

Bulgaria

Successful implementation of the Bulgarian Medicines Verification System

Challenge

In Bulgaria, projects to follow the European Union’s (EU) Falsified Medicines Directive (FMD) were a massive undertaking that spanned all stakeholders in the supply chain—manufacturers, wholesalers, hospitals and pharmacies. GS1 standards, specifically a Global Trade Item Number® (GTIN®) encoded in GS1 DataMatrix barcode, would need to be applied to each and every prescribed pharmaceutical pack for scanning, from manufacturer to pharmacist when dispensing the medicine.

Approach

In addition to GS1 standards, the Bulgarian Medicines Verification System (BgMVS) was created and is connected to the European hub of the European Medicines Verification Organisation (EMVO). GTINs are uploaded by manufacturers to the European hub so that when pharmacies dispense medicines, the pack can be certified as an “authentic” medicine.



Following the 2011 European Union Falsified Medicines Directive, which became mandatory as of 9 February 2019, the Bulgarian Medicines Verification Organisation (BgMVO) projects all focused on patient safety. Based on the European Union’s position to protect patients from falsified medicines, it was decided that all stakeholders in the supply chain should be included in this initiative.

The European Commission Delegated Regulation, (EU) 2016/161, supplements the directive, with rules regarding safety features for the packaging of medicinal products for human use. The regulation was adopted in October 2015.

Measures to counteract fake medicines include stricter record-keeping by wholesale distributors, tougher inspections by pharmaceutical producers, an EU-wide quality mark to identify online pharmacies and obligatory safety features on packages.

Using GS1 standards for identification

The main challenge associated with the project to address the FMD is that it is perhaps the largest ever European healthcare IT project. The project included all 32 European countries,

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2,500 European pharmaceutical manufacturers, hundreds of thousands of public and hospital pharmacies across Europe and more than 10 billion packs per year. In Bulgaria, the FMD effort included 200 manufacturers, 150 wholesalers, 3,500 pharmacies and 180 million packs per year.

The main focus of the project was the supply chain, especially wholesalers and pharmacists. The most important action was to create the GS1 DataMatrix barcode for printing on every single pack of prescribed medicines. The barcode itself and the identification information encoded in it had to be standardised, and global standards were to be used. Ultimately, the GS1 system of standards would uniquely identify each medicine.

Verifying the authenticity of medicines

In early 2018, the pilot project started in Bulgaria. A GS1 DataMatrix barcode has been applied on each medicinal product pack and encoded with the product's GTIN, lot/batch number, expiry date and serial number. (For some other countries, an additional piece of information was needed - the National Reimbursement Number - encoded as the fifth element in the DataMatrix barcode.) Applied by the manufacturer, the DataMatrix barcode is then scanned at the pharmacy to authenticate the pack, when the medicine is dispensed to the patient.

The Bulgarian Medicines Verification System is connected to the European hub of the European Medicines Verification Organisation (EMVO). Drug manufacturers upload their product data, including product identifiers or GTINs to the European hub. This data is then automatically transferred to the National Medicines Verification System of the EU country for which the respective batch is intended.

"The BgMVO is actually the second organisation of its kind to be legally established in Europe," says Ms. Iliana Paunova, Executive Director and one of the founders, Bulgarian Medicines Verification Organisation. "We are aiming to be in the first five or six pilot countries for the project."

End-users such as pharmacies and wholesalers are connected to the corresponding National Medicines Verification System. When a medicinal product is dispensed, the DataMatrix barcode is scanned so that the identification code can be verified and decommissioned from the system. This is to ensure traceability of medicines—from manufacturers to patients. As a result, the pack dispensed to the patient is verified as an "authentic" medicine.

An alert is generated if there is discrepancy between the data captured when the DataMatrix code is scanned on the pack and the data that is uploaded in the National Medicines Verification System. This means that the unique identification code has not been uploaded into the system, or it has been uploaded but has already been decommissioned.



Figure 1: Pilot packs ready to be verified

In case of an alert generated by the National Medicines Verification System, the pharmacist should not dispense the medicine to the patient, and it is required that the pharmacist inform the competent authorities. In the early phases of the implementation, users found challenges with scanners and pharmacy software applications.

BgMVO organises regular operational meetings with IT providers. The purpose of these meetings is to provide information on upcoming changes related to the implementation of new versions of the verification system. Discussions are also taking place about how to reduce alerts due to technical reasons in the software or barcode readers.

IT providers are informed about the standard requirements for developing verification applications, as well as the need to maintain an offline mode implemented in their applications.



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Widespread acceptance

With the introduction of the unified systems of medicines verification in Europe, the origin and quality of prescribed medicines that patients receive are assured.

By February 2021 more than 3,100 or 83% of retail pharmacies, hospital pharmacies and wholesalers were connected to the BgMVS. Currently, about 30% of the prescribed and dispensed packs in the system are decommissioned.

All Bulgarian manufacturers serialise and upload data for their products in the European hub. The coverage of COVID-19 vaccines is forthcoming.

The practical experience of pharmacists and other participants in solving specific cases with the application of the verification system has increased and the number of alerts generated due to technical issues with manufacturers and pharmacies has decreased.

Guidelines on managing alerts during the verification and decommissioning of medicines in the BgMVS were issued at the beginning of 2021. These instructions are published on the Bulgarian Drug Agency (BDA) website.

Looking ahead with BgMVS

The BgMVS helps to ensure the safety of patients. It also provides a high-level of security, but only when products are delivered to the supply chain in accordance with the EU FMD regulation.

To date, new on-time versions of the system are being implemented in Bulgaria, with work efforts to sustain progress.

“We are supported by society, state institutions and by the vast majority of stakeholders in the pharmaceutical supply chain. Protecting patients and delivering greater transparency of medicines throughout the supply chain—these are the benefits of the verification process that are well worth the effort,” says Ms. Paunova.

In 2020, changes in Bulgarian legislation related to the verification of medicines were adopted and are already being enforced. These changes establish the verification responsibilities of all actors in the pharmaceutical supply chain, as well as the penalties for non compliance.

Thanks to the joint collaboration of BgMVO, GS1 Bulgaria and the Association of Research-based Pharmaceutical Manufacturers (ARPharM) in Bulgaria, the pharmaceutical drug law in Bulgaria has been amended so that the GS1 GTIN will not be replaced by National Trade Item Number (NTIN) on the drug pack, but only linked to it in internal systems.

Applying standards to COVID-19 vaccines

As of 1 April 2021, the requirements for serialisation and verification will apply to



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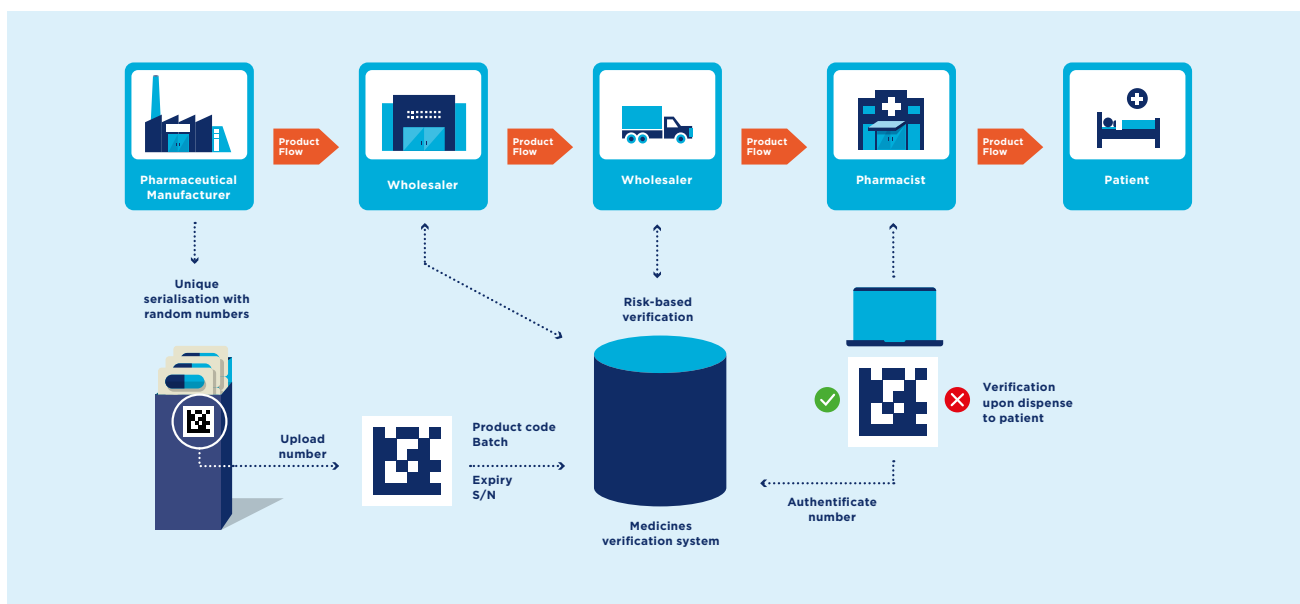


Figure 2: Preferred process

COVID-19 vaccines, for which an initial grace period was given by the European Commission in order to facilitate the vaccines' distribution.

After this period, the vaccines will be produced with a unique identifier based on GS1 standards to be given to people at immunisation points. By using the GTIN, DataMatrix barcode and application of the verification requirements, COVID-19 vaccines will be able to be scanned throughout the supply chain and when they are given to people at immunisation points. With GS1 standards-based identification, vaccines will be protected from falsification attempts.

BgMVO works in close cooperation with GS1 Bulgaria in providing expert advice to National Competent Authorities about the GS1 GTIN, the product identifier and supports manufacturers in implementing safety features. They jointly organise training workshops and conferences to promote the importance of GS1 standards for the verification of medicines, for the protection of the supply chain from falsified medicines and, ultimately, for patient safety.



Figure 3: Launching the system in hospital pharmacy

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About the author



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Desislava Dimitrova has more than seven years of experience as a GS1 expert in healthcare. She is responsible for business development within the healthcare sector and the implementation of the GS1 standards in healthcare. Ms. Dimitrova's mission is aligned with the overall mission of GS1 standards in the Healthcare sector: to increase patient safety, supply chain security and efficiency, traceability and accurate data synchronisation in healthcare.

About the organisation



Bulgarian Medicines Verification Organisation was established on 14 March 2016 in Sofia as a non-profit association to support the implementation in Bulgaria of Directive 2011/62/EU for preventing the entry of falsified medicinal products into the legal supply chain.

The founders of the BgMVO include five organisations representing the stakeholders involved in the manufacturing and distribution of medicines: the Association of Research-Based Pharmaceutical Manufacturers in Bulgaria, Bulgarian Generic Pharmaceutical Association, Bulgarian Association of Medicines Parallel Trade Development, Bulgarian Association of Pharmaceutical Wholesalers and Bulgarian Pharmaceutical Union. This governance model is aligned with the set-up of the European Medicines Verification Organisation. It includes all five stakeholders: innovative industry, generics industry, pharmacies, wholesalers and parallel distributors. It is the most important public-private partnership in Bulgaria so far for any industry.

The main purpose of the Falsified Medicines Directive is to ensure that patients are supplied with authentic medicinal products by building, operating and maintaining an effective drug verification system in the Republic of Bulgaria. BgMVO works in close collaboration with healthcare authorities in Bulgaria, with all stakeholder organisations and partners such as GS1 Bulgaria, IT software providers, media and patient organisations.

www.bgmvo.org/bg