Ethiopia

Laying foundations to fight substandard and falsified medicines

Challenge

Substandard and falsified medicines represent a real and growing risk to patient safety. The sheer complexity of the pharmaceutical supply chain makes it a difficult issue to stamp out. At best, any patients who ultimately use a substandard or falsified medicine will find it does not treat their condition. At worst, these products can cause actual harm.

In Ethiopia, a national study conducted in 2013 suggested 7.8% of medicines in the country were substandard, meaning they failed to meet quality standards and specifications. Various data since then has also identified products which are falsified, meaning they deliberately misrepresent their identity, composition or source.

Approach

In Ethiopia, work is underway to ensure each and every medicine in the country has a unique identifier with proper barcode. Scanning this will immediately identify the medicine. This will make it possible to track and trace products through the supply chain, but also to quickly identify any medicine which is fake or substandard.

The rise of substandard and falsified medicines

Back in 1985, the World Health Organisation (WHO) held a conference which served to draw attention to an emerging problem: that of substandard and falsified medications.

Four decades on, it is an issue which has become a significant concern. Such products are now found across the globe. Many are so-called 'lifestyle' drugs: the likes of hormones and steroids. But there are also medicines used to treat potentially life-threatening conditions, notably malaria and HIV/AIDS. That means substandard and fake medicines are a pressing concern on the continent in which that 1985 conference was held – Africa.

In Ethiopia, it is envisaged that traceability will play a crucial role in minimising the harm that can be caused by such products. In 2019, legislation was passed requiring all those involved in the country's pharmaceutical supply chain to use unique identifiers encoded in barcodes based on global standards. Scanning of these will make it possible to track and trace the journey of medicines through the Ethiopian healthcare system – and, importantly, to immediately identify any product that is illegitimate.

The legislation followed a national study in the early 2010s which suggested 7.8% of medicines in the country were substandard, meaning they failed to meet quality standards and specifications. Marketing surveillance since has also identified some products which are falsified, meaning they deliberately misrepresent their identity, composition or source.

The importance of standards

The infiltration of substandard and falsified medicines in the country has been combatted through regulatory mechanisms. That has included federal, regional and district regulation of medicines. There have also been efforts to bolster the ability to test for poor quality medicines. The laboratories run by the Ethiopian Food and Drug Authority (EFDA) became certified under ISO/IEC 17025:2005 as able to test medicine quality.

Such efforts were important, but unable to entirely address the issue. "Using those mechanisms alone it was really difficult to identify substandard and falsified medicines. In addition, full traceability with proper exchange of information among the supply chain stakeholders is crucial," explains Kidanemariam Gebremichael, lead for the country's pharmaceutical track and trace project.

That's why pharmaceutical manufacturers are now being asked to share their product and location master data with the Ethiopian Food and Drug Authority. This is core information such as the name of a product, strength, dosage form, expiry date, batch/lot number, its ingredients, location information of the manufacturer. The idea is to make sure that the same information is available about all medicines used in the country and, ultimately, to ensure supply chain efficiency, patient safety and data visibility.

Progressing towards full traceability

The country has already made good progress on its traceability plans since the passage of initial regulation. This has included:

- Establishing a traceability office to support the work.
- Establishing a national steering committee to drive traceability activities and oversee implementation of the initiative. Chaired by Heran Gerba, the director general of EDFA, it includes representatives from government agencies, professional associations, development partners, and supply chain stakeholders.
- Developing and endorsing laws and implementation strategies.
- Developing and issuing various guidance detailing how the traceability system will operate.
- Conducting awareness sessions with stakeholders including government, private sector and the general public.
- Developing the requisite foundational technology to support the traceability system. This includes iVerify, an application developed for the general public to be able to verify authenticity of medication. The iVerify app is linked to a database of authentic medicines maintained by the EFDA.
- Communicating with manufacturers and starting to receive master data, an important foundation for traceability.

In March 2021, the EFDA published the Pharmaceutical Products Traceability Master Data Guideline, which serves as a guide for supply chain actors and stakeholders to share master data using standardised data attributes. In December 2021, it published the Pharmaceutical Products Barcoding Guidelines and guidance on Global Trade Item Number (GTIN) and Global Location Number (GLN) allocation.

The EFDA, with support from the United States Agency for International Development (USAID) Digital Health Activity, is also developing a suite of systems to support traceability initiatives. This includes a National Product Catalogue (NPC) tool with an associated mobile application. The tool, designed as an information repository for managing master data, acts as a single source of information. Manufacturers and other pharmaceutical supply chain stakeholders will be able to share master data on the platform, and other local systems will use the tool to ensure standardisation in product nomenclature.

The NPC tool is integrated with existing electronic regulatory information systems such as i-Import and i-Register, which will automatically feed information about drugs approved by the EFDA into the NPC.

Another system under development is i-Clearance, which will be used to manage the clearance of pharmaceuticals from the port of entry. The tool will enable manufacturers to share pre-shipment information, including GTIN, expiry date, batch/lot numbers, and serial numbers and will make this information available to supply chain stakeholders prior to the arrival of the product in Ethiopia.

Patience and communication is key

Those working on the project in Ethiopia say patience is required in implementing pharmaceutical track and trace projects. "Manufacturers are requesting time and we give them time to arrange their packaging and labelling to our requirements," says Mr Gebremichael. "We are expecting them to label their products according to our requirements, but we're not stringently going after enforcement yet because we and they need to have platforms correctly structured and in place."

Communication about what is needed and why is crucial, he says, but this can present additional challenges in Ethiopia. "In most cases, we communicate through the agents that are available in Ethiopia because most of the manufacturers are overseas and we cannot approach them directly. So we approach the local agents, the importers in Ethiopia, but most of the time they are not clear on the traceability system and there are also communication gaps between the local agents and the manufacturers."

The importance of engagement

It's why a conference held in Addis Ababa in 2018 is cited as having been vital to advancing the case for traceability. The African GS1 Healthcare Conference brought together 350 participants in all, with 24 African countries represented as well as some other nations. The idea was to share knowledge on the overall implementation of traceability and on how using standardised barcodes throughout the healthcare supply chain can improve safety.

"The local manufacturers, local importers and the other local participants were excited and felt it should be implemented," remembers Yeshialem Bekele, track and trace project coordinator at Ethiopia's Food and Drug Authority.

"It increased the involvement of the stakeholders, especially supply chain stakeholders, and they were interested to engage in the project," adds Mr Gebremichael.

"I think engagement of all stakeholders is very important in implementing track and trace. We have to engage government institutions, especially those like the Ministry of Finance, Innovation and Technology and communication. Private institutions, including the manufacturers, importers, even the low-level institutions should also be engaged. The media should be engaged."

This too takes patience. It is part of the reason that Ethiopia's plan envisages seven years between the original intention to introduce a traceability system and its full implementation. But the communication that has taken place so far has led to a dedication to complete the journey.

About the authors

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Heran Gerba is director general of the Ethiopian Food and Drug Authority (EFDA). She has over 18 years of experience working in various managerial and technical positions in EFDA, including physicochemical and pharmaceutical microbiology analysis, head of a physicochemical division, team coordinator for the pharmaceutical microbiology section, good manufacturing practice inspector, and senior medicine dossier assessor. Heran earned a master's degree in pharmaceutical analysis and quality assurance and a bachelor's in pharmacy from the Addis Ababa University School of Pharmacy.

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Yeshialem Bekele has been the coordinator of the traceability unit at the Ethiopian Food and Drug Authority (EFDA) since 2018. She has 25 years of experience working in various managerial and technical positions in the health sector at federal level, and in regional health bureaus and hospitals.

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Kidanemariam G/Michael has 14 years of healthcare experience and has held various management and leadership positions within EFDA. He is currently the track and trace project manager and the pharmaceutical regulation advisor to EFDA. Mr Kidanemariam is responsible for implementing a pharmaceutical traceability system in Ethiopia and for digitisation and strengthening of the pharmaceutical regulation systems.

About the organisation

The Ethiopian Food and Drug Authority (EFDA) is a government organisation managed by the Ministry of Health. The EFDA, at present, is the national regulatory authority in the country mandated by Food and Medicine Administration Proclamation No. 1112/2019 to ensure the safety, quality, and/or effectiveness of food and medical products. Its headquarters are in Addis Ababa and it also has seven branch offices and 15 ports of entry (POE) across the country.

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