supplier then chooses what to do with rejected stock – possibly it is supplied to non-suspecting organizations.

**WHO Pre-qualification**
MEDS’ Quality Control Laboratory achieved WHO pre-qualification status in March 2009. It is the 1st faith-based laboratory worldwide, the 1st non-public laboratory in Kenya, and the 4th in sub-Saharan Africa (2 in South Africa). MEDS is currently setting up a microbiology laboratory.

**Heat unstable products**
In a project targeting the quality of oxytocine and methylergometrine (heat unstable products), the samples were collected at DSOs, hospital pharmacies, and maternity units in village clinics. The EPN members involved were MEMS from Tanzania, CBC from Cameroon, and Hôpital Koyom from Chad. The laboratory tests were carried out by MEDS Kenya and the confirmation tests by LAZ in Germany. The preliminary results show a failure rate between 40 and 50%. After confirmation of the results, further investigation of the circumstances of the supply chain and facilities’ storage needs to be done.

**Way forward**
Further steps are taken in using the Minilab® in different countries to check the quality of medicines. In Tanzania, the testing with the Minilab® is supplemented with further confirmatory testing using more sophisticated apparatus like HPLC but constructed with a low budget and self-assembled approach.

**TAKE HOME MESSAGE**

- Strive for excellent pharmaceutical drug supply services and you can build up an exemplary drug supply organization.
- Quality control mechanisms like laboratory analysis have a huge impact on the supplies you receive and how suppliers look at you.
- There is a need in EPN to exchange information and quality control test results within all drug supply organizations.
- The drug supply organizations at national level should retain reference samples of their products for their shelf life.

**TAKE HOME MESSAGE**

- The number of medicines with quality concerns is alarming.
- A deeper look into the whole supply chain, storage and handling of medicines has to be undertaken.
- Widespread pre-testing with the Minilab® in combination with follow up analysis for suspect results can establish a basic culture of quality testing with impact on our sourcing management.
DAY 2

Devotion
Rev. Paul Mbende Ngando

Mark 12, 41-44: Jesus judges the action of the rich and the poor.

Jesus sat down opposite the place where the offerings were put and watched the crowd putting their money into the temple treasury. Many rich people threw in large amounts. But a poor widow came and put in two very small copper coins, worth only a few cents. Calling his disciples to him, Jesus said, "Truly I tell you, this poor widow has put more into the treasury than all the others. They all gave out of their wealth; but she, out of her poverty, put in everything - all she had to live on". The widow reminds us to be compassionate to others who need our assistance and support.

Session 3: Non-Communicable Diseases

Key Note: What have FBOs done to address the growing need for medicines for NCDs? - Dr. Samuel Mwenda, CHAK

In the Kenyan context, recent deaths of prominent personalities to cancer have shifted perception on the magnitude of NCDs, e.g. Prof Wangari Maathai - Nobel Peace Laureate and leading environmentalist, Hon. John Michuki - long serving Cabinet Minister, and Hon. Njenga Karume - a very successful business man and politician.

A non-communicable disease is a medical condition or disease which is non-infectious. NCDs are often diseases of long duration and generally slow progression. WHO’s Global status report on NCD-2010 indicates: NCDs are the leading global causes of death, leading to more deaths than all other causes combined and they strike hardest at the world’s low and middle income population.

In 2007, NCDs were responsible for 63% of the global 57 million deaths. They include heart disease, hypertension, stroke, cancer, asthma, diabetes, chronic kidney disease, rheumatic conditions, osteoporosis, cataracts, injuries, etc.

The role of FBOs in NCD care
- Pre-service and in-service training of health workers
- Health education on healthy lifestyle – e.g. diet, exercise, avoidance of smoking, alcohol and drugs
- Provision of essential health services and follow-up for many common NCDs
- Diagnostic and treatment services
- Cervical cancer screening
- Palliative care services for terminal conditions
- Support to the referral system
- Supply of essential medicines and other commodities by the DSOs
- Partnerships with Government for training, clinical guidelines, medicines and supplies
- Partnership with donors for technical support, medical equipment, technology and infrastructure development

As an example, the Tenwek Hospital offers NCD treatment. It is a centre of excellence for oesophageal cancer management in Kenya, heart surgery, cleft lip and cleft palate repairs, cataract surgery, eye care, dental services, diabetes & hypertension treatment, palliative care for the terminally ill, major trauma management referral, and there are plans to establish a kidney dialysis unit.

Emerging issues
- Growing burden of cancers in developing countries with very limited resources for cancer diagnosis and management
- Growing incidences of lifestyle-related conditions such as diabetes, liver disease, hypertension, chronic renal disease
- Technological advancement in diagnostics

Challenges facing NCDs
- Inadequate funding and other resources
- High costs of treatment of some NCDs such as cancer, chronic kidney disease, CHD, injuries, etc.
- Need for sophisticated technology for diagnosis and patient monitoring
- Demand for chronic management and follow up of the conditions
- Inadequate training/capacity building opportunities on the
management of various NCDs
• Shortage of health workers

**Opportunities**

NCDs are increasingly getting national and international policy attention, e.g. in Kenya the 2 Ministers of Health have declared publicly their struggle with treatment of cancer and are advocating for institutions and resources to support cancer treatment.

Public-private partnerships with the pharmaceutical industry are set up to promote access to essential medicines for NCDs and NTDs. In Kenya, Norvo Nordisk and the Danish Embassy have partnered with MOH, MEDS, CHAK & KEC to make highly subsidized Insulin accessible through FBO health facilities.

**TAKE HOME MESSAGE**

- CHAK health facilities already provide health care for NCDs.
- Many NCDs cause a high financial burden for the institutions and the patients.
- The awareness within the ministries has to be created as well as possible public-private partnerships initiated.

In Kenya, Norvo Nordisk and the Danish Embassy have partnered with MOH, MEDS, CHAK & KEC to make highly subsidized Insulin accessible through FBO health facilities.

**TAKE HOME MESSAGE**

- Many measures were implemented in the health system in Ethiopia to lower the burden of health care including for NCDs.
- The health care services and local production of medicines have to be developed further to improve access.
- Health insurance systems may assist to buffer acute health expenditure for patients.

In 2008, the Federal MOH of Ethiopia in collaboration with partners conducted a national situational analysis on NCDs. The study revealed that diabetes mellitus, cancer, cardiovascular, renal and chronic obstructive pulmonary diseases are amongst the top NCDs in the country.

**TAKE HOME MESSAGE**

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In 2010, a situational analysis of NCDs care was conducted in Ethiopia’s Oromia Region in 33 hospitals. Access to equipment, medication, and laboratory diagnostics was variable from site to site. Medications are available to purchase, but there is always a shortage of free medicines for those who cannot afford to pay. There is a shortage of insulin and OHA for non-paying patients.

**The state of access to medicines for NCDs in Ethiopia - Hailu Tadeg, MSH**

Chronic diseases, such as heart disease, stroke, cancers, chronic respiratory diseases and diabetes are the leading cause of mortality in the world, representing about 60% of all deaths. Chronic Non-Communicable Diseases were assumed to be the problem of the affluent society. But nowadays, developing countries are no less affected due to a shift in lifestyle. Contrary to common perception, 80% of deaths from chronic disease occur in low and middle-income countries. The growing burden of chronic non-communicable diseases is gaining increasing attention worldwide, including in Africa. NCDs are projected to account for more than a quarter of all deaths by 2015 in Africa. Estimates indicate that the rate of increase of deaths from chronic diseases in the region will exceed that from infectious diseases, maternal and perinatal conditions, and nutritional deficiencies more than four-fold in the next 10 years.

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**Access to essential medicines and technologies for NCDs - Dr Richard Laing, WHO**

Access to chronic disease medicines is required for the fulfilment of MDG 8. The target is to provide access to affordable essential medicines in developing countries in cooperation with pharmaceutical companies. In September 2011, the UN General Assembly held a global summit to discuss Non-Communicable Diseases. The Essential Medicines Programme has prepared background documents that served as the basis of discussions.

To assess the differences in the availability of selected medicines for acute and chronic conditions, 50 surveys were undertaken in 40 countries (2003-2008) using the
WHO/HAI methodology, looking at price and availability. In the WHO/HAI surveys, the daily wage of the lowest-paid government worker is compared with the cost of standard treatments to estimate medicine affordability. For example: How many days’ wages does the lowest-paid government worker need to spend each month to purchase one salbutamol inhaler and one beclometasone inhaler from the private sector? If one day’s wage is generally considered affordable, it can be seen that even when the lowest priced generic equivalents are used, asthma treatment would be even more unaffordable.

The picture for the diabetes treatment if purchased from the private sector is not different. Using the standard treatment regimen glibenclamide 5mg, 2x/day together with metformin 500mg, 3x/day as a basis, the treatment regimen costs over 2 days wages in majority of countries, reaching 8 days wages in Ghana (generic medicines!). One can also imagine the impact of a concomitant condition such as hypertension on treatment affordability. When considering the affordability of chronic disease medicines, it must also be borne in mind that these are ongoing expenditures. They are therefore much less amenable to financial coping mechanisms, such as borrowing or selling assets, than one-time expenditures to treat acute conditions.

WHO has developed a report on Target 8.E of the Millennium Development Goals - In cooperation with pharmaceutical companies, provide access to affordable essential medicines in developing countries. This work has been undertaken as part of the development of a broader report of the MDG 8 Gap Task Force which was used as background information for the UN high-level meeting on MDGs in September 2008. There are only a few classes of medicines for NCDs with availability slightly above 50%. The majority is far below. For the majority of medicines, the net monthly treatment cost for one medicine is below 1 USD. An exception is insulin with about 4 USD.

**TAKE HOME MESSAGE**

- Access to chronic disease medicines is required for the fulfilment of MDG 8.
- Often the costs of even generic medicines for chronic disease are still too high.
- We should think about new ways to insure continuous medicine supply to patients with chronic diseases.

**Advocacy Intervention to the Programme Kibra Kebede**

Kibra Kebede from the Parkinson Patients Association of Ethiopia explained that they hardly have adequate treatment and they often go to traditional healers. The costs of the treatment are high. The patients often cannot work and so they lack income. Not all necessary medicines are in the essential medicines list and they have to be imported by private pharmacists. Treatment is often discontinued. Also family members outside Ethiopia are asked to import the medicines.

Being significantly impaired by Parkinson’s disease, Mrs Kebede’s appeal gave a sign to the conference that among NCDs, there are often chronic diseases which do not get enough attention.
Session 4: Addressing availability

Key Note: Contribution of DSOs in SSA on increasing access to medicines - Dr Andreas Wiegand, EPN

The start of any supply chain management is the evaluation of the demand at a specific health facility serving its nearby population. What kind of diseases occur in which dimensions at what time of the year? What do the treatment guidelines say on which kind of medicines should be used and how? The responsible personnel needs to know the circumstances of order and purchase from the DSO, the lead time, etc. in order to have enough stock, without an excessive overstock or long-term stock-outs. Is the personnel in our health facilities educated enough to fulfil these tasks?

Pharmacy staff
A survey of EPN together with members in eight different countries was performed from 2008 to 2010 looking at the professional education of the staff working in hospital pharmacies, health centres, and dispensaries. The staff consisted of 9% pharmacists, 24% pharmaceutical technicians, 29% pharmaceutical assistants, 10% nurses, and 27% attendants. Training of staff responsible for pharmaceutical services in FBO health facilities can be a measure to strengthen key capabilities in drug supply.

Drug supply organizations
Drug supply organizations can be seen as the spiders in their distribution network. They fulfil complex processes to order, store, distribute, guarantee quality, in other words manage the medical supply process. EPN conducted a survey together with its members in 2006 over 16 DSOs from 11 countries. The customers’ opinion showed that quality was the number 1 priority to cooperate with DSOs, the price for the medicines ranked 2nd. More than 50% of all suppliers fulfilled 75-100% of the demands. Another survey in 2011 with the focus on the availability of children’s medicine showed that on average 70% of the listed medicines were available. Another survey in 2011 focused on the availability of zinc sulphate. In comparison to ORS, its availability is very low which indicates that the recommended combined use is not followed.

Both surveys had a follow-up workshop to identify actions to improve the situation. In 2006, the priority fields identified requiring specific action were quality assurance, training, distribution/delivery services, procurement of medicines, storage and medicines management capacity, sustainability of DSO operation, and collaboration. In 2011, the follow-up workshop discussed who decides on the product range, how often is the portfolio updated, what factors influence the product range, and what factors lead to stock-outs. The overview highlighted different aspects of possible burning issues within DSOs and/or drug supply management.

Finally, EPN members were asked to identify their needs for strengthening supply chain management.

TAKE HOME MESSAGE

- EPN surveyed the human resource situation in pharmacies and dispensaries and consequently developed a training course for untrained staff.
- Stock-outs and missing products in DSOs or CHIs are an issue. Members should analyse the whole supply chain to identify the right measures.
- The big number of DSOs within EPN is impressive, even more so if the amount of medicines moved is looked at.

Lessons from GIZ on promoting pharmaceutical production in Africa - Dr Rainer Engels, GIZ

The GIZ is following a holistic approach to promote the pharma sector (e.g. in Ethiopia). The areas of focus are:
- Support of the regulatory authority in registration and market surveillance
- Support and development of institutional capacity and elements for setting up a national quality infrastructure in Ethiopia and the EAC region (cooperation with PTB)
- Reform of university education as well as vocational training
- Factory-level support

There are companies in Eastern Africa that are ready for quality production. GIZ tries to facilitate the public-private dialogue on pharmaceutical sector development, and to support the national and regional pharmaceutical sector strategy building processes.
in the EAC, Kenya, Ethiopia and Ghana via UNIDO. One key is the harmonizing of national patent laws to make maximum use of IP-flexibilities to foster local production. A further measure is the creation and support of regional pharmaceutical associations, e.g. the Federation of East African Pharmaceutical Manufacturers (FEAPM).

Registration and start-up operations are supported via GIZ. Furthermore via UNIDO and GIZ, there is support of the Industrial Pharmaceutical Training and Research Centre, St. Luke Foundation in Tanzania.

A major goal of the cooperation is the establishment of a bioequivalence centre in cooperation with companies from Ethiopia and Kenya and the School of Pharmacy of the University of Addis Ababa (Opening in Spring 2012). It will meet international quality requirements in Africa.

There is already a web portal for local pharma production. Its objectives are the creation of an information hub on pharmaceutical production in Africa, the strengthening of regional pharmaceutical associations, and the supply of a contact and presentation platform for manufacturers, associations and organizations. The long-term perspective is the transfer of platform ownership to a Pan-African Pharmaceutical Association in cooperation with an African public university. Another field of support is the capacity building for judges, patent office officials and other public servants from ministries of industry, trade and health in the implementation of TRIPS for Public Health. It is ongoing in four regions: East Africa + Egypt, West + Southern Africa, South America, South + Southeast Asia via UNCTAD and GIZ.

There is a blended learning course on TRIPS Flexibilities & Public Health. It is a worldwide blended-learning training system for experts from governments, patent and drug regulatory offices, pharmaceutical enterprises and civil society. Blended learning means the combination of face-to-face workshops and tutored online training (e-learning).

**TAKE HOME MESSAGE**

- A holistic approach including different segments of the pharmaceutical sector as well as several countries can have a huge impact on the access to medicines in East Africa.
- The harmonization of legal elements should not be forgotten beside all other efforts in technical development.
- Training is one of the key elements to build the required pharmaceutical personnel to strengthen local production.

**Case study: CHAN Medi-Pharm and contract manufacturing - Matthew Azoji, CHAN Medi-Pharm**

CHAN Medi-Pharm (CMP) Ltd/Gte is an ecumenical organization owned by the Catholic Bishops Conference of Nigeria, the Christian Council of Nigeria, and the Northern Christian Medical Advisory Council. It was established in 1979 as CHAN Medi-Pharm, a department of CHAN. It became autonomous in November 2004, and was registered as a company Limited by Guarantee in July 2006. In 2007, it initiated contract manufacturing.

CHAN faced the following challenges in sourcing products:
- Overdependence on one supplier
- Regulatory restrictions on distribution of IDA products
- Long supply lead times
- Challenges of Quality Assurance of locally procured products
- High cost of products
- Competition

The motivation for CHAN Medi-Pharm Ltd/Gte for Contract Manufacturing was to ensure availability and accessibility of assured quality low-cost generic medicines. For the selection of the manufacturer, communication, cGMP audits, audit visits, sharing of reports incl. the commitment to correct minor deviations, price quotations, projected minimum annual volumes & product specifications, price evaluations, and negotiations were necessary. Further steps were commercial & technical agreements, the trade mark registration, and the regulatory documents from selected manufacturers. Those had to be endorsed by the Nigerian High Commission in the manufacturers country. Out of 17 audited manufacturers, 6 were engaged in the end. CHAN Medi-Pharm currently has 33 essential medicines manufactured. 27 products are in the market. 5 are still undergoing registration including Oxytocin & Pentazocine.

CMP Purchase Prices were significantly lower than MSH Median Indicator Supplier Prices as at 2009: on average 53% lower. CMP Medicines contributed nearly 50% of revenues in 2011. CMP has received a first tender order from an International Procurement Agent. The product acceptability is very high. The gains from contract manufacturing are:
- Better supply lead times
- Credit facility
- Flexible delivery schedules
The challenges are:
• Degree of risk if one fails to research the company properly and engages a wrong firm
• High financial implications
• Involves high regulatory involvement
• Requires highly technical capacity in international trade, logistics and pharmaceutical audit.

TAKE HOME MESSAGE
• Well organized contract manufacturing with measures in place to guarantee quality is another option for safeguarding the access to medicines for health facilities.
• There is a bigger investment at the beginning but it will be paid back over time when the system is in place.
• The regulatory part of this approach needs to be taken seriously.

Think Zinc! Getting Zinc Sulphate into health facilities and onto prescriptions - Dr Andreas Wiegand, EPN
The global child mortality rate (under-five mortality) was
• 1990: 88 deaths/1,000 live births
• 2010: 57 deaths/1,000 live births

The Millennium Development Goal 4 (MDG4) strives for a two-thirds reduction by 2015, to 31 deaths/1,000 live births. The child mortality in sub-Saharan Africa is the highest rate in the world: 1 in 8 children die before age 5. The major killers are:
• Pneumonia: 18%
• Malaria: 16%
• Diarrhoeal diseases: 15%
• Preterm birth complications: 12%

Is the use of zinc a new paradigm in the treatment of diarrhoea in children? The EPN surveys in Chad, Kenya, and Uganda (2010), on the availability of children’s medicines showed that there is a mismatch of ORS and zinc, leading to the conclusion that the combined use of zinc is not put into practice. There is scientific evidence that the combined use of zinc and ORS reduces the seriousness and the likeliness of reoccurring diarrhoea. The development of measures against the underutilization will bring the world closer to achieving the Millennium goals.

TAKE HOME MESSAGE
• If we do not put diarrhoea management in children back on our agenda, we will fail to reach the Millennium goal number 4.
• There is an under-utilisation of zinc tablets compared to ORS. Zinc is a key element of the treatment which can improve the outcome for children.
• Think Zinc => Identify needs and start campaigning within organizations. The EPN secretariat is happy to assist.

Footnotes to the report
6. MSH International Drug Price Indicator Guide 2010 (http://erc.msh.org/mainpage.cfm?file=1.0.htm&id=1&temptitle=Introduction&module=DMP&language=English)
Final Remarks From The Editor

By Andreas Wiegand

The contributions and discussion of the biannual EPN Forum 2012 clearly reflected the experiences with drug supply available within the members of EPN. For “younger” members, this is a chance to learn and ask for advice to build up their supply structure and backbone for pharmaceutical services.

The media often highlight scandals of counterfeit medicines especially within Africa. Several ongoing initiatives presented demonstrate actions taken to improve and ensure the quality of the accessible medicines.

The EPN Forum 2012 enabled members and representatives of well respected international organizations to strengthen the network and intensify cooperation. In our vision, we follow the word given to us in the Bible,

Philippians 2:1-30:

So if there is any encouragement in Christ, any comfort from love, any participation in the Spirit, any affection and sympathy, complete my joy by being of the same mind, having the same love, being in full accord and of one mind. Do nothing from rivalry or conceit, but in humility count others more significant than yourselves. Let each of you look not only to his own interests, but also to the interests of others. Have this mind among yourselves, which is yours in Christ Jesus, ...
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