



Assessment Study of the Pharmaceutical Sector in Somaliland Report from a visit to Somaliland 2012 04 12 – 2012 04 22

The study trip was performed by two pharmacists, Ulf Rydell and Rhoda Elmi, representing the organization Pharmacists without Borders, Sweden.

1. PURPOSE OF THE MISSION

In corporation with Somaliland Quality Control Commission (SQCC) following activities were performed:

- 1) to review aims and goals of the national strategies of the Somaliland (S.L.) government to provide essential and safe medicine to the people of S.L. and to review procedures to cope with Quality Assurance of medicines;
- 2) to review the organization, establishment, resources, procedures and practices of the public and private pharmaceutical sector;
- 3) to review importation, whole-sale and retail sales of pharmaceutical products in S.L.;
- 4) to review human resources within the pharmaceutical sector in S.L.;
- 5) to make recommendation for improvements pertaining to items 1) to 4).

2. BACKGROUND

Pharmacist Rhoda Elmi coming from Somaliland (S.L.) got a request from SQCC to assist in strengthening the pharmaceutical sector. Rhoda was after that given a small scholarship from Pharmacists without Borders (FuG) for this mission. Rhoda then asked pharmacist Ulf Rydell, who has been working in several low-income countries and has a great experience in this kind of work, to assist her in this mission.

Ulf and Rhoda concluded that the best way of doing this was to first perform an assessment study in S.L. in order to find out the present situation, what need to be rectified and which parts that are most urgent to start with.

Somaliland is a young "nation" which declared its independence only 20 years ago. Before, the country was involved in civil wars for a long time. This may be one explanation why there today are hardly any adopted rules, regulations or legislation existing in the pharmaceutical sector.

2010 a group of whole-salers started an organization to strengthen the quality of imported medicine and at the same time make an effort to prevent the influx of fake and substandard drugs from unserious drug salesmen/importers and even from smuggling.

2011 the Somaliland Quality Control Commission, SQCC, was appointed by the President to strengthen the quality of goods entering the country, not only on pharmaceutical products but also on food products, electrical equipment, building materials etc. SQCC is collaborating with different ministries e.g. Ministry of Health, when it comes to pharmaceuticals.

SQCC does not yet have any Control Laboratory of their own. Instead they use, when needed, WHO QC-lab in Nairobi. Assistance is sometimes also given from Central Hospital Laboratory in Hargeisa that can perform semiquantitative analyses for some products.

Besides quality control, SQCC does also have the duty to propose regulations for the pharmaceutical sector and to propose a National Drug Policy.

A few public and private hospitals give a subsidized medical treatment to certain groups (poor people) but as a rule people always have to pay for treatment and medicine. Many pharmacies are owned by prescribers. Special aid programmes, e.g. TB-programme, provide drugs free of charge for their patients.

3. ACTIVITIES

Litterature research was made via internet but no documents or reports have been found for this sector within Somaliland.

Interviews have been made with professionals like staff at hospitals, laboratories and pharmacies, with university staff and politicians. Also see travel report, Annex 1.

DIWO

The first visit was made to Drug Importer and Wholesale Association, DIWO, where we met four out of five boardmembers. DIWO was established in 2010 by pharmaceutical import trading companies, the main purpose of the formation of this organization came after considering currently growing business in Somaliland having no National Quality Control system to carry out quality control testing and ensure safety standards of all drug and pharmaceutical products. The second objective was to get every member informed about the importance of understanding that medicines must be properly manufactured, stored and dispensed and that pharmaceutical products can inflict harmful effects on human health if this has not been done.

The organization has set up six key rules, e.g. to buy from accredited manufacturers, to hold routine follow up meetings in order to make assessment on new development and that DIWO is committed to collaborate with Ministry of Health in Somaliland.

Somaliland Quality Control Commission, SQCC

SQCC is a new governmental agency which has been set up to protect Somaliland from the hazards of unsafe consumer products. SQCC began operating officially in 2011. In the past few months SQCC has opened offices in other major cities e.g. Berbera, Burao, Borama and Erigavo. SQCC has been working to develop policies and regulations for food safety and quality control of pharmaceutical medicines. Before SQCC started, the country has had no agency that controlled the quality and standards of consumer products.

SQCC started after DIWO. From now there is a good cooperation between DIWO and SQCC. In the future most of the tasks performed by DIWO will be performed by SQCC. Among these are instructions about what kind of documents that are needed for import.

SQCC have 66 employees out of which 30 are inspectors, 4 microbiologists, 2 chemists and 1 electrical engineer. Personnel are employed at all entry ports. For drug control there is today no qualified person at SQCC. In the beginning each ministry had their own control body but SQCC has now a combined direct mandate from the president. This is in order to avoid conflicts of interests. According to SQCC a Letter of Understanding (LoU) or regulations has to be made in order to divide respective area. Help from outside (experts) is wanted to develop this LoU and so that all parties can have a clear picture of respective area and responsibility.

A draft National Drug Policy (NDP) is proposed by SQCC. Some NDP:s from other countries have been used as templates.

Manhal hospital in Hargeisa.

Discussions with the director, specialized in eye surgery, and visit to the hospital pharmacy. The hospital is mainly a specialized eye hospital. Almost all such eye operations in the country, mainly cataract operations, are performed at this hospital. Specialist doctors from other countries are often contracted as consultants.

Central Hospital of Hargeisa.

Discussions with the director being a medical doctor, visit to the hospital pharmacy and the hospital laboratory. The laboratory had received equipment from German Pharma Health Fund for simple analyses of 53 different drugs. During 2012 so far 80 drugs had been controlled. 5 % were found to be fake. It was only possible to test if the drug is total fake, not substandard.

Edna Adan Maternity and Teaching Hospital in Hargeisa, Somaliland.

Discussions with the director being nurse and midwife. Visit to some hospital wards, the hospital pharmacy and some class room. This hospital is an education hospital which have training for nurses, midwives, laboratory technicians and pharmacy technicians. Education for the latest category was started because no educated people are available at the pharmacies. The first step of this education is for one year, which gives a certificate. The cleverest pupils can continue another year to obtain a diploma. 63 + 50 pupils have so far been educated. 50 students are presently attaining this class.

Several community pharmacies have been visited in Hargeisa and Berbera, both large and better developed ones as well as small and less developed ones.

Visit to the Minister of Health

There is a steering committee at the ministry, composed by 4 people, to tackle all problems within the pharmaceutical sector. One is an importer. Members from the committee visit pharmacies for control. According to the minister, they have not found any substandard drugs except one having only 70 % active substance.

Today, nobody is allowed to import drugs unless being a member of DIWO. The big problem is that a lot of drugs anyway enter the country by trucks and cars and then enter the black market.

According to the Minister, it is not possible today to regulate that trained personnel has to be a prerequisite for business as there are no such people available in the country. To get a temporary solution, plans have been discussed to initiate a three months training course for pharmacy technicians but so far such training does not exist. The Minister also express that there is a great need to get external financing to build a control laboratory.

Visit to the Minister of Finance

At the end of the mission our group had the opportunity to discuss our preliminary findings. The Minister was very aware of the problems and expressed the same concerns as given by professionals at SQCC, hospitals, pharmacies etc.

Visit to the General Director of Ministry of Commerce

Also the General Director was very aware of the problems and expressed the same concerns as the Minister of Finance.

The Minister of Presidency underlined that Somaliland needs all expertize assistance in order to improve the present situation of the pharmaceutical sector.

The President gave us time for a long meeting. The Minister of Finance and the Minister of Presidency were also present at this discussion. The President was very interested in our activities, findings and our preliminary recommendations. We had a very good opportunity to discuss with him and explain our view of the pharmaceutical sector. He expressed that he wants to do everything to support all necessary regulations to ensure the availability of safe medicine.

A Final report was given to SQCC. The session was attended by people from SQCC and other invited and concerned people. The whole session was also recorded by the National Television channel and was broadcasted the same evening. An English version was made as a documentary which was later broadcasted in Somaliland National TV channels all over Europe.

Outside the actual mission lectures at Edna hospital and Gollis University were given concerning Antibiotic Resistance. There were approximately 50 pupils and lecturers at Edna hospital and 60 medical students and lecturers at Gollis University attending these lectures.

4. FINDINGS

Negative findings:

There is a profound lack of pharmaceutical professionals in the country. There are no pharmacists or pharmacy technicians at the pharmacies. Other professionals in the pharmaceutical field like wholesalers and importers lack training for their job and especially there is no pharmaceutical knowledge in the governmental sector.

There are virtually no existing regulations or legislation updated for Somaliland conditions.

Importers of drugs have no pharmaceutical education or access to such competence like Good Distribution Practice (Quality Assurance of drugs when importing them, Proper stocking and storing, Maintenance of cold-chain etc.)

The pharmacy outlets have no educated personnel to maintain a pharmacy store concerning, storage, dispensing, counseling patients, ethics etc.

There is lack of adopted modern regulations concerning pharmacy licensing, e.g. who should own a pharmacy and what is needed to get such a license.

Many prescribers own a pharmacy which may lead to irrational, unnecessary and excessive prescribing.

There is no national quality control laboratory which leads to virtually no control of pharmaceutical products.

It is impossible to implement new guidelines and suggestions due to the lack of educated people to fulfill the recommendations.

Substandard and fake medicines are frequently detected in the market. Irrational prescribing, irrational advice given from pharmacies and frequent and sometimes very harmful adverse effects are found. Many substandard and obsolete drugs are sold, e.g. banned drugs and combination products having up to five ingredients per single dose, so called quick-fix drugs. Some drugs used in Somaliland are not allowed to be used in the country of manufacturing.

This was told by people from the ministries, hospitals, SQCC, DIWO and not at least by Somaliland people returning from many years living in high-income countries. Many of the last category being used to medicine with high quality, told us they always bought their own medicines from abroad.

See some quotes below from different people interviewed:

There is really a great need that the government realizes the problem and as soon as possible start to tackle this problem.

A great national problem is that the pharmacy business is like any other business, e.g. to sell clothes.

There are no special rules or control of drugs; they enter the country like all other goods. What is needed is a lot of regulations concerning this sector.

The impression of people selling medicine is that their first interest is not well-fare of the patient. Economical winning seems to be their driving force.

There is a great need of some kind of control mechanism over the importers.

There is so much rubbish on the market. The most common import of substandard drugs comes by car from Somalia and Ethiopia. What is needed in this country is to build some model pharmacies with a high quality and to announce to all people they have good medicines.

There should definitely be educated personnel at the pharmacies. It should not be too hard to train several paramedical pharmacists during a relatively short period. Then, after some years, there should be a prerequisite to be a pharmacist in order to own or run a pharmacy.

Positive findings:

Most professionals like medical doctors, importers and people at the ministries have a clear picture of the existing situation and all are expressing a willingness to do something about it.

The President is positive to approve all suggestions on regulations and legislation that can assure safe and rational use of drugs in Somaliland.

Education of pharmacists is ongoing at a university in Hargeisa. Presently 40 students are studying the second year out of four.

A one-year and a two-year training course for pharmacy technicians are ongoing at Edna maternity hospital in Hargeisa.

SQCC has got the mandate from the President to elaborate/propose regulations and a National Drug Policy for Somaliland. Proposal for some regulations and parts of a National Drug Policy from other countries have been drafted.

SQCC will control and approve all import documents.

If a DIWO member suspects fake or substandard drugs in the market, this will be reported to DIWO. In such cases, DIWO will take a first contact with the importer to urge him to withdraw the product from the market. If this importer does not comply with this he will be reported to MoH.

DIWO has succeeded in stopping fake medicines several times.

There is a good collaboration between DIWO and SQCC.

5. RECOMMENDATIONS IN PRIORITY ORDER

- 1) Somaliland should employ external pharmaceutical expertise, as short term consultant(s), to assist Drug Importers to
 - a) Find suppliers of Good Quality Medicines
 - b) Formulate demands and conditions in contracting drug distribution companies
 - c) Monitor suppliers service and quality and to set criteria for selection of accredited suppliers.
 - d) Learn about Drug Distribution Practice
- 2) A list of banned drugs should be made.
- 3) SQCC needs a legal authority from the President to act and to effect regulations and proposals to drug legislation.
- 4) SQCC should elaborate regulations on import and sale of drugs from all wholesalers or pharmacies
- 5) Somaliland should employ external pharmaceutical expertise as short term consultant(s) to
 - a) elaborate regulations on licensing of wholesalers/importers of drugs
 - b) set up criteria for getting a license as wholesaler, e.g. to either be a pharmacist or to have a licensed pharmacist employed in the company.
 - c) elaborate regulations on licensing pharmacy owners
 - d) set up criteria for licensing pharmacy stores e.g. about storage, banned drugs, temperature, hygiene, stock control system, expired drugs monitoring etc.
- 6) Somaliland importers should only be allowed to import drugs from companies conforming to Good Manufacturing Practice and approved by the Medical products agency in the country of manufacturing.
- 7) The use of WHO Certificate Scheme, Certification of Good Manufacturing Practice and Batch certificates should be more frequently used in the procurement process.
Set conditions in procurement contracts should be enforced.
- 8) A budget for sampling and quality control testing of "suspected" drugs should be allocated in the MoH budget.
- 9) Somaliland should employ a drug quality control specialist to elaborate a plan for suitable equipment and premises for a quality control laboratory, including draft cost for such a laboratory.
- 10) Ministry of Health or the President should act to effect a comprehensive drug legislation based on SQCC: s proposals.
- 11) The Government should discuss the issue of Conflict of Interest when prescribers also are importers of drugs and/or own a pharmacy outlet.
- 12) Somaliland should employ external pharmaceutical expertise as short term consultant to give training to all pharmacists/drug sellers in Good Pharmacy Practice. This should also be included in the curricula at the university for pharmaceutical students and at Edna maternity hospital courses for pharmacy technicians (if not already done).

- 13) SQCC should strongly suggest and support the establishment of a National Drug Policy. Somaliland should employ a pharmacist to elaborate a comprehensive NDP. Among the first steps to be taken are the establishment of registration procedures based on the Essential Drugs Concept, followed by an updated legislation and an inspectorate.

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