LANDSCAPE ANALYSIS OF VERIFICATION AND SERIALIZATION SYSTEM IN UKRAINE

March 2019
About This Report
This report presents the output of landscape analysis from USAID’s Safe, Affordable, and Effective Medicines for Ukrainians (SAFEMed) Project to evaluate the challenge with substandard and falsified medical products around the world and how the implementation of verification systems have been able to combat this issue.

Contributors
Ivan Loboda, Senior Technical Advisor, SAFEMed
Michael Shumilin, Consultant, SAFEMed
Olena Vlasyuk, Monitoring and Evaluation Technical Advisor, SAFEMed

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In addition, the legal analysis portion was completed by Meghan Iorianni who is a U.S. Attorney Advisor to the Antimonopoly Committee of Ukraine. The views expressed in her legal analysis do not reflect the views of the U.S. Federal Trade Commission.

DISCLAIMER
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<td>INN</td>
<td>International Nonproprietary Name</td>
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<td>NEML</td>
<td>National List of Essential Medicines</td>
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<td>SAFEMed</td>
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In order to gain more in-depth understanding of the overall problem with substandard and falsified (SF) medical products and how other countries have combated the issue, USAID’s SAFEmed project carried out a landscape analysis that included a desktop review of policies and guidance on the subject matter coupled with interviews with relevant stakeholders in Ukraine to understand their perspective on the issue.
INTRODUCTION

With funding from the United States Agency for International Development (USAID) the Safe, Affordable, and Effective Medicines for Ukrainians (SAFEMed) project applies health system-strengthening best practices to create evidence-based interventions and strengthen Ukraine’s pharmaceutical system in line with the Ministry of Health’s (MOH) health care reform objectives. SAFEMed seeks to improve access to appropriate, quality medicines to maximize availability within MOH’s budgetary constraints. SAFEMed interventions work to institutionalize rational medicine selection, strengthen and systematize public procurement of pharmaceuticals and commodities, support sustainable public sector pharmaceutical financing, and strengthen the pharmaceutical supply chain in collaboration with the Government of Ukraine (GOU), the MOH and the National Health Service of Ukraine (NHSU), civil society partners, other implementing partners, and the private sector. SAFEMed’s approach aligns with Ukraine’s National Health Care System Reform and the partnership agreement between Ukraine and the European Union (EU), which requires that pharmaceutical reforms align with EU standards.

The strategic approach of SAFEMed supports PEPFAR’s priority of sustainable partnerships by building the capacity of the MOH and its sub-units to effectively and reliably specify, select, and procure all health commodities required for the Ukrainian health system; this includes ARVs, medicines for TB and multidrug-resistant TB, HIV diagnostics, and techniques and approaches that are sustainable and will become self-sufficient over time. SAFEMed takes a broad view of the health environment, including recognizing the need to build transparent and corruption-free entities that will increase the population’s confidence in the health system of Ukraine. This includes utilizing the skills and knowledge of Ukraine’s specialist anti-corruption implementing partners to design organizational structures that are the least vulnerable to corruption and the ability to assess corruption risk in the design and development of entities, such as the Central Procurement Agency (CPA) and the proposed health technology assessment (HTA) entity. In pursuit of its goal, SAFEMed has three primary project objectives:

1. Strengthening governance within the pharmaceutical sector of Ukraine;
2. Optimizing the financing of the pharmaceutical sector; and
3. Increasing the availability and appropriate use of medicines in Ukraine.

Activities are implemented via technical, financial and legal assistance in the following work streams—priority settings, procurement, reimbursement, supply chain—as well as quality assurance with focus on bioequivalence and verification coupled with communication as cross-cutting areas. When combined, work streams and activities collectively strengthen the system from all angles—from medicines selection to forecasting to actual procurement to assuring quality.

In order to gain more in-depth understanding of the overall problem with substandard and falsified (SF) medical products and how other countries have combated the issue, SAFEMed carried out a landscape analysis that included a desktop review of policies and guidance on the subject matter coupled with interviews with relevant stakeholders in Ukraine to understand their perspective on the issue. This landscape analysis is one of the key first steps in the process of implementing verification policies in Ukraine.
METHODOLOGY

In February – March 2019, SAFEMed conducted a landscape analysis to develop a clear and timely perspective of challenges and opportunities for the introduction and roll out for the coding of secondary packages of medicines in Ukraine. The core objectives of this landscape analysis were to:

- Build more in-depth understanding of the current ecosystem for creating and adapting the central medicines verification strategy in Ukraine
- Conduct a legal review of the legislation from the European Union
- Validate initial findings through interview of key in-country stakeholders in Ukraine
- Develop recommendations and options for the future to the Ministry of Health of Ukraine for the introduction of the system of coding of secondary packages of medicines (aka as medicines verification system) in Ukraine aligned with European Union standards and modern approaches. Such recommendations will serve as a starting point to:
  - Inform decision making for medicines verification strategy development and policy changes
  - Bring together key stakeholders from the public and private sectors, donor community and patients’ groups to identify local, sustainable solutions owned by government, supported by the private sector, and appreciated by patients
  - Pilot and document the medicines verification system in one Ukrainian oblast.

Literature review

The landscape analysis began with a desk-based literature review of publicly-available information accessible online in English, Ukrainian, and Russian. Key findings from the literature review were summarized in the background session of this report.

Mapping of key stakeholders

The online research was then supplemented by face-to-face meetings with key in-country stakeholders to validate initial learnings from the literature review. As a next step, SAFEMed conducted stakeholder mapping exercise to identify key in-country influencers, thought leaders and decision-makers representing respective government agencies, private sector, patient’s groups and leading donors. A total of 20 stakeholders were identified. See next page for the list of key stakeholders.

Interviews with key stakeholders

SAFEMed reached out to all 20 stakeholders, out of which 16 were available for a meeting conducted by the project staff. The meetings took place on March 18 – 26, 2019 in Kyiv, Ukraine. All interviews/meetings were conducted using semi-structured questionnaire guide. See Annex A for a sample of the questionnaire used. Association Agreement between the European Union and the European Atomic
Energy Community and their member states, of the one part, and Ukraine, of the other part, served as key guiding principle for the development of questions.

These dialogues provided additional information not readily available otherwise. The findings from these discussions also served to validate desk-based research, and provided new insights needed for the development of potential options feasible for Ukraine.

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  • AMMU  
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  • Central Procurement Agency  
  • eHealth  
  • Urkvaccine  
  • Ukrmedpostach  
  | • Patients of Ukraine NGO  
  • Orphan Diseases of Ukraine Union  
  • Medicines Control NGO  
  • UNICEF  |
BACKGROUND

Substandard and Falsified (SF) Medical Products

The World Health Organization (WHO) estimates that about 10% of medicines in low- and middle-income countries are substandard and falsified (SF) medical products.¹ The falsification of drugs is an ongoing threat to public health, especially in the fight against tuberculosis (TB), malaria, HIV/AIDS, and viral hepatitis. It also contributes significantly to the emergence of antimicrobial resistance and costs global economies from $10 billion to $200 billion per country per year.² However, SF medical products are not only a public health issue. They represent a major trade and security concern, and no single entity can win this battle alone. An effective solution to the problem is multifaceted and requires joint and coordinated efforts between law enforcement, customs, border control, health authorities, and pharmacies, as well as consolidated public and private resources.

Due to the severity of the problem, in 2013 the WHO established the Global Surveillance and Monitoring System (GSMS) that has been leading the global effort against SF medical products. The WHO has also been providing training to staff in identifying and reporting SF medical products and with increased training there has been an increasing amount of reports submitted to the GSMS with 21% of the reported cases coming from the WHO European Region.¹

In the past there have been a number of confusing designations for SF medical products. In fact, until recently the WHO officially used the term “substandard/spurious/falsely-labelled/falsified/counterfeit medical products” (SSFFC) in an attempt to capture the different types of products that are referred to when discussing the subject matter. In order to reduce confusion and remove the focus form intellectual property concerns, the WHO coined a new term that is focused on public health, substandard and falsified (SF) medical products, that includes three types of products³:

- **Substandard medical products**: Also called “out of specification”, these are authorized medical products that fail to meet either their quality standards or their specifications, or both.
- **Falsified medical products**: Medical products that deliberately/fraudulently misrepresent their identity, composition or source.
- **Unregistered/unlicensed medical products**: Medical products that have not undergone evaluation and/or approval by the national or regional regulatory authority for the market in which they are marketed/distributed or used, subject to permitted conditions under national or regional regulation and legislation.

Consequences of SF Medical Products

SF medical products pose a significant health threat to patients and health systems. When medicines do not function appropriately they can have detrimental effects but they can also prolong illness. This often leads patients to return to their physician, who spends more time and resources on the diagnosis or new medication or this leads patients to lose trust in the health system and not return to the physician at all, allowing the illness to continue. All the meanwhile, the patient is suffering and their quality of life is reduced.

Another major consequence of SF medical products is the spread of drug-resistant infections. This is a problem that does not only concern one patient or country, it is a significant global health problem. Individuals are able to travel and move around more easily now than they used to, that means that infections are easily spread from one individual to the next. It is not sufficient enough for only some countries to implement regulations that require more quality control of medicines because individuals from those countries will still be prone to diseases.

Lastly, SF medical products are simply a waste of money – for all parties involved. Although patients may think that they are saving money because they are purchasing a cheaper drug, more often than not, once they realize that the drug is not effective, they will have to spend even more money to purchase the appropriate drug. Patients may also need to spend more money to treat any adverse reactions from the SF medical product. In the long term, they are losing more money. In addition, health systems, insurance companies, and pharmaceutical manufacturers are also losing money when SF medical products are on the market. Health systems and insurance companies are often required to double pay for the medication or burden the cost if patients are poor and cannot afford the costs. Pharmaceutical manufacturers may need to recall their product at their own cost in addition to possibly losing out on profit from that product. Most importantly, the money lost due to SF medical products is income provided to criminals.

Where do SF Medical Products Come From

There are a number of reasons why SF medical products exist around the world. They mostly occur in areas where there is a shortage of products and the demand is high, coupled with low risk for detection.

Cost of medicines is one of the leading causes that SF medical products make it on the market. This often occurs when the national health system or health insurance cannot cover the full or partial cost of the medicine and the patient has to pay out-of-pocket. In these situations, patients become desperate and go looking for a cheaper version of the same medication, even if it means that they are possibly risking their health even further to purchase an illegally supplied drug.

On the other hand, there are also cases when patients can afford to purchase medicines but the drugs simply do not exist in the country. This is often the case in countries where there is war, disasters, epidemics, geographic isolation, and poor infrastructure. These are prime conditions for less reliable products to enter the market and thrive.

In addition, the more complex the supply chain system – the higher the risk that products can become falsified or of low effectiveness. In the current, highly globalized market, products are rarely made only in one location. A pill that is bought in one country is likely to have been made from ingredients and
supplies from a number of countries, and possibly even repackaged before reaching its end destination. The more hands that a product touches the higher the chances are that mistakes are made, bad practices are applied, or unethical activity occurs. However, aware of the challenges that complex supply chain systems bring, stakeholders from all parts of the supply chain cycle came together to form the “Roadmap to Promote Global Medical Product Quality and Supply Chain Security” project. This collaborative multi-year project commissioned by the Asia Pacific Economic Cooperation (APEC) developed the Supply Chain Security Toolkit (Figure 1) that provides guidance for an effective supply chain at every step. The toolkit focuses on the prevention of SF medical products in the supply chain and provides tools and best practices for each step of the supply chain cycle.

Lastly, SF medical products enter the system due to poor governance and a lack of technical tools and capacity. Countries where rates of SF medical products are the highest are often the same countries that lack a strong regulatory system and rules to enforce appropriate quality controls. Legislation that outlines in detail the rules that the supply chain system must follow is essential in order to protect the safety of the patients. Lack of a strong regulatory system can also be due to the lack of technical capacity within the country to uphold the standards or the resources (well-equipped laboratories, storage facilities, etc.) to uphold them appropriately.

**The Solution to SF Medical Products**

The WHO provides a three pronged approach to tackling the problem of SF medical products:

- Prevent,
- Detect,
- Respond.\(^4\)

In order to truly reduce the amount of SF medical products in a given country, the WHO recommends that first it is vital to take steps to prevent the production of SF medical products all together. This can be done by preventing shortages from occurring and thus reducing the need for SF medical products to

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be created; education and awareness; promoting the rational use of medicines; and ensuring that appropriate facilities that perform quality checks exist. Next, it is vital to detect the drugs that are already within the system. The implementation of technologies that promote information sharing and the continuous collaboration among stakeholders throughout the supply chain are key to accomplishing detection. Lastly, countries need to respond when cases of SF medical products are identified. A key to accomplishing a strong system for response is through an effective and transparent regulatory system. The challenge is to implement actions that are simultaneously working in all three areas.

**Verification as a Means to Prevent and Detect**

Verification of medicines has been a key solution to preventing and detecting SF medical products. Although it is a process that can put an additional financial burden on the pharmaceutical supply chain and is also complex due to the nature of the supply chain itself, it is also an extremely effective process if implemented by the whole system. Figure 2 provides a depiction of countries that have already established or are in the process of establishing a verification system. Countries that are especially relevant for Ukraine, due to proximity are Turkey, the European Union, and Russia. Turkey has already been working with a functioning verification system since 2011, whereas the European Union and Russia are starting their implementing in 2019.

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**In USA**, since November 2017, DSCSA requires manufacturers to mark packages with a product identifier, serial number, lot number & expiration date. DSCSA has a phased implementation process and will come into full force in 2022.

**In Brazil**, the National Drug Control System since 2016. The system requires 2D barcodes on individual medication packs that will include a unique randomized serial number, registration number, expiration date.

**In Argentina**, manufacturers must serialize every sales unit in line with GSI standards for the serial number & barcode format.

**In Egypt**, since September 2017, “track and trace” requirements include barcoding serialization, and government reporting on all pharmaceutical products. With the introduction of a barcode tracking system.

**In Turkey**, all medicinal products must adhere to trace and trace regulations since 2011, including unit and aggregation level requirements that follow GSI standards.

**In India**, has implemented progressive serialization & barcoding requirements enforced only at a regional level, which are widely regarded as less demanding than US & EU regulation.

**In Pakistan**, is planning to introduce 2D barcodes on all medicinal products. All registered drugs manufactured after 15 December 2017 are required to embed a 2D barcode data matrix on the packaging. The new rule apply to all conventional drugs – imported, exported or manufactured domestically, including biologics.

**In South Korea**, serialization requirement cover all pharmaceutical product manufacturers since 2016. Following reporting enforcement introduction for wholesale distributors in 2017.

**In China**, since 2015 all pharmaceutical products must comply with serialization and government reporting requirements; companies must run a query with the Chinese government to capture serial numbers, which then are included in the packaging.

**In Europe**, new serialization program in place since Feb 2019.

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![Figure 2 2018 World Serialization Map](image)

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SAFEmed Landscape Analysis
Preventing SF Medical Products in the European Union


Finally, the EU adopted the Falsified Medicine Directive (FMD), referred to as Directive 2016/161/EU, effective as of February 9th 2019. This regulation details the characteristics of the safety features each of the stakeholders of the healthcare supply chain should have already implemented. It aims at improving the public health and protecting patients from being affected by SF medical products and outlines the critical steps to build a safe system to trace medical products distributed in Europe: a total of 32 countries. The intended result of this legislation is to have an overall safer healthcare supply chain, with enhanced patient safety, and improved insights into supply chain operations. The EU FMD requires stakeholders of the supply chain to put in place a series of systems to comply with the Directive. This legislation can be qualified as complex and requires the pharmaceutical industry to change processes and IT systems, but there are already solutions on the market to assist with the implementation process.

In addition, in order to increase patient safety, the EU has put in place several systems to facilitate the communication across Europe:

- The European Medicine Verification System (EMVS)
- The National Medicine Verification System (NMVS)

The systems aim to increase patient safety by tracing medical products across borders and across the supply chain. All stakeholders in the supply chain will need to work with one or both of these systems.

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8 European Medicines Verification System (EMVS). Available at: https://emvo-medicines.eu/mission/emvs/
Through verification of the Unique Identifiers (UI’s) or serial numbers, and by connecting to these EU systems, the different actors of the supply chain can make sure that the medical products that are passing through their hands are not counterfeit, stolen, recalled, or expired.

The NMVS will function as the platform of verification for a variety of stakeholders ensuring product authentication, see Figure 4.

The following (Figure 5) represents a map of the serialization and verification system; and the main features of the two components, that are planned to be used by European Medicines Verification Organization (EMVO) and National Medicines Verification Organization (NMVO). Although the similarity of the structure of EMVO and NMVO is highly desirable, in some details national systems created in countries may differ from the EMVO infrastructure.

**Figure 4 Proposed Medicinal Flow After Implementation of Directive 2016/62/EC**

**Figure 5. Map of Serialization and Verification System**
Legal Review of Directive 2011/62/EC

Preliminary Legal Analysis of Directive 2011/62/EC

Directive 2011/62/EC serves as a supplement to Directive 2011/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use. This directive introduces two obligatory safety features, a unique identifier and an anti-tampering device, to the packaging of certain medicinal products for human use, and establishes the technical details of the unique identifier, the market participants responsible for verifying the safety features in the supply chain, and the management of the system storing the unique identifiers.

As with all draft legislation and regulatory proposals, it is critical to examine the necessity of the regulation, its economic and social impact, and its effects on competition in the relevant market(s). While most laws in some form restrict competition in the relevant market(s), regulation is deemed necessary where there is a countervailing public interest the legislation seeks to protect. In this instance, the overwhelming public interest is patient and population health and safety in relation to counterfeit pharmaceuticals.

Once a countervailing interest exists that necessitates regulation, the overarching goal in drafting the legislation is to establish the least restrictive means of structuring the measures necessary to protect that interest. The evaluation that takes place from a competition standpoint is called a competitive impact assessment, which examines the draft legislation, its economic and social impact on all market participants, and its overall impact on competition, productivity, and economic growth.


Directive 2011/62/EC's first objective is to establish the technical details of the unique identifier used on certain medicinal products to prevent counterfeit supplies from entering the market. This can be achieved through a number of ways, including full harmonization of the composition of the identifier and the data carrier to protect against falsified recalled and expired medicines or partial harmonization. While full harmonization exceeds the minimum requirements necessary to ensure effective authentication of a medicinal pack, full harmonization provides significant efficiencies through standardization all while incurring the same fixed costs as partial harmonization. For both full and partial harmonization, the market participants required to verify the medicinal packs must invest in the verification equipment. By only requiring partial harmonization of the identifier with the data carrier, those same market participants will incur the cost of multiple pieces of equipment to verify divergent number formats. Therefore, while full harmonization exceeds the minimum requirements for authentication, the overall economic impact on market participants relative to the effectiveness of the measure is reduced.

Directive 2011/62/EC's second objective is to introduce proportionate verification of safety features in order to combat counterfeit medicinal products. This objective can be achieved either through end-to-end verification in which systematic verification of the safety features takes place at the dispensing point or through risk-based verification in which verification of the safety features takes place both at the dispensing point and by wholesale distributors. End-to-end verification meets the minimal measures for verification to ensure detection of counterfeit medicines before the dispensing point; however, such
minimal measures allow false medicines to circulate in the EU for months or even years before detection. Further, end-to-end verification shifts the burden of cost and detection solely on pharmacies and retailers, which would bear not only the economic impact but also the social impact of loss of reputation if any false medications evade detection. Meanwhile, risk-based verification not only ensures an appropriate level of verification of safety features, but also adds additional verifications in instances in which there is an increased risk of falsification. Such risk-based verification adds an additional cost to wholesale distributors and shifts the social burden to both pharmacies and wholesale distributors. While risk-based verification has a heightened economic impact to the wholesale distributor, the investment costs to the wholesale distributor would likely already be incurred as a result of the obligation for the wholesale distributor to record the batch number of the medicinal product. Therefore, while risk-based verification results in increased cost to market participants, it is the most effective and proportionate mechanism for verifying the safety features and achieving the supply chain and patient safety goals of the legislation.

Directive 2011/62/EC’s third objective is to ensure interoperability of the repository system, free movement of medicines, and supervision by the competent authorities. This objective asks the most effective and efficient means of managing the repository system to achieve these goals. The same or relatively similar management costs will be borne by any market participant(s) that manage(s) the central repository; therefore, the question remains—which market participant(s) is/are best situated to effectively and efficiently manage the central repository? Management can rest in one of three entities: 1) the stakeholders, with supervision by the relevant competent authorities; 2) an established public authority at the EU level; or 3) an established public authority at the national level. Evaluation of the management by each entity contemplates both economic impact and the effectiveness of such management by established authorities.

**Management by stakeholders with supervision by the relevant competent authorities**

Management of the repository by stakeholders shifts significant financial burden to manufacturers and parallel importers to establish and maintain a centralized repository that would consist of a network of national data repositories linked via a hub, which would serve as the verification platform. This management structure places repository management responsibility on those market participants most entrenched in the industry and, therefore, the most knowledgeable. Additionally, these market participants have a significant economic and social interest in maintaining the integrity of medicinal products. While maintenance of the repository by manufacturers and parallel importers themselves can yield substantial risk of abuse and lack of transparency, the management approach also contemplates oversight by relevant competent authorities. This oversight does not appear to incur considerable costs to national authorities, with the only cost requirements being human personnel for monitoring.

Management by stakeholders with oversight by competent authorities coupled with the hub and spoke model for information transfer to a central repository achieves the additional objectives of having interoperability of the repository and the ability for medicines to move freely throughout the EU. As such, this management approach demonstrates high efficacy in achieving objectives without increasing social or economic costs.
Management by an established public authority at the EU level

Management of the repository by an established public authority at the EU level achieves the goal of interoperability and the free movement of medicines throughout the EU with oversight by an official body; however, it does not engage the major market participants to coordinate and invest in the system. Such management by a public authority requires industry knowledge and technical expertise and would require significant additional resource expenditure by the public authority to initiate a pilot program and coordinate the interests of the major stakeholders in order to achieve a system comparable to that already contemplated by industry stakeholders. Management of the repository by an established public authority at the EU level would require increased input costs, time, and expertise development as opposed to management by stakeholders themselves. Such management structure is, therefore, less effective and very inefficient from an economic standpoint.

Management by an established public authority at the national level

Management of the repositories by established public authorities at the national level decentralizes the repository system and does not meet the objective of interoperability of systems. It also requires each of the 28 member states to expend considerable resources to establish their own repository. The same additional financial burden and lack of expertise that would exist with the established public authority at the EU level would be replicated in every member state. This leads to increased costs to each member state. The benefits of a system led by national authorities would be the independence from private organization and the avoidance of conflicts of interest; however, the burden born by each state is not necessary to achieve these initiatives. This management structure, therefore, is less effective and substantially less efficient in achieving the overall objectives in comparison to the two other proposed management structures.

Preliminary Conclusions

An initial competitive assessment of Directive 2011/62/EC demonstrates the mechanism by which the regulation can achieve the overarching goals of public safety and supply chain stability in the pharmaceutical market as it relates to counterfeit medicinal products. The measures for establishing standardized verification procedures for medicinal products are narrowly tailored and cost conservative so as to achieve the goals of maintaining public health and safety and the free movement of medicines throughout the EU. The least restrictive and most effective mechanisms for doing so require the following:

1. Full harmonization of the composition of the identifier and the data carrier to protect against falsified, recalled, and expired medicines;
2. Systematic verification of the safety features at the dispensing point and risk-based verification by wholesale distributors; and
3. Management of the repository by stakeholders with supervision by the relevant competent authorities.

The conclusions outlined illustrate high-level concepts contemplated in a competitive impact assessment. The more comprehensive approach supporting this high-level analysis illustrates the direct social and economic impacts as well as the costs borne by each market participant operating in the pharmaceutical industry and demonstrates a more thorough substantiation for the conclusions drawn in this preliminary legal analysis of Directive 2011/62/EC.
Understanding the Pharmaceutical Supply Chain Stakeholders

There are four vital stakeholders, who under Directive 2011/62/EC have to collaborate and share data to support serial number authentication and traceability. These stakeholders, from the perspective of the EU, are the following:

Manufacturers

Serialization will require manufacturers to redesign their labels to accommodate the new 2D barcode. Changes in labeling may also involve alterations to or redesign of packaging structure or graphic elements. This will likely have an impact on multiple packaging processes, which will need to be resolved, either through increased labor force or greater automation, if current production levels are to be maintained.

Manufacturers’ IT architecture will need to be capable of generating, storing, capturing and transmitting millions of serial numbers for numerous supply chains. That will inevitably entail significant capital investment to update exiting equipment, hardware and software and retrain staff.

The EU FMD details how central data repositories will be set up, either at national or supranational level and connected to a European Hub – a non-profit organization funded by manufacturers and brand owners. The legislation requires unique identifiers i.e. serial numbers to be uploaded to the European Hub, with verification of medicines performed in the NMVS. To that end, system interoperability, data ownership and access levels have been agreed by stakeholders, based on mutually endorsed principles.

Wholesalers and Distributors

The obligations of wholesalers and distributors are broadly similar to those of manufacturers: to secure the supply chain and verify any suspicion of falsified medicines. Primary wholesalers who buy from the original manufacturer or Marketing Authorization Holder (MAH) will not need to do risk-based verification as the product is coming from a trusted source.

Secondary, wholesalers who buy product off the market or from other wholesalers need to complete risk-based verification. Those that sell ‘out of market’, such as to universities for research, must decommission serial numbers. Distributors must complete risk-based verification for saleable returns prior to reselling the product, regardless of product source.

Pharmacies

This diverse group encompasses community pharmacies, dispensing clinical practices, hospital pharmacies and internet pharmacies. Pharmacists will be responsible for making their connections to the database, as well as for software upgrades. Community pharmacists will need to scan the barcode to verify products at the point of dispensing to the patient. This will also alert the pharmacist in real-time if the product is out of date, recalled or withdrawn from the supply chain. Hospital pharmacies do not deliver directly to the patient but to departments or doctors, with many medicines administered in the hospital environment from stock held in clinical areas, such as wards, theatres, Accident & Emergency departments and Intensive Care Units. It is not always possible to identify in advance which packs of medicines are destined for dispensing directly to patients and which will go to clinical areas. In practice, it may prove impractical to scan twice – on receipt and at the point of dispensing. Hospital pharmacies will need to authenticate and decommission medicines before dispensing them (or recommission them...
in certain cases). Online pharmacies enable consumers to buy an assortment of medication through e-commerce sites. While many are reputable, others have been a major contributor to the drug counterfeiting trade. In all cases of drug counterfeiting, the product, packaging and label information are designed to look like the original product.

**Patients**

Ultimately, the purpose of both the EU FMD is to improve patient safety by securing the supply chain. We can expect to see the emergence of consumer apps linked to the validation system that will enable mobile scanning of the 2D barcode, enabling patients themselves to verify drug safety for extra assurance.

**Technical Details of the Serialization and Verification Process**

As pharmaceutical supply chains are complex and global by nature, many are looking to standardize an identification system. GS1 is a globally recognized and endorsed standard, and based on a foundation of unique identification keys (Global Trade Item Number). It enables product attributes to be recorded, including batch or lot number, expiry date and unique serial number, and is visualized as a GS1 DataMatrix2 2D barcode, which enables a substantial amount of data to be encoded in a small physical space.

1. To assign a unique identification number, each secondary packaging of the drug have to be sealed with a Special Sticker, which, at the opening of the packaging would irreversibly spoils its surface and prevents the possibility of back gluing
2. Unique code is assigned and printed only on a sealed with special sticker package that already contains the drug inside
3. The quality of codes printed should be scanned with standard cost scanner in the pharmacy
4. For serialization and verification of the hospital medicinal products by logistic company or by

![Diagram of Primary Packaging of Medicinal Products Inside Tertiary Packaging](source:https://webhp207.sap-ag.de/.../1202017310466162992132/SAPAdvancedTrackTrace.pdf)

*Figure 6. Primary Packaging of Medicinal Products Inside Tertiary Packaging*
hospital, it is necessary to provide the possibility to scan aggregated codes (printing of all unique codes of each Primary packaging of the medicinal product inside on the tertiary packaging (see Figure 6):

**GS1 Two-Dimensional Barcodes**

**GS1 DataMatrix**

Symbol ID: \[d2\]  
Capacity: 3116 Numeric capacity, 2335 Alphanumeric capacity  
Omnidirectional  
Supports all keys  
Supports attributes

**GS1 QR Code**

Symbol ID: \[Q3\]  
Capacity: 7089 Numeric capacity 4296 Alphanumeric capacity  
Omnidirectional  
Supports all keys  
Supports attributes

GS1 is a not-for-profit organization based in Belgium that has established itself as a leader in developing standards for business communication, one of the tools it uses to accomplish this, is the barcode. The GS1 system is globally recognized and widely used because it meets specifications of regulations from around the world. It offers two options of 2D codes, the GS1 DataMatrix and the GS1 QR Code. They both meet the requirements of the legislation, however, the QR code holds more information and can also lead individuals to a website through a URL. This has motivated organizations to add QR Codes to their products in order to promote marketing and to enhance the customer experience.

**Ukrainian Context**

According to the analytical report, published in open sources by Proxima Research Company\(^9\),\(^10\) Ukrainian Pharmaceutical Market continued its steady recovery and growth. As of 2018, its characterized by the following core indicators:

- The total value of pharmaceutical market in Ukraine, including retail and hospital segments, was estimated at 85.0 billion UAH or 3.3 billion USD with a 19.9% growth compared to 2017
- The total market volume was estimated at 1.3 billion units
- The total market grew 21.5% in value and by 4.5% by the number of units
- 2018 sales by pharmacies also known as «pharmacy basket” that includes medicines, food supplements, cosmetics and some supplies increased by 22.5% vs. 2017

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\(^9\) Госпитальный рынок лекарственных средств по итогам 2018 г. Helicopter View. Available at:  
https://www.apteka.ua/article/489644

\(^10\) Аптечный рынок Украины по итогам 2018 г.: Available at: Helicopter View. https://www.apteka.ua/article/486600
- "Pharmacy basket" sales were also estimated as 1.8 billion units, with 4% growth vs. 2017

Figure 7 Size of Ukraine Pharmaceutical Market

Figure 8 Latest Ukrainian Pharmaceutical Market Trends and Growth Figures
In addition, currently Ukrainian state-regulated and financed, Hospital Market in Ukraine has also demonstrate a steady growth across all indicators in 2018:

- Total value of the Ukrainian hospital market is estimated at 10.5 billion UAH with a 19.3% growth
- Total volume of the Hospital Market was estimated at 143.3 million units with 23% growth
- Hospital sector constitutes 12.4% and 10.5% of the entire pharmaceutical market by volume and by value, respectively.

While experience steady growth of the pharmaceutical market in the past 3 years, Ukraine faces the same problem that many other countries in the world regarding SF medical products – the lack of evidence. There are some articles that claim 10% to 40% of the market is SF medical products\(^{11}\) however, there is actually no real reliable data. However, if we apply the most liberal projections and assume that only 1% of the medicines on the market are either substandard or falsified, it means that every year 13 million items on the Ukrainian market are putting the lives of Ukrainians at risk.

The most common ways that substandard and falsified medical products enter the supply chain in Ukraine include:

- Smuggling
- Illegal re-packaging of drugs with expired shelf life
- Production and delivery of medicines from unlicensed manufacturing sites
- Online pharmaceutical products sales and delivery via informal networks

- Other illegal mechanisms

In an effort to begin combatting this critical issue, in December 2018, the Cabinet of Ministers of Ukraine (CMU) approved, decree No. 1022, entitled "State Strategy for the Implementation of the State Policy of Providing the Population with Drugs until 2025". According to this decree, the circulation of medical products is subject to state regulation at all stages from the manufacturer to the patient — by adopting normative documents, monitoring compliance with international practices, and controlling its implementation by all participants of the process. The decree also states, that the system of state regulation in the field of drug control does not fully meet current requirements, the legislation does not apply in all areas, and monitoring is not systemic.

In October 24, 2017, State Service of Ukraine on Medicines and Drugs Control (SDS) introduced implementation of the first stage of the Automated Tracking System in the process of pharmaceuticals circulation from the manufacturer to the final customer. It was introduces as a pilot project. Ukrainian domestic pharmaceutical industry, joined the pilot project, taking the first steps to implementation of a labeling and tracking system using GS1 ECC200 codes and following European Federation Pharmaceutical Industry and Associations (EFPIA) recommendations. The essence of pilot project was the following:

1. Interchem, a pharmaceutical manufacturer company, produced 1000 packs of "Amixin IC"
2. Product was distributed by BADM and retail network "Kyiv Pharmacia"
3. During the pilot, successful verification of serialized 1000 packs of "Amixin IC" took place.

13 Interview with Deputy Head of State Service of Ukraine On Medicines and Drugs Control (SDS)
KEY FINDINGS FROM STAKEHOLDER INTERVIEWS

After meeting with a variety of stakeholders from different parts of the system, we gained an understanding of the major concerns that stakeholders have regarding the implementation of a verification system in Ukraine. Although some views on the topics varied significantly, there were some key themes that were voiced by almost all stakeholders.

Everyone agrees that there is a lack of data regarding this topic that allows for significant speculation. Some stakeholders believe that this is a significant problem and needs to be dealt with immediately, whereas others do not see a problem at all and believe that it is just some loud parties attempting to amplify the issue to further their own interests. Overall, stakeholders believe that there is anywhere from 1% to 50% of falsified medical products in Ukraine compared to the world average of about 10% of the market. As long as there continues to be a lack of reliable figures on the topic, the more push back the MOH will face in gaining support from some stakeholders.

The lack of reliable data could also be due to the fact that stakeholders are oftentimes referencing different types of falsified medical products. During the interview with SDS, they reported that there are only about 1% or less of falsified products in Ukraine, however when we clarified whether or not that figure included grey or parallel import they said “No”. The SDS was only referring to products that are purposefully manufactured under false pretenses. Although they agreed that grey import products are also a problem and if those products were included then the figure would be closer to 10% of the market. This was the case with other stakeholders as well. As the MOH moves forward in implementing verification system in Ukraine, it is vital that it explicitly defines the types of medical products it is referring to, so that all stakeholders are using the same terminology when discussing the topic.

It is also unclear what type of falsified medical products burden the system the most: generic medicines or expensive medicines like those for orphan diseases and cancer. Some stakeholders believe that it makes more sense for Ukrainian manufacturers to falsify generics because they are cheaper to make and more of them can be sold. Others believe that more expensive medicines are the only ones worth falsifying because it is easier to get a fast return on investment on them. The lack of reliable data contributes to the lack of understanding about which medicines are being falsified.

In addition, stakeholders almost unanimously voiced their desire for a thorough and well-planned process as the MOH drafts legislation for the implementation of verification. Most stakeholders are interested in waiting to see what barriers the EU faces as it implements its new legislation and learning from their mistakes instead of repeating the same ones in Ukraine. Stakeholders mostly agree that it does not make much sense to build a system that is unique to Ukraine, in fact this would defeat the purpose because there would not be an integration with the EU system and falsified medical products would continue to make their way to Ukraine. The codes that Ukraine decides to utilize should, at minimum, contain all the same information that the EU requires. A desire to ensure that all relevant parties are consulted throughout the process was all voiced. Stakeholders believe that it is the best way to ensure that all are on board with the new policy and implementing it.

Stakeholders request a clear and hard timeline for implementation. Many stakeholders believe that if there is no hard date for when all parties must transition to the new system then it will never happen. Stakeholders have different opinions on how much time is needed in order to implement a new system.
Some believe that it is not a complicating process and a start date a year from now is realistic. It has taken the EU several years to implement a fully integrated system, however technology was not as advanced then as it is now and some believe that it would be much easier and faster to implement a similar system now. Others believe that this is something needs many years to implement, anywhere from five and even ten years would be more realistic.

A major concern voiced among the majority of the stakeholders was regarding the government body that will oversee the implementation of verification for medicines and then maintaining it throughout the years. Stakeholders have very little trust in SDS being able to handle such complex undertaking, and believe that they will not be effective or transparent in implementing verification in Ukraine. Many stakeholders were aware of a pilot that SDS attempted several years ago and believe that the pilot was not only unsuccessful but that SDS did not share any information regarding the pilot or its results to any relevant parties. Stakeholders cautioned that the government body that will administer this program moving forward must be very carefully selected in order for the program to be affective.

Stakeholders voiced mixed opinions regarding the best place to begin implementing coding and marking for medicines. It seems that many individuals interviewed do not have enough information about what this would truly entail to make a decision about whether it would be better to being with medicines procured by the government first or enforce implementation for the whole system at one time. There are pros and cons to both ways and the MOH would need to outline what implementation would look like in various scenarios and choose the path that has the most benefits and least amount of confusion. For example, if coding and marking was only to be implemented on medicines in the reimbursement program, would it be more or less complicating for manufacturers to mark only a portion of the drugs that they produce. In addition, would there be any effect if only a portion of medicines are being marked and traced and others are not. On the other hand, if the policy is to be implemented on all medicines at once, would it be a burden too great for the system to handle at one time.

Cost of implementation is a major concern for many stakeholders but it is not clear which part of the system would have to carry the burden of the cost the most. It is assumed that it would be the manufacturers. International manufacturers, especially those in the EU, are already prepared for this change since they are producing medicines for the EU. However, Ukrainian manufacturers are probably not as prepared and would need to purchase a significant amount of equipment. Additionally, it is unclear what type of equipment would need to exist at the border in order to scan all medicines that are entering the country and who would burden the cost of purchasing that equipment.

It is essential that border control and customs is one of the components of the system that is on board with the new policy and understand the severity of performing their job appropriately and in a transparent manner as part of the holistic approach to the establishment of the verification system in Ukraine. There is a significant amount of corruption that can occur at the border, and if the system is not enforced there, then the problem would continue to be perpetuated throughout the country, especially since the Eastern border of Ukraine is currently open due to the conflict with Russia.

Most stakeholders also referenced the problem that currently exists with medicines that are being sold on the internet. Unfortunately, it seems that even if a system of coding and marking was implemented, it would not prevent this problem from occurring. Internet pharmacies are currently not regulated at all and it is unclear where those medicines are coming from exactly, likely countries like Turkey. As of now,
the best way to combat purchase of medicines from the internet is to educate the population of the risks that exist with purchasing medicines that have not traveled along a regulated supply chain and are more likely than not inappropriately stored and handled along the way.

Overall, all agreed that implementing verification of medicines in Ukraine is a multifaceted problem that requires a significant amount of resources and collaboration among all relevant stakeholders. All parties understand this fact and are ready to face the challenge, if it is a process that is conducted in a systematic and rational way. All interviewed stakeholders agreed that falsified and counterfeit medical products are an issues in Ukraine that must be combated. The implementation of such a policy would allow for a better understanding of how medicines move from point of production to point of sale and this insight would be valuable in reducing corruption and increasing transparency within procurement of medicines, in addition, with an electronic verification system in place a significant amount of paperwork would be reduced that could potentially minimize human errors. The challenge for the MOH is to put together a policy that all stakeholders can agree on or at least be comfortable with, so that the amount of push back during implementation is reduced.
1. Ukraine’s MOH is currently undertaking the development of its system for verification and serialization of medicines in Ukraine. To make this system work, we recommend establishment of the cross-sectoral and inter-ministerial Working Group to make sure that all key counterparts are included in the dialogue as early as possible with clearly defined roles and responsibilities.

2. Currently, across the globe, in general, and in Ukraine, in particular, there are a number of definitions in circulation when it comes to the subject of medicines verification. We recommend to accept new definition of substandard and falsified medicines developed by the WHO in 2017, and utilize it moving forward to avoid confusion and misinterpretation.

3. Taking holistic and transparent approach to the development and implementation of the verification system that addresses all components of the pharmaceutical supply chain is key. In order for the verification system to work, we recommend to go above and beyond health system and include customs, boarder control and legal bodies that will help to prevent, detect, and properly respond to substandard and falsified medicines.

4. Substandard and falsified medicines represent a growing public health risk with an “untold cost of lives” of many patients in Ukraine and elsewhere. We recommend to develop a targeted patient-education communication strategy and a campaign that will go in parallel with the government efforts to establish verification system. Patients’ needs to be properly and systematically educated about (1) the risks of purchasing medicines through obscure channels, including cheaper online pharmacies and other outlets that are illegal in Ukraine, (2) new medicines verification system that the government is putting in place and the pace of its introduction and the roll out, and (3) how to use new verification from the patient perspective.

5. Given the global nature of the pharmaceutical market, we can anticipate the movement of medicines across proximal borders. The EU has developed a mechanism to support the free movement of pharmaceuticals across borders and in doing so has also developed a standard operating procedure for uniformity among nation-states for the verification of medicines to combat the excess counterfeit medicinal products in its markets. Ukraine, while not an EU member state, should seek to adopt these best practices not only to raise its verification and serialization system to international standards, but also to allow for ready interconnectivity to the current EU verification platform should Ukraine enter the EU.

- We recommend that Ukraine adopt the standards set forth in Article 4, Commission Delegated Regulation (EU) 2016/161, Composition of the unique identifier, modeling its composition in accordance with those of German and French pharmaceutical identifiers. Maintaining the minimal standards of the unique identifiers and developing a composition mirroring those found in proximal EU countries would yield the effectiveness and efficiency standards discussed in the competitive impact assessment conducted on Directive 2011/62/EU. Further, we recommend that Ukraine adopt the standards set for in Article 5, Commission Delegated Regulation (EU) 2016/161, Carrier of the unique identifier, again raising its standards on European market practices. The full harmonization of the
composition with the unique identifier and the carrier was found to be the most efficient, cost-conservative mechanism of achieving uniformity in the unique identifiers. This uniformity allows for medicines to be identified in a central verification platform without an intermediary step of cross referencing to communicate with the European based central verification system. By adopting these practices now, Ukraine is able to benefit from the cost and efficiency analysis that the EU has engaged to determine the best practices on electronic coding and provides an ease of incorporation should Ukraine enter the EU.

- We recommend that Ukraine develop a platform that allows for risk-based verification by wholesale distributors as well as end-to-end verification by manufacturers and pharmacies. This division of risk preserves the goal of public safety in combatting the presence of counterfeit pharmaceuticals in Ukraine and raises the participation standards of both pharmacies and wholesalers in the verification process. The verification platform should meet the minimum requirements and procedural methods laid out in Chapters IV, V, VI, Commission Delegated Regulation (EU) 2016/161. By adopting these standards, Ukraine achieves international standards that have been found to be the most cost effective means of ensuring public safety as well as a secure supply chain. This adoption further supports manufacturers and provides additional savings by preventing the loss of reputation that results from counterfeit medicines and the losses incurred from having to replace the counterfeit products found on the market.

- Finally, we recommend that Ukraine develop a repository system in accordance with Chapter VII, Commission Delegated Regulation (EU 2016/161). This is the most significant recommendation if Ukraine seeks to enter the EU. By adopting the standards set forth in this chapter from the beginning, Ukraine not only raises its standards to international best practices, but also enables a smooth transition by ensuring its ability to link its pharmaceutical repository into the central EU hub.

Ukraine has the unique opportunity to benefit from a highly honed system developed over the course of a decade that combats the existence of counterfeit pharmaceuticals on the market. This is a significant issue currently in Ukraine, and the EU has developed a complete, cost-conservative, and efficient methodology for counteracting the effects of counterfeit drugs in the prescription market. This methodology not only ensures to the best of its ability public health and safety but also protects the supply chain from bearing the additional economic and social costs of having counterfeit medicinal products on the Ukrainian market.
Ви мабуть знаєте, що деякі лікарські засоби на українському ринку контрафактні. Здебільшого, це пов’язано з динамічним зростанням споживання лікарських засобів в Україні та невідповідністю механізмів контролю їхнього обігу. Розповсюджені методи потрапляння контрафактних лікарських засобів на український ринок включають контрабанду, переупаковку препаратів з вичерпаним терміном придатності, виробництво ліків на неліцензованих виробничих підприємствах, а також продаж лікарських засобів через Інтернет та через неофіційні мережі та механізми доставки. В грудні 2018 року Кабінет Міністрів України затвердив Постанову №1022 щодо лікарських засобів. Щоб прискорити впровадження цієї урядової постанови проект SAFEMed, за фінансування Агентства США з міжнародного розвитку, надає підтримку Міністерству охорони здоров’я в розробленні доцільних варіантів верифікації лікарських засобів в Україні.

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<th>Англійська</th>
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<tbody>
<tr>
<td>1. What do you think about the issue of sub-standard medicines in Ukraine? How does it affect you and your organization?</td>
<td>Що Ви думаєте про проблему лікарських засобів, що не відповідають стандартам, в Україні? Яким чином це впливає на Вас та Вашу організацію?</td>
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<td>2. What do you know about medicines verification system in EU or other countries that work to address the issue of sub-standard pharmaceutical products?</td>
<td>Що Ви знаєте про системи верифікації лікарських засобів в ЄС або в інших країнах, які направлені на вирішення проблеми лікарських засобів, що не відповідають стандартам?</td>
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<td>3. From your professional stand point, how do you assess the risks and opportunities related to the introduction of mandatory medicines verification system in EU that came into effect on February 9, 2019?</td>
<td>З Вашої точки зору, як Ви оцінюєте ризики та можливості, пов’язані із впровадженням обов’язкової верифікації лікарських засобів в ЄС, яка вступила в дію 9 лютого 2019 року?</td>
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<td>4. What is your opinion about introduction of medicines verification system in Ukraine?</td>
<td>Що Ви думаєте про впровадження системи верифікації лікарських засобів в Україні?</td>
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<td>5. In addition to reducing substandard medicines on the Ukrainian market, can you think of other benefits of having medicines verification system in Ukraine on both individual packages and pallets/boxes?</td>
<td>Крім зменшення кількості лікарських засобів, що не відповідають стандартам, на українському ринку, чи можете Ви знайти інші переваги впровадження системи верифікації в Україні як для окремих упаковок, так і для палет/коробок?</td>
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<td>6. Would you and your organization support establishment of the medicines verification system in Ukraine? Why and why not?</td>
<td>Чи Ви та Ваша організація підтримали би впровадження системи верифікації лікарських засобів в Україні? Чому?</td>
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<td>7. What are key barriers for the introduction of the medicines verification system in Ukraine?</td>
<td>Які існують основні перешкоди для впровадження системи верифікації лікарських засобів в Україні?</td>
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<td>8. How can we address such barriers?</td>
<td>Як ці перешкоди усунути?</td>
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<td>9. If we are to introduce such system in Ukraine, where do we start and why?</td>
<td>Якщо ми впроваджуватимемо цю систему в Україні, з чого слід починати та чому?</td>
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<td>10. What role do you see for your organization in the introduction and roll out of the medicines verification system in Ukraine?</td>
<td>На Ваш погляд, яку роль Ваша організація може відігравати у впровадженні та розгортанні системи верифікації в Україні?</td>
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<td>Thank you!</td>
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