Serialization and Product Verification – Helping to Secure the Legal Supply Chain for Greater Patient Safety

Joint Position: EFPIA, IFPMA, PhRMA

November 2013

The global R&D based pharmaceutical industry is committed to ensure patient safety and is actively engaged in helping to secure the legal supply chain, namely through serialization, worldwide. With many different systems currently in the pipeline, our goal is to promote serialization based on international standards in order to favor harmonization and reduce any disruption to medicine supply and availability.

This engagement is part of our global anti-counterfeiting strategy and is complementary, among other, to our support to the Council of Europe MEDICRIME Convention as well as to fighting illicit online pharmacies.

The past decade has seen the threat of counterfeit medicines increase. According to reporting to the Pharmaceutical Security Institute, incidents of counterfeiting were documented in every therapeutic category and every region of the world, and today 123 countries have experienced this phenomenon.[1] According to the World Health Organization (WHO) "in many African countries, and in parts of Asia, Latin America, and countries in transition, a much higher percentage of the medicines on sale may be counterfeit…"[2]

A considerable amount of counterfeit medicines reach the patient through illicit online pharmacies; however, the threat of falsified medicines penetrating the legal supply chain (even in industrialized countries with effective regulatory systems) is also very real.[3]

[1] http://www.psi-inc.org/geographicDistributions.cfm
[2] WHO, http://www.who.int/mediacentre/factsheets/fs275/en/index.html
[3] World Health Organization, "Medicines: spurious/falsely-labeled/falsified/counterfeit (SFFC) medicines," Fact Sheet No275, May 2012, http://www.who.int/mediacentre/factsheets/fs275/en/.

Our Position

- No single solution will prevent counterfeiting. Rather, a holistic approach comprising use of covert and overt anti-counterfeiting features, a well-regulated, secure supply chain and appropriate laws and penalties to deter and punish counterfeiters, is necessary to provide maximum patient protection.

- Within this framework, the R&D based biopharmaceutical industry supports product serialization and verification as one tool to help stop counterfeits penetrating the legitimate supply chain and to help to ensure that patients receive the right medicine.

- Given the significant resources and investments in capital equipment and software systems necessary to facilitate product serialization and verification, it is critical that systems be implemented in a step-wise, scalable manner, to realistic timelines and with suitable consultation with relevant stakeholders. They should also be established using globally recognized common standards in order to minimize fragmentation and instead increase harmonization worldwide. We believe that initiatives based on international and harmonized standards, such as GS1, represent the most efficient way forward.

- Systems should, at the same time, be sufficiently flexible to accommodate differences in product packaging, market size, technical infrastructure, and supply chain complexity. They should be sufficiently tested in advance of implementation dates to ensure product supply to patients is not adversely impacted as a result of system failures.

- We stand ready to work in partnership with public authorities across the world and the World Health Organization (WHO) in establishing the most effective system in the interests of patient safety.

The Importance of Using Harmonized International Standards

In March 2013 discoveries of fake versions of 20mg and 40mg packs of omeprazole, a gastric reflux treatment, led to the discovery of a sophisticated network of manufacture and packaging in at least four European countries, through which the fake omeprazole was supplied through wholesale drug distributors to pharmacies in Germany[4] [5]. On 17

[4] http://www.ft.com/intl/cms/s/0/bd988804-afed-11e2-8d07-00144feabdc0.html#axzz2lAzWj6MF

May 2013 French customs officers seized 1.2 million doses of fake aspirin hidden in a cargo of tea that arrived from China in the French port of Le Havre[6]. The powder of the medicines was mostly glucose and contained no active ingredients. The fake aspirin was destined for a Spanish company based in the Balearic Islands for distribution in the Iberian peninsula, the south of France and French-speaking Africa. In February 2012, the U.S.'s FDA issued a warning indicating that a counterfeit version of a widely used cancer drug (bevacizumab) purchased from non-US and unlicensed suppliers by medical professionals may have been administered to patients in the U.S. The FDA sent letters to a number of medical practices to inform them that they may have purchased unapproved and counterfeit versions of the drug.[7] According to the FDA, the counterfeit version of the medicine did not contain any of the medicine's active ingredients.

EFPIA, IFPMA and PhRMA support the use of harmonized and internationally recognized standards for the identification of products. This will ensure smooth transition from current state-of-play and flexible implementation with an appreciation of the global nature of the threat. Critically, in order to maximize the efficient flow of electronic product-specific information and to minimize any negative impacts on product supply, serialization and product verification should be based on non-proprietary, harmonized international standards.

In contrast, if individual countries select proprietary coding or verification systems outside the internationally recognized standards, this is likely to generate a highly fragmented system and increase burdens significantly for manufacturers. It could also make it more difficult to ensure prompt verification, patient safety, alignment with other national programs, and negatively impact product availability.

EFPIA, IFPMA and PhRMA believe that serialization initiatives should conform to the internationally recognized standards, for example a GS1 2D barcode. Using GS1 standards allows manufacturers to deploy a single set of standards across their operations and with supply chain partners, to identify and serialize products. If multiple standards are used, the complexity of operations is amplified many times, driving up costs and introducing a higher risk of error in terms of the ability for companies and

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[5] http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Adviceandinformationforconsumers/counterfeitmedicinesanddevices/FalsifiedMedicineRecallsandpreviouslyseencounterfeits/index.htm

[6] http://www.eubusiness.com/news-eu/france-china.or9/

[7] FDA, "Counterfeit Version of Avastin in U.S. Distribution," February 14, 2012, <http://www.fda.gov/drugs/drugsafety/ucm291960.htm>

governments to uniquely identify products and to facilitate product verification, including through coding and serialization of regulated medicines and tamper resistant packaging. Using GS1 standards also ensures that a single barcode can be used by several countries.[8]

Additional Supply Chain Benefits

Beyond securing the supply chain and increasing patient safety, serialization and product verification also allows for additional supply chain benefits. Potential advantages include the possibility of:

- allowing for the automated checking of expiry dates,
- better pharmacovigilance,
- reduced medication dispensing errors,
- a reduction in the number of fraudulent reimbursement claims,
- higher effectiveness in preventing recalled products from being supplied to the patient,
- more efficient handling of product returns, and
- improved logistics such as stock management processes for pharmacies.

Serialization and Product Verification Systems: a Growing Trend Worldwide

The expansion and growing sophistication of the counterfeit drug trade poses a global risk to patients and to public health as well as a long-term threat to the research-based biopharmaceutical industry. Verifying the authenticity of medicines via product serialization could play a key role in helping to minimize these dangers. It is therefore increasingly favored or under active consideration by Governments across the world.

Serialization involves assigning a unique identifier (e.g. a number) to an item (e.g. pack, case or pallet). This identifier is stored on a database along with other information about the item (e.g. manufacturer, batch info, etc). Items can then be scanned and verified against the database using the unique identifier for authenticity and/or can then be traced throughout the supply chain using the unique identifier or at a specific point (e.g. at the dispensing point).

[8] For further details, see "Strength in Unity: the promise of global standards in healthcare", McKinsey & Company, October 2012

No commonly recognized serialization system currently exists. A growing number of serialization initiatives have instead been launched worldwide in order to help tackle the threat of counterfeit medicines and ensure greater oversight of and accountability by those engaged in medicines distribution.

In the EU, the Falsified Medicines Directive (Directive 2011/62/EU), published in July 2011, aims at preventing the entry of counterfeit medicines in the legal distribution chain. It lays the ground for an EU-harmonized system of mandatory safety features for prescription-only medicines allowing verification of the authenticity and identification of an individual pack by a serial number or 'unique identifier'. The EU serialization requirements are likely to apply as of the end of 2017.

Other countries such as Belgium, Italy, Turkey, South Korea, China, Brazil, India, and Argentina have introduced or are considering implementing serialization and product identification systems, although differing approaches may be taken. In the US, the state of California requires manufacturers to serialize packages starting 2015, and for products to be distributed with an electronic pedigree beginning in 2016 for wholesalers and 2017 for dispensers. This pedigree must be created and maintained in a harmonized electronic system.