

Pharmalink

A Publication of Ecumenical Pharmaceutical Network

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**Assuring the
quality of medicines**

About Ecumenical Pharmaceutical Network (EPN)

Ecumenical Pharmaceutical Network (EPN) is an independent, not-for-profit, Christian organization whose mission is to support churches and church health systems provide and promote just and compassionate quality pharmaceutical services for all. The work of EPN is not just aimed at having quality pharmaceutical services provided by church institutions, but also at working towards services that allow no discrimination and guarantee equal access to all.

About the cover image

A pharmacist does quality testing as part of quality assurance of his products. The illustration is one of many that EPN has developed for its *Guidelines for effective and efficient pharmaceutical services*. The 25 guidelines are aimed at supporting health facility managers, pharmaceutical personnel and all those involved in pharmaceutical service delivery, to ensure quality services. *Illustration by David Radoli.*

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Editorial

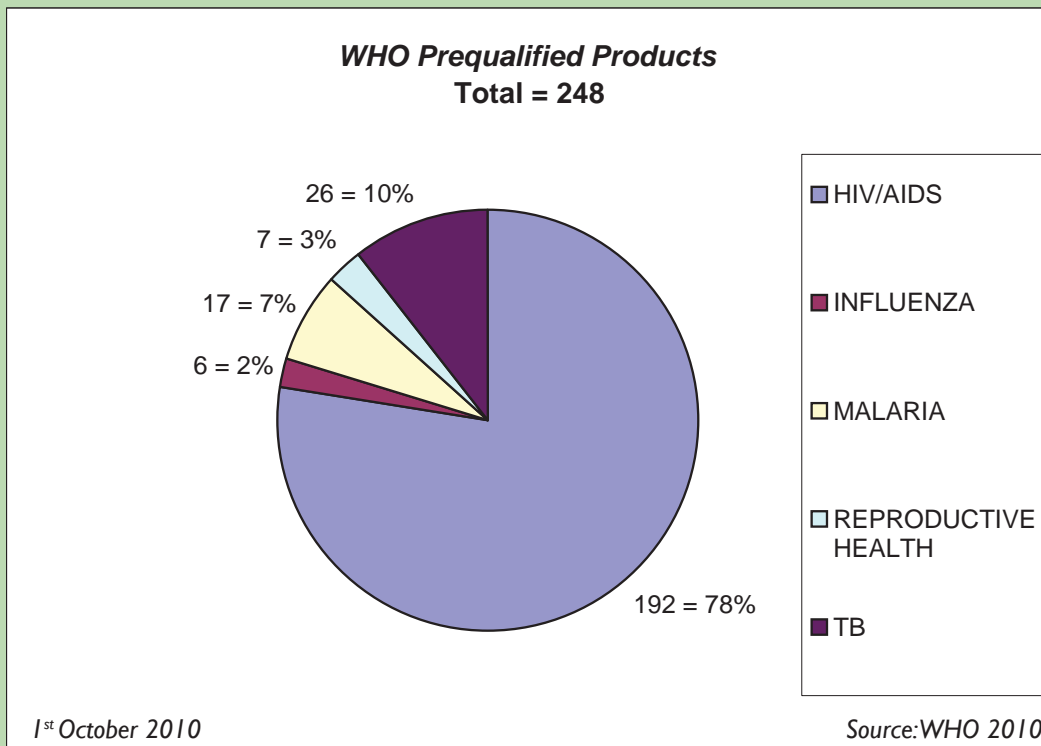
EPN, its members and partners have been working for many years to increase access to essential medicines and promote their rational use. An important requirement for these objectives is the quality of medicines. As much as medicines are essential to curing or even preventing diseases, if their quality is not assured, they can become a health hazard. Medicines that do not contain the right active ingredients in the right dosage or contain harmful substances, medicines that are not manufactured, transported or stored under the right conditions, can all pose a health risk to patients.

Regulatory bodies have the ultimate responsibility for the quality of medicines in their markets. Nevertheless, pharmaceutical wholesalers, distributors and all other institutions along a medicines supply chain can and should take quality assurance into their own hands and set up mechanisms to pick out counterfeit and substandard pharmaceuticals and ensure that the medicines they provide are safe and effective. Patients as well should not stand powerless, especially in developing countries. Buying only from licensed outlets and avoiding medicines that appear to have been tampered with are some of the measures any member of the public can take.

Even in resource-limited settings, steps can be taken to evaluate the quality of medicines and reduce the risk of having poor quality medicines in the supply chain. Such mechanisms include visual inspection and proper storage and handling. For a number of years, WHO has supported national and global medicines procurement by prequalifying medicines which meet international standards (p3).

For those who wish to test the medicines, the minilab provides a relatively low-cost, low-tech option. From page 6, the head of QA at JMS in Uganda reflects on the benefits and challenges of using this technology. Supplier audits require significant resources. A workshop by action medeor and EPN (p8) showed that joint audits are more cost-effective and increase the impact on the supplier. MEDS in Kenya operates a WHO prequalified quality control laboratory for physical and chemical analysis of medicines and active pharmaceutical ingredients (p11).

It is our hope that you will find useful information in this issue, whether you are producing, buying, selling or taking medicines.



Therapeutic area	TOTAL
HIV/AIDS	192
INFLUENZA	6
MALARIA	17
REPRODUCTIVE HEALTH	7
TB	26
TOTAL	248

WHO medicines prequalification: value for money also for faith-based pharmaceutical agencies

Deus Mubangizi

Globalization of pharmaceutical production has made medicines procurement more complex: an ever-growing number of manufacturers obtain their active pharmaceutical ingredients (APIs) from different sources, use different quality standards and may trade across many different borders. Selecting a medicine for bulk procurement and attempting to verify its quality can therefore be both difficult and time-consuming. The WHO List of Prequalified Medicines exists to make this task easier.

Using internationally-accepted norms and standards, the WHO Prequalification of Medicines Programme (WHO/PQP) evaluates priority medicines for treating HIV/AIDS, malaria, and tuberculosis. It also evaluates influenza-specific antiviral medicines, zinc for managing

acute diarrhoea and products for reproductive health. Evaluation incorporates comprehensive review of the quality, safety and efficacy of the products, based on information submitted by the manufacturers, and inspection of the corresponding manufacturing site(s) (for APIs as well as for finished products (FPs)). Products found to be acceptable are added to the WHO List of Prequalified Medicinal Products.

Use in confidence

For faith-based organizations, the fact that prequalified medicines meet international standards is helpful. This is because the national regulatory standards of a country may not be sufficient for dealing with newer types of medicines or medicines purchased in other countries, or may vary from one country to

another. The latter can complicate procurement issues for any procurement organization seeking to make a single, bulk purchase of a product for distribution in more than country.

Most importantly for those who are seeking to maximize the impact of procurement funds, prequalification by WHO is a strong indicator of quality. This was demonstrated by the results of a recent study funded by the European Union. In 2008, over 900 antimalarial samples were collected in Cameroon, Ethiopia, Ghana, Kenya, Nigeria and Tanzania. About 30% of the samples were tested by quality control laboratories. Eighty-three of the tested samples were of WHO-prequalified products, while 184 were of products that had not been prequalified by WHO. Only 3 of the WHO-prequalified product samples (3.6%) deviated from pre-specified quality criteria, compared to 73 (39.7%) of the non-prequalified product samples. Procurement agents can confidently use the WHO List of Prequalified Medicinal Products to guide them in at least some of their bulk purchasing decisions.

Quality information and quality testing

WHO/PQP makes available extensive information on medicines quality. This includes detailed information on: products that have been prequalified; sites at which products are manufactured; and clinical research organizations that have conducted a bioequivalence or other clinical study linked to a product submitted for evaluation. Application of this information may extend far beyond the immediate product to which it refers.

World Health Organization Public Assessment Reports (WHOPARs), for example, contain a summary of the product's bioequivalence and quality specifications. This includes stability data that demonstrates that the product meets quality standards, is effective, safe and can be stored as indicated. They also contain information for clinical use — reviewed and approved by WHO/PQP experts — based on information found in the patient information leaflet and information on product characteristics that has been provided by the manufacturer. This information is invaluable

WHO/PQP: Our efforts in Africa

WHO/PQP is often asked: what are you doing to help pharmaceutical production and medicines regulation in Africa. The answer is: "Really quite a lot".

We constantly encourage African manufacturers to submit their products for evaluation. And we are beginning to see real progress. The WHO List of Prequalified Medicines currently includes products manufactured by two sub-Saharan African manufacturers. Other WHO-prequalified products are manufactured at sites in Africa, under licence, that have passed inspection by WHO/PQP. Three further products — submitted by manufacturers in Kenya, Tanzania and Zimbabwe are now being evaluated — and it is hoped that some of these will be prequalified soon.

Concurrently, WHO/PQP continues to organize training workshops for African manufacturers and regulators aimed at boosting the quality of pharmaceutical production and the capacity to regulate it. Workshop topics range from scientific assessment of therapeutic interchangeability of multisource (generic) medicines, to compliance with Good Manufacturing Practice. WHO/PQP also organizes assistance for pharmaceutical manufacturers, to help resolve difficult technical issues.

At WHO headquarters, a three-month rotational assessor position offers developing country regulators the opportunity to increase their expertise in dossier assessment. Assessors from Ethiopia, Ghana, Kenya, Tanzania, Uganda, Zambia and Zimbabwe have all benefited. African regulators also participate in WHO/PQP assessment sessions held in Copenhagen, Denmark and in inspections of manufacturing sites. Back home, regulators who have worked with WHO/PQP not only share with their fellow regulators the new expertise that they have acquired, but also help expedite national registration of prequalified medicines.

The ultimate goal of all these efforts is better medicines for Africa.

*Dr Lembit Rägo, Coordinator, Quality and Safety: Medicines,
Department of Essential Medicines and Pharmaceutical Policies, WHO*



WHO Prequalified quality control laboratories in the African region (16th September 2010)

in terms of understanding the nature and characteristics of the prequalified product. But it can also contribute to development of an understanding of the safety, quality and efficacy issues of other, similar types of products. Similarly, WHO Public Inspection Reports (WHOPIRs) are very useful for procurement agents who are conducting risk assessment

relating to the potential purchase of other products manufactured at the site in question. Sites that have passed inspection by WHO/PQP manufacture products under acceptable conditions. These products are likely to be safer than those coming from sites that do not comply with current WHO Good Manufacturing Practices.

WHO/PQP also prequalifies pharmaceutical quality control laboratories. A number of the laboratories prequalified to date are found in Africa. They play an important two-fold role: checking that pharmaceutical products circulating on their national market meet international standards and identifying any products for which problems of quality have become observable. As with WHO-prequalified medicines, procurement agents can rest assured that the services of a WHO-prequalified laboratory can be counted upon, no matter where that laboratory is located.

Further information on the WHO Prequalification of Medicines Programme, including on WHO-prequalified medicines and WHO-prequalified QCLs, can be found at: <http://www.who.int/prequal>

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Model requirements for the storage and transport of time and temperature sensitive pharmaceutical products

In order to reduce the quality loss of time and temperature sensitive pharmaceutical products (TTSPPs) during storage and transport, WHO is developing guidelines to support regulators, logisticians and pharmaceutical professionals in industry, government and the international agencies. The document, which is currently undergoing public review, sets out the principal requirements and provides vital information on major aspects of good storage and distribution practice for TTSPPs: importation, warehousing sites, storage buildings, temperature-controlled storage, materials handling, transport and delivery, labelling, stock management, record keeping, environmental management, quality management and training of personnel.

The intention is that the listed requirements should be directly applicable in less developed countries as well as in the industrialized world. To this end, supplementary materials will be developed to show how the requirements can be achieved, particularly in resource-constrained settings.

http://www.who.int/immunization_standards/public_review/en/index.html



The GPHF-Minilab[®] at JMS, 2010

Using the GPHF-Minilab[®] The JMS experience

Joanita N. Lwanyaga

The GPHF-minilab[®] (Global Pharma Health Fund) is a compatible, self-contained, portable and easy-to-use mini laboratory for the detection of counterfeits and substandard pharmaceuticals. In developing countries with limited access to laboratories and resources, the minilab technology is of great importance for the quality assurance of medicines.

Supply of good quality essential medicines is indisputably one of the pillars for the delivery of good health care. Without assurance that medicines meet acceptable standards of quality, safety and efficacy, any health service is evidently compromised¹.

Joint Medical Store (JMS) in Uganda is committed to the provision of medicines, medical equipment and related health care supplies of assured quality at affordable prices. This is achieved through efficient and effective operations managed by a dedicated and responsive team committed to

quality, continuous improvement and customer satisfaction. JMS has committed resources to ensure the provision of quality products and services that meet acceptable national and international standards and consumers' needs. Its quality assurance system includes prequalification of suppliers, quality inspection at receipt, certificate of analysis review, proper storage and handling, meticulous GMP audits of manufacturing sites and continuous quality analysis of products.

The challenge of quality testing

Provision of quality products remains a challenge in Uganda and the limited availability of testing facilities makes the situation even worse. Very often recourse is made to foreign laboratories to carry out required tests. However, this has its own challenges which from the experience of JMS include: regulatory and logistical constraints on the one hand and delays in getting back results on the other.

The donation by Difam of a minilab to JMS in August 2009 came in at the right time when JMS was establishing a Quality Management System. Since then, the organization has been able to test more samples as a proportion of batches received. In addition, other benefits have accrued from the minilab project:

- Pre-testing of medicines before receipt to facilitate quick and evidence-based decision making.
- Strengthening the post-marketing surveillance.
- Equipping the QA staff with skills to assess quality of medicines with minimum resources.
- Attaining remarkable cost savings in the Quality Assurance scheme.
- Monitoring storage conditions through random analysis of stored medicines.

JMS' experience with the minilab is that when used appropriately, it can provide a certain level of assurance. From roll out, JMS has been able to test over 43 samples using the minilab and of these the three samples that failed using the minilab also failed assay test in an analytical laboratory. Some of the challenges the DSO has noted while using the minilab are mainly associated with:

limited product range, limited dosage forms and subjectivity in interpretation of the results. In addition, it can only detect grossly substandard medicine samples.

In conclusion, the minilab is a valuable resource for any quality assurance system. However for better results, it should be used in conjunction with a comprehensive system of quality assurance with access to an analytical laboratory where suspect samples can be sent for confirmatory testing.

References

1. Quality assurance of pharmaceuticals: a compendium of guidelines and related materials. Vol. 2, Good manufacturing practices and inspection. – 2nd ed. World Health Organization, 2007.

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Paul Mutebe, Quality Assurance Officer at JMS, August 2009



Supplier Auditing: a shared experience of Quality Assurance

Christoph Bonsmann, Christine Haefele-Abah, Christine Liedtke

The quality of medicines is one of the major concerns of health care providers and patients and remains a major public health challenge in developing countries. Poor quality medicines are a direct risk for patients, as their use can result in treatment failure or even death. Each single case undermines the credibility of national health and regulatory authorities. Recent examples¹ were seen in Tanzania (Metakelfin, antimalarial – underdosed, found in 40 pharmacies, 2009) and China (Glibenclamide, antidiabetic – overdosed, 2 people died, 2009).

The extent of substandard medicines is difficult to estimate but generally one can state that the magnitude is higher where regulatory and

enforcement systems for medicines are weaker¹. As a consequence, a Pharmaceutical Supply Organization operating in such an environment must have a comprehensive quality assurance system to prevent potential health threats.

Various mechanisms for ensuring quality of pharmaceuticals have been developed over time, seconded by several guidelines. Typical mechanisms are drug regulatory authorities, national quality control laboratories and recently the WHO prequalification program. The most prominent guideline for the pharmaceutical manufacturing is the WHO Good Manufacturing Practices (GMP)², followed by other “Good Practices”

like Good Storage Practices³, Good Distribution Practices⁴ or Good Practices for Quality Control Laboratories⁵ summarized as GxP. Due to successful harmonization, these guidelines are being used with very little modifications throughout the world for pharmaceutical manufacturing.

A Model Quality Assurance System for Procurement Agencies issued by WHO⁶ assists specifically Pharmaceutical Supply Organizations with implementing quality standards and focuses on aspects such as random analytical testing and prequalification of manufacturers and their products. One important element of supplier qualification represents auditing of manufacturing sites according to GMP, which, however, requires profound technical expertise and experience.

Practical Experience

In order to assist faith-based pharmaceutical supply organizations in auditing as part of their vendor pre- and requalification schemes, a workshop was offered to EPN members under the title “Supplier qualification and auditing” in Nairobi in April 2009. During the workshop, professional GMP audits were planned and conducted at three manufacturing sites with the necessary theoretical training ahead. Two internationally experienced senior auditors were engaged and the necessary funding secured from action medeor and Difäm.

The following EPN members took part: Joint Medical Store (JMS) – Uganda, Mission for Essential Drugs and Supplies (MEDS) – Kenya, Christian Health Association of Malawi (CHAM) – Malawi, action medeor International Healthcare – Tanzania. An ambitious programme was worked out in detail, taking into account the needs of all involved EPN members leading to the following workshop objectives:

- To conduct joint WHO GMP audits of 3 Kenyan manufacturers.
- To train participating pharmacist, enabling them to conduct GMP inspections of pharmaceutical manufacturers.

The workshop started with a 2 day theoretical training based on WHO GMP principles².

Furthermore, the audit agenda which was submitted to the manufacturers in advance was discussed. Equipped with this theoretical knowledge, the auditing team inspected the companies spending 2 days on each individual audit. The team size was determined not to exceed 8 people to allow

first-hand experience as well as the necessary professionalism during the auditing. It was agreed that the communication between audited company and auditing team must be channelled by the chief auditor to keep the disturbance of such a big group as low as possible.

Although it was a challenge to perform auditing and training simultaneously, the high discipline of the group allowed for professional execution of the audits. The participants who had either no or limited experience in GMP audits learnt theoretically and practically how to prepare and conduct an audit and how to finalize a report. To perform this under real conditions was a very unique and well appreciated experience.

According to the feedback of the participants, the audit tour was very beneficial and the expectations and objectives were met. The participants acquired new skills in pharmaceutical Good Manufacturing Practices auditing of manufacturers as a way of vendor prequalification. In the opinion of the participants, this project was a very important step to improve Quality Assurance Systems in not-for-profit wholesalers in East Africa. They were convinced that the combined capacity of MEDS, JMS, CHAM and action medeor International Healthcare will have a greater impact together than through individual efforts.

The participants expressed interest in additional training and seminars in future, in order to become conversant with GMP-audits. They also hoped that this will not be an end but a beginning to a joint manufacturer audit scheme.

Common Market – Joint Audits?

GMP audits are one of the cornerstones of supplier pre- and re-qualification. However, the impact of an audit is dependent on the authority of the auditing body and the quality of the performed audit. The highest authority is normally represented by a drug regulatory authority where there is a product marketed or intended to be marketed. This is due to the simple fact that a regulatory authority has the ultimate power to shut down production or to terminate marketing of a product. On the contrary, a Pharmaceutical Supply Organization from outside the country buying erratic small quantities has very little objective auditing authority. In such a case, even permission to audit might be an obstacle because audits are costly and time-consuming for a company. The request might simply be rejected or postponed.

Faith-based pharmaceutical organizations can enhance their authority in two ways. First, the more professionally and profoundly an audit is prepared and executed, the more it will be seen as added value from the companies' perspective. If there is a smooth transition between auditing and consultancy, it is more likely that changes to the better will be implemented. And secondly, the more purchasing power the organization represents, the more auditing power it will gain.

The EPN workshop in Nairobi demonstrated that:

- High quality joint audits are performable by pharmaceutical agencies and acceptable by the pharmaceutical companies.
- The East African pharmaceutical agencies share a number of pharmaceutical manufacturers where joint audits would help to utilise limited resources and increase the auditing performance.
- Together, church pharmaceutical agencies have a significant purchasing power in East Africa. A common market needs a joint quality assurance system.
- A GMP auditor needs a lot of theoretical but even more practical experience. A single training, however intensive, is not sufficient to perform as an auditor.



Future endeavours

The workshop on supplier auditing was taken as a starting point because auditing offers a lot of “action” compared to the dry paperwork which is the daily bread of the Quality Assurance staff. The hope was to motivate participants for future endeavours. The next step should be to conduct a comprehensive workshop along the “Model Quality Assurance for Procurement Agencies”⁶ where participants identify and discuss their strengths and weaknesses.

The vision must be to frame a joint quality assurance system where synergies are utilised and modern tools like secure databases are used to share information. A vision which needs commitment from the management as it requires qualified personnel, financial resources and persistence for the benefit of our customers, across the region.

References

1. World Health Organization, Fact sheet N°275, January 2010
2. WHO Technical Report Series, No. 908, 2003, Annex 4: Good Manufacturing Practices for pharmaceutical products: main principles
3. WHO Technical Report Series, No. 908, 2003, Annex 9: Guide to good storage practices for pharmaceuticals
4. WHO technical Report Series, No. 957, 2010, Annex 5: Good distribution practices for pharmaceutical products
5. WHO technical Report Series, No. 957, 2010, Annex 1: Good practices for pharmaceutical quality control laboratories
6. Model Quality Assurance System for Procurement Agencies, WHO/PSM/PAR/2007.3 Download under: http://www.who.int/medicines/areas/quality_safety/quality_assurance/QualityAssurancePharmVol2.pdf

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Quality assurance at MEDS

Wycliffe Nandama

The supply of good quality essential medicines is undoubtedly one of the prerequisites for the delivery of healthcare. Mission for Essential Drugs and Supplies (MEDS) Kenya has put in place an elaborate and well documented quality assurance system that ensures the procurement and supply of safe, effective and quality medicines and medical supplies to its customers. Quality assurance at MEDS includes the presence of a formulary committee, supplier audits, visual product evaluation, laboratory analysis and customer feedback.

MEDS Formulary committee

MEDS has constituted a formulary committee that is comprised of professionals of diverse backgrounds and levels involved in healthcare delivery. They are drawn from MEDS, the health institutions it serves, academia and relevant

regulatory bodies. This committee meets annually to review MEDS catalogue of essential medicines and medical supplies guided by the essential medicines concept developed by the World Health Organization (WHO) as well as national treatment guidelines.

Supplier Audits

A Pharmaceutical Technical Committee (PTC) consisting of experienced pharmaceutical and laboratory staff regularly inspects suppliers. They evaluate manufacturers and distributors for adherence to Good Manufacturing Practices (GMP) and Good Distribution Practices (GDP) respectively. Compliance with GMP and GDP guidelines is a pre-requisite for the prequalification of suppliers. This ensures that products are sourced from suppliers who meet internationally recognized quality standards.

Visual Product Evaluation

Products are visually screened by the PTC to ensure they meet pre-determined quality specifications e.g. labelling requirements prior to being stocked. Suppliers sign contracts that bind them to meet these standards. All goods delivered by suppliers to MEDS are further inspected by a receiving team to ensure adherence to contractual requirements. Every batch of medicine supplied is required to be accompanied with a certificate of analysis indicating that they have been tested from the source and shown to pass the test for quality. Consignments that do not meet set criteria are rejected and not received in MEDS.

Quality Control Laboratory

MEDS operates a WHO prequalified quality control laboratory which it utilizes to ascertain the quality of medicines it procures and distributes. The achievement of WHO prequalification placed the laboratory among a limited number of laboratories around the world that have attained this status. It scored a first among faith-based organizations and became the fourth laboratory to be prequalified in sub-Saharan Africa. The laboratory is used to analyse new products as well as carry out continuous monitoring of the quality of medicines stocked through random sampling of products from MEDS warehouses. Activities of the laboratory have contributed immensely in reducing incidences of quality failures as suppliers are aware of continuous monitoring of the quality of the products they supply to MEDS.

The laboratory is prequalified for physical and chemical analysis of medicines and active pharmaceutical ingredients including pH, loss on drying, water content, conductivity, refractometry,

friability, disintegration, dissolution, density, uniformity of dosage units (mass, content), HPLC (UV- VIS detection), Gas Chromatography (GC), UV-VIS spectrophotometry, Thin Layer Chromatography (TLC), identification by chemical reaction, volumetric titrations, polarimetry, determination of related substances and degradation products. In order to assure continued reliability of generated results, the laboratory participates routinely in the WHO proficiency testing scheme which enables it to compare performance with other laboratories around the world.

Using this laboratory, MEDS wishes to collaborate with the government and other organizations involved in pharmaceutical supply, in combating the menace of sub-standard and counterfeit medicines within the region. They can submit samples to the laboratory for analysis at competitive rates.

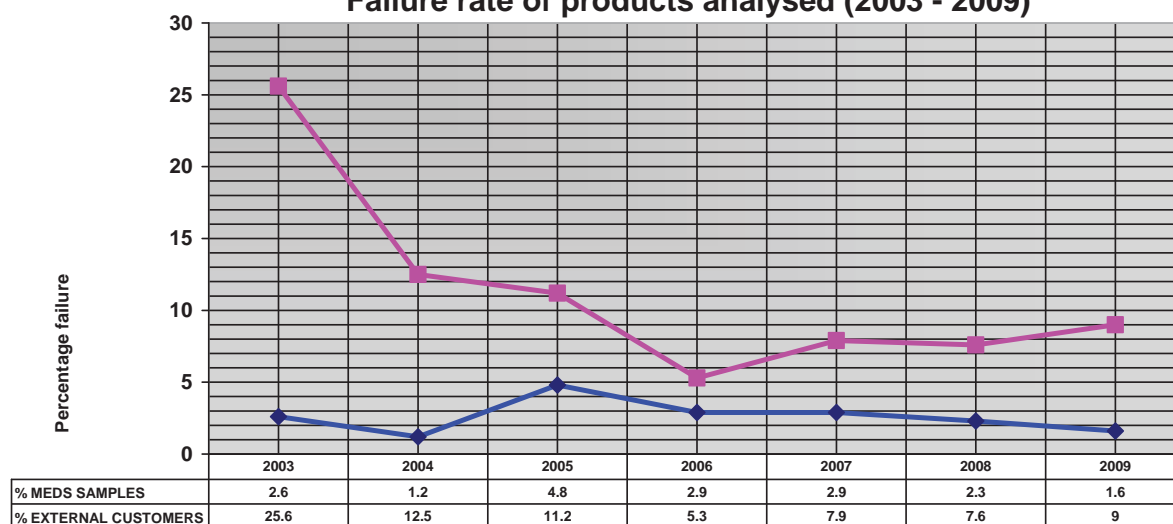
Customer Feedback

There is a mechanism in place which allows customers to give valuable feedback on the quality of medicines supplied to them. As a result, MEDS has built a wealth of information on the quality of products in the market, thus saving customers valuable time and other resources that would be used in gathering such information. A computerized batch-tracking system ensures effective and rapid withdrawal of any defective product from the market place.

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Failure rate of products analysed (2003 - 2009)



	2003	2004	2005	2006	2007	2008	2009
NO. OF MEDS SAMPLES	383	338	271	315	274	355	366
NO. OF EXTERNAL SAMPLES	137	160	170	244	266	291	188

Voluntary testing of quality of medicines supplied by EPN member institutions

Ecumenical Pharmaceutical Network has among its membership 16 faith-based Pharmaceutical Supply Agencies, serving more than 8000 health facilities with a combined turnover of more than 40 million USD per year. Medicines are procured from companies in Africa, Asia or Europe. Very few of these have their own quality control facilities. Those that do not have such facilities, have to depend on the information given by the wholesaler or the manufacturer, which can be unreliable. This is why, in 2009, EPN, MEDS and Difäm started a quality testing project for faith-based pharmaceutical agencies from various African countries. The objective was to determine the quality of locally and internationally procured medicines by the organizations. Ten commonly used essential oral formulations were targeted (Amoxicillin, Ciprofloxacin, Doxycycline, Ferrous Sulphate, Fluconazole, Ibuprofen, Metronidazole, Quinine, Sulfadoxine/Pyrimethamine and Sulfamethoxazole/Trimethoprim).

Organizations were invited to send samples to the quality control lab of MEDS in Kenya. 13 EPN member organizations from 11 countries participated in the first two rounds of this project. 92 samples were tested, of which 25 (27%) were manufactured within the country from where they were submitted. Four samples were produced by European or Canadian companies. All others were procured from other African or Asian countries (68%).

“All samples contained all necessary active ingredients in the right amounts.”

Encouraging results

83 of the 92 samples complied fully with the pharmacopoeia requirements. The nine samples (almost 10%) which failed all did not comply with the dissolution test. This was the only parameter for which there was no compliance. Insufficient dissolution time is a common problem in products produced by companies based in low or middle income countries, because the technique for obtaining an adequate dissolution period is difficult. Since dissolution affects absorption and subsequent blood levels, poor dissolution can influence therapeutic outcomes.

	Number of samples tested	Number of samples passed
Doxycycline	9	8
Sulfamethoxazole/Trimethoprim	11	7
Ibuprofen	10	10
Amoxicillin	9	9
Ferrous Sulphate	9	9
Sulfadoxine/Pyrimethamine	7	6
Ciprofloxacin	10	10
Fluconazole	7	6
Metronidazole	11	11
Quinine-sulphate	9	7

Overall, the results of the quality control tests were positive, although the sample size is small and results cannot be generalized. Church Pharmaceutical Agencies are aware of the importance of purchasing from reputable sources.

Detailed results of all tests are available to EPN members via the website <http://www.epnetwork.org/resources-for-members>. Registration is required.

Project carried out by MEDS/Kenya in cooperation with Difäm Tübingen/Germany as a Project of the Ecumenical Pharmaceutical Network. Funded by Difäm/Bread for the World. Started 2009, ongoing.

Quality issues in pharmaceuticals

Dr Guru Prasad Mohanta



This illustration on storage and management of medicines is part of EPN's Guidelines for effective and efficient pharmaceutical services.

While 'quality' is difficult to describe, in pharmaceuticals it is defined in terms of suitability for the intended use. Thus, several aspects are of importance: efficacy and safety of the product, conformity with specifications in terms of identity, strength, purity and other characteristics as specified in pharmacopoeia or pharmaceutical regulations. Quality Assurance covers all aspects that individually or collectively influence the quality of a product. For pharmaceuticals, it covers four major areas: quality control, manufacturing, distribution and inspection.

While a lot of attention is paid to quality assurance of the manufacturing processes, often distribution is a neglected area. Once products leave the manufacturing premises, they are not always kept in appropriate storage conditions, leading to deterioration of the products. The mandatory expiry date printed on the label is dependent on recommended storage conditions. If appropriate storage is not ensured, products can expire well before the expiry date! Such products are public health hazards. They not only lack effectiveness, they may even cause toxicity in patients.

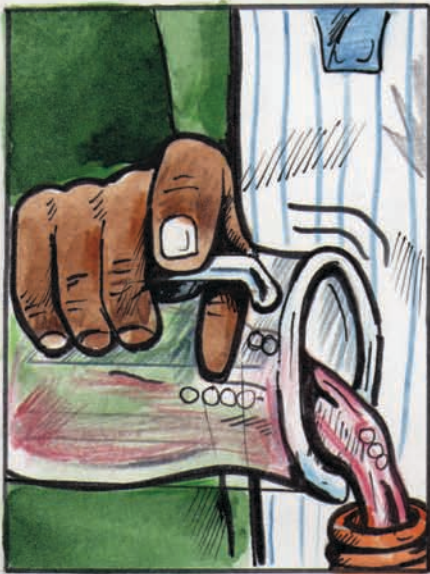
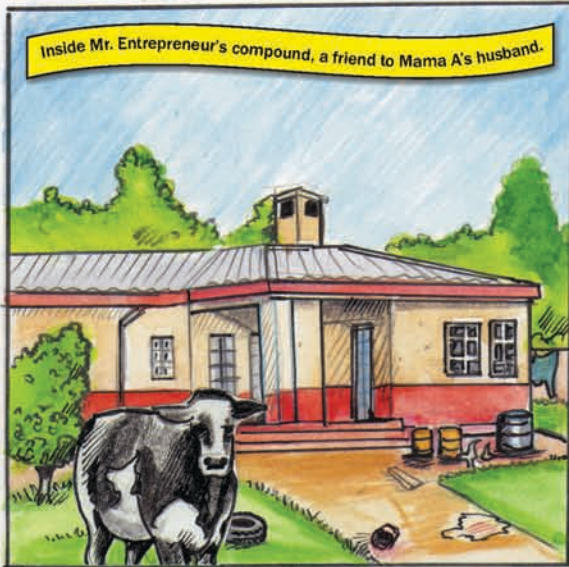
The procurement of pharmaceuticals is also an important step in the medicines logistic system, ensuring safety, efficacy and quality of the products. In a resource limited setting, when it is difficult to test the quality of the products to be procured or the procurement agency does not have a full fledged quality assurance system, it is recommended that use of WHO's pre-qualification scheme or certification of pharmaceutical products (COPP) be considered as strategies.

Quality of pharmaceuticals has been and should be a concern for everybody: manufacturer, suppliers, regulators and the end users, health care professionals and patients. But quality is dynamic and quality specifications vary from country to country. It is important that the specifications are not unnecessarily stringent as this would increase the cost of the product, thus threatening affordability, especially in resource constrained situations.

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Substandard medicines



To be continued.....



USAID FROM THE AMERICAN PEOPLE



Strengthening Pharmaceutical Systems



This comic strip is part of a series developed by EPN to provide information on containing the spread of antimicrobial resistance. Funding for the comic strips has been provided by the USAID supported SPS program of MSH.

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