Quality Infrastructure for the Health Sector

We need to be healthy to lead a life worth living that we can determine ourselves. According to the United Nations, we have the right to the best possible healthcare. And for us to be able to implement this right, medical diagnostics must be accurate and reliable. Drugs and vaccines must likewise be effective. This is not the case everywhere in the world. To this end, quality infrastructure helps to provide the right conditions for improved healthcare. It ensures, for example, that drugs contain the correct amounts of active ingredients, that medical equipment both works well and measures properly and that this leads to reliable results. All these quality assurance measures are also essential for effectively preventing and fighting pandemics.
Initial Situation

Only those of us who are healthy can participate in the social and economic aspects of life. Global health and physical self-empowerment are thus currently in the focus of German development cooperation. Germany’s dedicated development policy in the health sector is based on Goal 3 of the 17 Sustainable Development Goals (SDG) of the United Nations: Good Health and Well-Being. The development policy aims to reduce the mortality rate of mothers and newborns as well as to combat AIDS, tuberculosis, malaria and other neglected tropical diseases. To achieve this, research and development on vaccines and drugs combating diseases that mainly affect developing countries are to be supported. Furthermore, access to important drugs and vaccines that are affordable is to be improved.

The SARS-CoV-2 pandemic showed how relevant worldwide vaccine production and well-functioning healthcare systems are for combating such diseases. These systems are not conceivable without the contributions made by a suitably developed quality infrastructure. In many newly developed countries and in most of the developing countries, the majority of people do not have access to adequate healthcare. What is more, medical services such as laboratory diagnostics and pharmaceutical manufacturing still do not meet international good practices there. Regulatory authorities and control laboratories often lack qualified staff and the necessary technical equipment to be able to monitor and adequately examine imported and locally manufactured drugs. In addition, the complex supply chains in the pharmaceutical sector extend the responsibility of the regulatory authorities. They have to examine vast amounts of information and monitor different processes which take place outside their national borders and possibly exceed their capabilities. This might lead to fake or poor-quality healthcare products not being detected before they make their way to the market. Patients are therefore put at risk as they cannot rely on the accuracy and correctness of the laboratories’ measurement results, on the ingredients of drugs or even on their efficiency. In addition, the high costs of new imported drugs and vaccines as well as the absence or poor quality of distribution systems have consequences. They limit the access to high-quality drugs along with the supply of such products.

A competent and demand-oriented quality infrastructure is important for strengthening the healthcare systems in our partner countries. This type of quality infrastructure also ensures the conditions that are required for local drug and vaccine manufacturing. It enables reliable and comparable measurements, analyses and imaging methods in medical laboratories as well. Doctors must be able to rely on these results as they base their diagnoses on them. Without assuring the quality of these processes, false diagnoses are a routine problem – a problem that puts the lives of many patients in the developing countries and emerging economies on the line. Moreover, feminist development policies state that health must not be a matter of gender. This means that the governments of our partner countries are being supported in providing women and men with equal access to healthcare.

Contribution

PTB’s International Cooperation group is contributing significantly to health protection by establishing a suitable quality infrastructure. It does this by strengthening its partners’ capabilities and competences via bilateral or regional projects all over the world while focussing on the needs of its partners. Those cooperating partners are national authorities, laboratories, manufacturers of medical and pharmaceutical products and their associations as well as international networks and organizations such as the World Health Organization (WHO). PTB’s contributions to developing a functioning quality infrastructure are geared to Germany’s Federal Ministry for Economic Cooperation and Development’s (the BMZ’s) core area of health, social protection and population policy. PTB’s contributions are furthermore especially relevant to three topics in the health sector:

- The production and quality assurance of drugs and vaccines
- Quality management in medical laboratories and
- The reliability of medical devices
Drugs and vaccines
The effectiveness and safety of drugs is of crucial importance for sound healthcare. National authorities in our partner countries are therefore being strengthened in their ability to exercise their control and monitoring tasks. One way of doing this is by improving market surveillance. In addition, it will be possible for drug and vaccine manufacturers as well as the control laboratories of the regulatory authorities to apply the relevant principles for manufacturing and examining drugs and vaccines. This will take place in each quality control step and will be in line with international standards (good manufacturing practices), standards of the International Organization for Standardization (ISO) and the directives of the WHO.

Extending vaccine production in developing countries is a particularly important instrument for globally fighting and preventing pandemics. Since 2021, the BMZ has been supporting the setting-up of vaccine production on the African continent in line with international standards. In cooperation with the African Union and international partner institutions, PTB is working on enabling local enterprises to manufacture and market high-quality vaccines and drugs. These include malaria vaccines and essential drugs such as antibiotics and analgesics. The quality control and approval realized by the regulatory authorities are two of the biggest challenges. PTB supports the capacity building of such regulatory authorities on the African continent with a special focus on Ghana, Senegal, Rwanda and South Africa.

Medical laboratories
Quality assurance and quality management (QM) in medical laboratories have increasingly gained importance following the SARS-CoV-2 pandemic. PTB supports the introduction of such QM systems. By doing so, it significantly strengthens trust in the work of medical laboratory diagnostics for the best possible healthcare for the population. Only the services of medical laboratories based on measurement and analysis results make it possible to evaluate the health condition of patients. These, in turn, lead to correct diagnoses being made. To this end, uniform standards such as norms are required to ensure the comparability and reliability of the laboratory results. In therapy, properly adjusted applications and reliable monitoring data are of paramount importance for treatments to be successful.

The international standard ISO 15189 lays down the specific requirements for QM in medical laboratories throughout the world. Applying these requirements is intended to guarantee both the expertise of the personnel and the quality of the laboratory services as well as consistently valid analysis results. This also ensures international comparability across national borders. Such comparability is becoming more and more important in these times of increasing mobility, especially in the healthcare sector. PTB projects, for example in the Palestinian Territories, are accompanying medical laboratories as they achieve accreditation (that is, the recognition of their competence by an independent accreditation body). This step is often a prerequisite for the acceptance of laboratory results at home and abroad. PTB also gives expert advice and support to providers of interlaboratory comparisons. These comparisons are a central instrument for ensuring the quality and comparability of laboratory results. Supporting the bodies that perform such tasks helps them to fulfil their important role.

Medical devices
Modern medicine depends on reliable medical devices and accurate measurements. Quality infrastructure plays an important role here too. Simple medical products such as thermometers or blood pressure monitors – but also complex devices like X-ray and ultrasonic equipment or medical lasers – have to be tested and calibrated in numerous ways. Measurements for diagnostics and therapy monitoring have to be carried out using exactly defined methods which can be found in norms and technical regulations. In addition, the staff have to be trained to work with this equipment. At the national level, this requires the suitable legal framework conditions and ideally the introduction of QM systems in the medical facilities. PTB provides support here both in the field of standardization and in the field of metrological assurance via national metrology and calibration institutions. It also supports the numerous aspects of quality assurance.
Impacts

By promoting the quality infrastructure in BMZ’s partner countries, PTB is helping to make demand-oriented, competent and internationally recognized services available for the health sector. Patients benefit directly from improved diagnostics and treatment in a number of ways, including functioning QM systems that help to prevent false diagnoses. PTB also supports regulatory authorities and control laboratories to assume their monitoring and control functions more competently and efficiently according to international good practices. This leads to more effective protection against ineffective or fake drugs and vaccines. In addition, it ensures confidence in locally registered drugs that are on the markets. This, in turn, increases the availability of safe and affordable healthcare products and contributes to the population having better access to quality-assured healthcare services.

With PTB’s projects being geared towards international standards and good practices, we can ensure that no isolated stand-alone solutions are established. This also avoids interference with the ever-growing international networks in the healthcare sector. Cooperation, exchanges of information and harmonization are growing more and more important in the complex pharmaceutical sector with its global supply chains. PTB additionally supports this exchange between the private and public pharmaceutical sector as well as the harmonization initiatives in the field of international practices in numerous projects. Some of our work in this sector has been at the continental level in Africa and also in Nepal.

Quality assurance in the healthcare sector has positive effects on protecting health and preventing pandemics too. A well-developed quality infrastructure also contributes to improved systems of prevention by reliably diagnosing risk factors. These risk factors might relate to cardiovascular diseases, cancer, diabetes and also pathogens at an early stage. Such activities help to reduce costs for national healthcare systems.

This is also true if vaccines and essential drugs are manufactured locally. By doing this, risks caused by trying to curb pandemics or diseases that mainly affect developing countries (e.g., malaria, tuberculosis, helminthiasis, AIDS) are minimized.

All in all, improved healthcare systems make a considerable contribution to good governance with positive social effects and an impact on development policy. Resilient and effective healthcare systems are essential for meeting the current challenges of climate change affecting human health and future worldwide pandemics. A well-functioning quality infrastructure therefore gives the health sector the support it needs.

Quality infrastructure is not everything, but without quality infrastructure, everything is nothing.