Challenges for Implementing Pharmaceuticals Drugs Traceability in Developing Countries

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Abstract; The purpose of this paper is to focus on the challenges for the implementing digital traceability of pharmaceuticals drugs in developing countries. The digital traceability of pharmaceutical drugs has been proving a very impactful process to minimize the risk of counterfeit and illicit drugs in the market. Developed countries like Unites States of America in 2018, and Europe in 2019, made unique identifier with 2D barcode mandatory in each drugs packet. Unique identifier on each packets provide provision of digital traceability since drug manufacturers encode them and keep the data in their repository Any stakeholders in supply chain can easily verify the authenticity of product by asking manufacturer to compare product values with their database. Implementing digital traceability of pharmaceutical drugs in developing countries will be challenging due lack of technical infrastructure, weak regulations, geopolitical instability, poverty, low literacy, and government willingness. Developing countries are facing economic depression and unable to allocate funds on research and development which can improve overall healthcare system. Recently COVID-19 also played a major role for collapsing their entire healthcare infrastructure. Developing countries impacted by global supply chain restrictions and unavailability of resources which created inflation and unemployment.

Keywords: Drug Traceability, Pharmaceutical Serialization, Developing Countries, Technical Infrastructure, Track and Trace System.

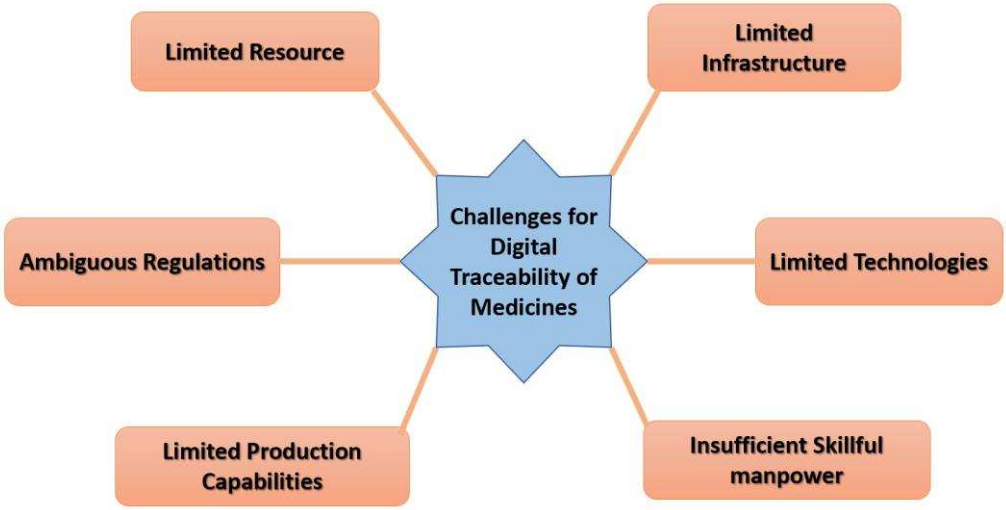
I. INTRODUCTION

In many developing countries falsified or counterfeit drug have been a serious threat to public health for a long time. These countries are either lack of essential medicines for main disease or available with counterfeit drugs. Providing safe, effective, and affordable essential drugs and supplies is one of the elements of health for all indicators set by World Health Organization (WHO) in Alma Ata in 1978 and revitalized in 2008. It is

estimated that about 30 percent of the world's population lack regular access to essential medicines and that in the poorest parts of Africa and Asia, the percentage is more than 50 percent [2-4].

Developing countries have limited provisions to treatments for infectious diseases, which are the main cause of morbidity and mortality in developing countries, and the supply of medicine to cure other diseases, is difficult or depended on supplies of develop countries as charity or WHO grants. Infectious and parasitic diseases account for only five percent of the disease burden in high-income countries [6] but represent about 50 percent of the developing countries' burden of disease [5]. Essential medicines are diverted to these countries by drug traffickers and criminals. Mostly essential drugs are available illicitly in black markets on very high price, contaminated or inferior quality. These drugs do not improve patient health and many occasion poised serious health condition. Studies have shown that, out of 1,556 new active substances developed between 1975 and 2004, only 21 were intended for treating neglected tropical diseases including tuberculosis and malaria [6]. Criminals and drug traffickers are taking advantage of existing inaccessibility of medicine for public and supply counterfeit drugs into market.

Figure 1: Challenges for Implementing Digital Drug Traceability in Developing Countries.



II. LIMITED INFRASTRUCTURE AND PRODUCTION CAPABILITIES:

Major Pharmaceutical companies does not invest and establish production units in developing countries due to geopolitics, market inaccessibility and government instabilities. They are more focused on manufacturing and circulation of branded medicines in developed countries like USA and Europe due to per capita income and pricing monopoly. Developing countries faces major challenges on pharmaceutical industries investment due to poor infrastructure and lack of government funds for research and infrastructure improvements. Existing pharmaceutical units are struggling to meeting global standards due to need of heavy investments in new production and packaging machineries. Digital pharmaceutical products traceability provisions require additional space in manufacturing units for specialized packaging equipment's to print the unique identifier in all packaging levels, label grading systems, barcode printer and vision systems. This setup needs huge financial investment for manufacturers. Wholesaler and dispenser also need to invest on drug scanner and specialized software which must connect to centralized database for verification. Since developing countries does not have sufficient infrastructure so implementing digital drug traceability is a question.

III. UNSECURE AND UNRELIABLE TECHNICAL INFRASTRUCTURE FOR DIGITAL DRUG TRACEABILITY

Technology advancement is another main challenge in developing countries for authenticating and tracing pharmaceutical products digitally. In recent years, some developed countries like US and Europe have adopted serialization regulation under which drug manufacturer require to print a unique identifier printed with the 2D barcode on individual drug unit. This unique identifier is key source for authenticating drug and tracing its origin of manufacturing. Printing unique identifier and keeping its key data in repository required special packaging equipment, tamper proof seals and global traceability software. The entire setup to serialize drugs for digital traceability required huge investment and developed infrastructure (secure network, high speed internet, skilled resources, and fully digital warehouses).

Majority of pharmaceutical manufacturers consider this traceability provision as additional investment which may increase drug cost. It has been noticed that printing unique identifier in drug pack is not sufficient for checking drug authenticity and traceability. For real time traceability and validating authenticity, all stakeholder's system should be connected to each other with a centralized cloud system [7] (EU-FMD model

for Europe). Due to lack of technical system integration for validating authenticity drugs digitally, criminals or counterfeit manufacturers can easily copy the product unique identifier and supply into the markets.

India is leading manufacturer and exporter of Generic drugs. On 10 January 2011, Directorate General of Foreign Trade (DGFT), issued a public notice announcing all pharmaceutical drugs exporter must implementation of a track and trace system for serialization as per GS1 standards. Under this notice, all export pharmaceutical consignments should be serialized at various packaging levels using GS1 barcode standards. [9]. Drug manufacturers in India faced grave challenges to implement track and trace solutions due to non-readiness of traceability technologies aligned with DGFT requirements. Many manufacturers had old packaging equipment's which were not capable of encoding serialization data in packaging hierarchy.

India's DGFT regulation also made obligatory for manufacturer to upload Serialization data in DAVA portal (centralized database) in specific format. Due to limited technical capabilities of DAVA portal and its irregular operational functionalities, drug manufacturers and exporter were facing custom issues. The main cause was DGFT requires the use of a product numbering scheme that is inconsistent with global data standards. As a result, manufacturers are forced to choose between changing their entire numbering scheme—a cost that cannot be justified—and applying multiple product numbers to packages. The latter has caused significant operational challenges in countries of import and slowed or stopped the distribution of pharmaceuticals made in India. The drug manufacturer and exporter faced key challenges of portals irregular operational, drug. Another major issue is the availability of Internet in every part of developing countries for drug traceability and authenticity. Digital drug authentication and traceability is completely depending on internet availability and connectivity with governments centralized database. Due to unavailability of basic infrastructure like communication, radio frequency and communication towers, it is very difficult to provide internet connectivity and secure network to drug dispensers in villages and remote areas.

IV. AMBIGUOUS REGULATIONS

Regulatory obligation plays a vital role to implement track and trace system for traceability.

Developed countries like US in 2018 and Europe in 2019 implemented serialization compliance successfully for drug traceability. Before making digital traceability an obligatory regulation, DSCSA a drug controlling body of FDA runs pilot programs with joint initiative of drug manufacturers, wholesale distributors and community pharmacists. [10] Joint pilot programs are very important to understand current industries status and challenges, stakeholders' capabilities and improvement require to implement regulations.

Developing countries generally does not focus on pilot programs with the collaboration of all stakeholders. Majority of the policies in developing countries and directed without and due diligence. In India, DGFT's requirement that manufacturers upload "dummy" or fake serial numbers for primary packages (i.e., individual vials, blister cards, or bottles) that are not serialized is possibly the most confusing requirement. Since the DAVA system requires the upload of serial numbers for these primary packages, DGFT advised manufacturers to upload "dummy" or fake serial numbers for primary packages that are not serialized.

Government and regulatory bodies must assess impact on current market capabilities, assessment and due diligence, availability of basic infrastructure & technologies and complexity of defined processes before enforcing compliance.

V. INSUFFICIENT TECHNO-FUNCTIONAL RESOURCES FOR IMPLEMENTING AND SUSTAINING DRUG TRACEABILITY

Drug counterfeiting a serious threat to public health. It is a collective job for every stakeholder in supply chain to prevent counterfeiting and illicit drugs. Implementing and sustaining serialization system for drug traceability required skillful resources. Serialization and drug traceability processes involve packaging lines, Barcode readers, scanner, label grading system, site and global level serialization system which can handle drug traceability globally. Any human, mechanical and technical error can cause adversely to human life.

The technical literacy rate in developing countries is not promising. The fact sheet released by the United Nations Educational, Scientific and Cultural Organization [12] (UNESCO) from the Institute for Statistics shows that Sub Sahara Africa and Southern Asia have the lowest literacy rates with literacy rate below 50 percent in most countries. Low availability of techno-functional resources to implement and sustain end to end serialization and drug traceability process is another challenge for developing countries.

VI. CONCLUSION:

Counterfeit and illicit drugs are global problem. Majority of counterfeit drugs are supplied in developing or poor countries like south Asia and Africa, the proportion of fake pharmaceuticals can rise to 70 percent. Roughly one-third of the world's countries lack effective drug regulatory agencies, making them easy prey for counterfeiters. The absence of anti-counterfeiting measures exposes millions of people to potentially lethal chemicals and undermines the growth strategies of companies looking for new markets.

Implementing drug traceability system is necessary for stopping counterfeit and illicit drugs but developing countries are facing key challenges such as insufficient grants for infrastructure improvement, unavailability of secure technology and incapability of local pharmaceutical manufacturers to adopt and invest on drug traceability system. They also face other challenge such as grappling with structural vulnerabilities such as persistent social and economic inequalities, conflict and forced displacement, declining trust in government, the impacts of climate change, and environmental fragility.

Developing countries can adopt some best practices to mitigate drug counterfeit until they implement good drug traceability system. They can promote people awareness programs, audio-visual advertisements, seminars, and door to door campaign to educate about drug purchasing sources. Similarly, government can also setup government funded pharmacy and regression monitoring on private drug vendors.

In good healthcare system healthcare professionals as well as patients should be vigilant about the source of medicines. They should evaluate the response, educate others regarding inspection of the authenticity of the drug acquired, and report in the case of suspected drugs. Government and pharmaceutical manufacturer must be educated about the implementation of good drug traceability technology and make consumers aware of such strategies used. Regulatory authorities must conduct regressive monitoring plans and devise necessary measures to ensure the absence of counterfeits, strict the law and increase penalty for pharmaceutical counterfeiting based on the risk on public health.

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