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REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

on trends in the falsification of medicinal products and measures provided according to Directive 2011/62/EU as required in Article 3 thereof

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1. EXECUTIVE SUMMARY

In June 2011, the European Parliament and the Council adopted Directive 2011/62/EU ([1]), also known as the Falsified Medicines Directive. The Directive had two purposes: (i) to address an increase in the number of falsified medicinal products detected in the EU; and (ii) to strengthen the supervision of the legal supply chain for medicines for human use. The Directive introduced harmonised European rules to ensure that falsified medicinal products do not enter the legal supply chain of the single market and reach patients. It stipulates that medicinal products for human use subject to prescription must bear safety features on their packaging.

Detailed rules for these safety features are laid down by Delegated Regulation (EU) 2016/161 ([2]). The Delegated Regulation became applicable in 2019 and introduced verification mechanisms and obligatory safety features for medicinal products. These verification mechanisms and safety features are:

1. a unique identifier (a 2-dimensional bar code), the authenticity of which proves the legitimacy of an individual pack of a medicinal product;
2. an anti-tampering device, the integrity of which demonstrates the authenticity of the medicinal product in its packaging.

Article 3 of Directive 2011/62/EU requires the Commission to present a report to the European Parliament and to the Council at the latest five years after the date of application of the Regulation. The report must contain: (i) a description of recent trends in the falsification of medicinal products; and (ii) an assessment of the contribution made by the measures provided for in this Directive to preventing the entry of falsified medicinal products into the legal supply chain.

The present report delivers on this obligation. It is based on the findings of the *Study supporting the report to the European Parliament and to the Council on trends in the falsification of medicinal products and measures provided according to Directive 2011/62/EU* written by an external consultant in 2023. The Study examined the effects of the measures laid down by the Falsified Medicines Directive and the Delegated Regulation in the EU and EEA. It is published on the Commission's homepage[3].

For the reasons set out below, it is not yet possible to draw final conclusions as to the effects of the Directive and the Delegated Regulation. Nevertheless, it is safe to say that, overall,

([1]) Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products OJ L 174, 1.7.2011, pp. 74-87.

([2]) Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use OJ L 32, 9.2.2016, pp. 1–27.

([3]) see at: https://health.ec.europa.eu/publications/study-supporting-report-european-parliament-and-council-trends-falsification-medicinal-products-and_en

substantial and steady progress in detecting falsified medicines has been observed since the Directive and the Delegated Regulation came into application. Most cases of falsification have been detected in the *illegal* supply chain (often via unauthorised sales on the internet). Even on the few occasions that falsified medicinal products were identified in the *legal* supply chain, the national authorities, in collaboration with the supply-chain operators, promptly addressed the matter. Medicinal products that are purchased in the official channels, i.e. physical or online authorised pharmacies, can be assumed to be safe.

The Falsified Medicines Directive and the Delegated Regulation increase the hurdles and the cost of falsification for criminals. They also make it possible to generate data that can help to swiftly detect and investigate suspicious packages and track falsifying activities.

However, it is not yet possible to assess in detail the effect that the measures set out in the Delegated Regulation have had because they are not yet completely implemented. There are five main reasons for this incomplete implementation: (i) many pharmacies are still not connected to the EU system; (ii) some of the pharmacies that are connected to the system may not yet be using the IT system effectively; (iii) some IT systems developed at national level still trigger a level of false alerts that is too high; (iv) the governance of the system by the responsible organisations representing supply-chain operators has sometimes led to internal conflicts on the use of the information contained in the EMVS; and (v) the lack of standard procedures to qualify cases as *confirmed cases of falsification* and the lack of centralised files reporting all cases across the EU/EEA make comparisons and trend analysis particularly difficult.

Furthermore, the legislation granted Belgium, Greece and Italy an extended transition period to adapt their existing system to the EU rules. Belgium voluntarily applies the rules as of 9 February 2019. Greece and Italy are only due to join the EU system in 2025. Therefore, a full assessment of the impact of the Falsified Medicines Directive and Delegated Regulation is currently not possible.

Over the past years, the Commission has continuously engaged with national competent authorities (NCAs) and stakeholders to ensure progress towards full implementation, and it is committed to continue to do so.

2. INTRODUCTION AND LEGAL FRAMEWORK

In June 2011, the European Parliament and the Council adopted Directive 2011/62/EU ([4]), also known as the Falsified Medicines Directive, to strengthen the supervision of the legal supply chain for medicines for human use.

Delegated Regulation (EU) 2016/161 ([5]), laying down the detailed rules for the safety features appearing on the packaging of medicinal products for human use, complements the Directive. The safety features link to a data repository governed by non-profit organisations representing the supply-chain operators ([6]). The Delegated Regulation has been in application since 9 February 2019 and covers prescription medicines, although its scope can be extended to non-prescription medicinal products at risk of falsification.

Greece and Italy still use an extended transition period granted to Member States that already had a system in place. They are obliged to join the EU system by February 2025.

The verification operates as an end-to-end system. Safety features are placed on the medicinal products at the manufacturing stage and must be verified at the end of the supply chain upon decommissioning of the medicine packs. Additional verifications are required along the supply chain when a risk of introduction of a falsified medicine is deemed significant.

Article 3 of the Falsified Medicines Directive requires that the Commission presents a report to the European Parliament and to the Council on the following:

a) a description, where possible including quantitative data, of the trends in the falsification of medicinal products in terms of categories of medicinal products affected, distribution channels including sale at a distance to the public by means of information society services, the Member States concerned, the nature of the falsifications, and the regions of provenance of these products; and

b) an evaluation of the contribution of the measures provided for in this Directive regarding the prevention of the entry of falsified medicinal products in the legal supply chain. That evaluation shall in particular assess point (o) of Article 54 and Article 54a of Directive 2001/83/EC as inserted by this Directive.

The Commission asked an external consultant to conduct a study ('the Study') on the two subjects cited under (a) and (b) above from the perspective of: (i) the parties involved in the supply chain; and (ii) the Member States' enforcement authorities. The resulting *Study supporting the report to the European Parliament and to the Council on trends in the*

([4]) Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products OJ L 174, 1.7.2011, pp. 74-87.

([5]) Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use. OJ L 32, 9.2.2016, pp. 1-27.

([6]) Manufacturers, marketing authorisation holders, wholesalers and persons authorised or entitled to supply medicinal products to the public.

falsification of medicinal products and measures provided according to Directive 2011/62/EU is the basis for the present report.

3. TRENDS IN THE FALSIFICATION OF MEDICINAL PRODUCTS

This section addresses point (a) of Article 3 of Directive 2011/62/EU.

3.1. Quantitative data on falsified medicinal products

The Falsified Medicines Directive amended Directive 2001/83/EC, i.e. the Community code relating to medicinal products for human use, and defines a 'falsified medicinal product' as:

> *Any medicinal product that has a false representation of: (a) its identity, including its packaging and labelling, its name and its composition, (b) its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder, or (c) its history, including the records and documents relating to the distribution channels used.*

This definition distinguishes 'falsified medicinal products' from 'counterfeit medicinal products'. The latter infringe intellectual property rights or trademark law. Statistics on counterfeit medicinal products are often used as a proxy to estimate trends in falsified medicinal products, but falsified medicines are not necessarily counterfeit.

Neither the European Medicines Agency (EMA) nor the NCAs consistently monitored cases of falsification before the adoption of the Delegated Regulation. The EMA did not keep distinct records for falsified medicines and other issues involving medicines in the supply chain, such as thefts. As a result, it is difficult to assess how the situation has evolved.

Since the adoption of the Delegated Regulation, the EMA has recorded and coordinated the exchange of information on falsified medicine notifications for centrally authorised medicines ([7]). According to the EMA, 30 potential cases of falsification were detected in the EU/EEA between 2011 and 2016 included, and there have been 11 confirmed cases of falsified medicines since 2019.

Member States are responsible for supervising and investigating the supply chain, and deciding on measures to be taken in the event of suspected and confirmed cases of falsification for nationally authorised medicines. In addition, when a suspected case is notified to the EMA it must be further investigated by Member States.

The diversity of measures and approaches implemented by Member States, including in terms of classification into *suspected* and *confirmed* cases, as described in detail in the Study, makes it impossible to draw clear conclusions as to trends. Cases from different Member States cannot be easily aggregated for the purpose of an overall analysis.

It is also possible that some cases of falsification are undetected. This is due to: (i) the protracted implementation of the Delegated Regulation (the so-called stabilisation period

([7]) EMA webpage on falsified medicines. https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/compliance-post-authorisation/falsified-medicines-reporting-obligations.

further described below); and (ii) the slow process for connecting operators to the system. The number of cases reported does not therefore necessarily reflect adequately the actual trend of falsified medicinal products on the market. This is further described in the second part of the Study.

In summary, the differences between national processes and the lack of centralised data are factors that make it impossible to provide reliable quantitative data on trends in the falsification of medicinal products. Complete implementation and a standardised reporting system would allow to draw conclusions as to the quantification of suspected and confirmed cases of falsified medicinal products.

3.2. Categories of medicinal products affected

According to the NCAs, the categories of medicinal products most likely to be falsified are expensive medicines such as anti-cancer injections ([8]) and 'lifestyle drugs' such as muscle-building steroids and sexual enhancers. These products promise the largest revenues for falsifiers and are widely purchased online.

3.3. Member States concerned, regions of provenance, and distribution channels

The pharmaceutical supply chain often crosses borders between EU countries. Consequently, all countries are at risk of having falsified medicinal products on their market.

The Falsified Medicines Directive is intended to protect those purchasing medicinal products through legal means (in authorised stores and online pharmacies).

According to the Study, most cases of falsifications have been detected in the *illegal* supply chain. Illegal supply chains differ from legal ones as they operate deliberately outside the applicable laws. It is possible that medicines available in the legal supply chain are diverted to illegal networks of distribution.

The Study gives the example of a colon-cancer medicine stolen from hospitals, manipulated, and re-introduced into the legal supply chain under false credentials, and then distributed by wholesalers ([9]). Similar observations were made in the EU-funded project MEDI-THEFT launched in November 2021 ([10]). The existence of unauthorised online traders increases the availability of falsified medicines. Authorities have difficulties in effectively monitoring online sales as online sales are typically for small shipments that are not detected by existing enforcement mechanisms.

([8]) Data submitted by NCAs show that there can be as many as several thousand prescribed anti-cancer medicinal products which are priced per dose depending on the country. These prescribed anti-cancer medicinal products are particularly targeted by falsifiers.

([9]) Both authorised and non-authorised wholesalers were involved. For more details, see the case studies presented in the Study related to this subject matter.

([10]) Medi-Theft at https://www.transcrime.it/en/projects/medi-theft/.

Given the differences in reporting between Member States, the Study could not identify specific regions of provenance or distribution for falsified medicines.

The rise of online sales has increased the risk of illegal traders entering the supply chain. Only legal online pharmacies displaying the common logo ([11]) participate in the EU medicines authentication system set up under the Falsified Medicines Directive and are a reliable source of supply. The logo allows the public to clearly distinguish a legal website from an illegal website.

3.4. Conclusions

Based on the information made available by the Study, the Commission considers it impossible at this stage to draw clear conclusions as to trends in the falsification of medicinal products.

It is only possible to make the following three broad points.

- The categories of medicinal products that are most often subject to falsification are expensive prescription medicines and products in high demand such as 'lifestyle drugs'. These are in particular sold outside the legal supply chain via non-authorised websites.
- The widespread access to online sales increases the risk that falsified medicines could be distributed through illegal suppliers. There is the need to unlock the full potential of the common EU logo to protect consumers and patients from falsified medicinal products available on online markets.
- The Study could not identify specific regions of provenance or distribution for falsified medicines.

4. CONTRIBUTION MADE BY THE MEASURES THAT AIM TO PREVENT THE ENTRY OF FALSIFIED MEDICINAL PRODUCTS INTO THE LEGAL SUPPLY CHAIN

This section addresses point (b) of Article 3 of the Falsified Medicines Directive, i.e. assessing the contribution of the measures set out in the Directive on falsified medicinal products in the legal supply chain. This section analyses the functioning of the measures provided for in both the Falsified Medicines Directive and the Delegated Regulation, i.e. the implementation of point (o) of Article 54 and Article 54(a) of the amended Directive 2001/83/EC outlining the scope and the measures introduced.

The measures: (i) lay down concrete mechanisms to prevent falsified medicines from entering the legal supply chain; (ii) set out arrangements for the governance of the repositories system; (iii) describe the safety features to be used (unique identifier, anti-tampering device); (iv) set out the verification activities; and (v) set out how to report falsified medicinal products.

([11]) The common logo for legally operating online pharmacies/retailers in EU countries was first introduced by Directive 2011/62/EU as one of the measures to fight against falsified medicines. In 2014, the European Commission adopted the new common logo through Implementing Regulation 699/2014.

4.1. Governance of the repositories system

The Delegated Regulation lays down a stakeholder-led governance model allowing supply-chain operators to organise themselves. Non-profit legal entities representing the operators in the supply chain manage the system. At EU level, the European Medicines Verification Organisation (EMVO) is responsible for setting up and managing the European Medicines Verification System (EMVS). At national level, national medicines verification organisations (NMVOs) implement and manage the verification systems connected to the EMVS. In this two-tier architecture, national data are stored and managed nationally, but transfer of information across borders is possible. Marketing authorisation holders bear the costs of the system. All operators engaged in the supply chain participate via their representative associations at EU and national levels. Software providers run the information technology system under service contracts (two providers govern the EMVS). These contracts do not guarantee swift adaptation of software.

The nature of the commercial and contractual relations with the software providers has led to delays in the development and rolling out of the IT tools.

Every EU/EEA Member State has an NMVO in place. The only exceptions are Belgium and Luxembourg, as both use the Belgian Medicines Verification System.

NCAs supervise the functioning of the NMVOs and have access to reports from the repository system to track suspicious packages or behaviours. Such investigations can be complicated by the two-tier architecture as a full 'audit trail' (i.e. the ability to trace back the supply chains, sources and origins of the falsification of a product beyond the national territory of a given country) is in practice not immediately available to NCAs, even though this is stipulated in the Delegated Regulation (Article 35(1)(g)).

The two-tier architecture is also due to the specificity of this stakeholder-led governance model. It creates challenges in finding common approaches, as there can be significant divergence in the positions of stakeholders represented on the management boards of the organisations in charge at EU and national levels impacting their ability to take strategic decisions.

4.2. Scope

The scope of the Delegated Regulation covers prescription medicines and non-prescription medicines identified to be at a high-risk of falsification. However, the legislation allows Member States to extend the scope to address national needs. For example, some Member States require an anti-tampering device to also be placed on non-prescription medicines ('over-the-counter' products).

The primary objective of the Falsified Medicines Directive and Delegated Regulation is to prevent falsified medicinal products from entering the legal supply chain. In addition, and in line with the legislation, several Member States also use the safety features for purposes

related to pharmacovigilance, pharmacoepidemiology and reimbursement. Figure 1 outlines the replies received from NCAs about what they used the repositories system for.

Figure 1. Use of the repositories system by the NCAs

	BE	BG	CY	CZ	EE	FI	FR	DE	HU	IE	LT	MT	NL	PL	PT	SK	SL	ES	SE
Supervising	X	X		X						X	X	X		X	X		X	X	X
Investigating	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Reimbursement	X	X													X			X	
Pharmacovi-gilance or pharmacoepi-demiology		X															X	X	

Source: Survey to NCAs

The current scope, with its flexibility, correctly reflects the objective of minimising the risk brought by falsified medicines. It appropriately balances the risks posed by falsified medicines with the administrative burden involved in preventing these risks.

4.3. Unique identifier and anti-tampering device

The technical specifications of the unique identifier (UI) make it possible to securely identify legitimate medicinal products. They also harmonise the product coding system. The Study showed that most of the stakeholders and all NCAs that replied consider the UI adequate.

The purpose of the anti-tampering device (ATD) is to guarantee that medicinal packs are not opened or otherwise altered before dispensing. It has become apparent that the absence of precise requirements for the design of the ATD and for its verification can reduce the effectiveness of this safety measure. Even though there are no mandatory specifications, the document ISO 21976:2020 ‘Packaging – Tamper verification features for medicinal product packaging’ is available for manufacturers to consider. This document specifies requirements and provides guidance for the application, use, and checking of tamper-verification features on the packaging of medicinal products.

4.4. Verification mechanism

As indicated in paragraph 4.1 on the governance of the repositories system, the EMVS builds on a two-tier architecture. National repositories (NMVOs) are linked to a central hub which is managed by the EMVO. NCAs and stakeholders in all Member States confirm the functionality and appropriateness of this architecture.

The Commission has continuously engaged with national authorities and stakeholders. Consequently, combined with the support provided by EMVO, the number of users and medicinal products registered in the EMVS continues to grow, especially for community pharmacies. Figure 2 and Figure 3 illustrate the number of stakeholders connected to the EU system in March 2024 and in January 2023 (excluding Italy and Greece).

Figure 2. Stakeholder connection overview as of calendar week 9, 2024

End-User Type	Not Connected	Connected	Percentage Remaining
Wholesalers	1	4113	0.023%
Pharmacies	6	116 311	0.013%
Healthcare Institutions	760	6451	10.543%
Dispensing Doctors	58	817	6.633%
Other Decomm. Channels	60	381	13.613%

Source: EMVO report, March 2024

Figure 3. Stakeholder connection overview as of calendar week 52, 2022

End-User Type	Not Connected	Connected	Percentage Remaining
Wholesalers	13	4074	0.323%
Pharmacies	3967	113 639	3.373%
Healthcare Institutions	1049	6374	14.133%
Dispensing Doctors	56	819	6.403%
Other Decomm. Channels	60	436	12.103%

Source: EMVO report, January 2023

However, many operators that are currently connected to the EMVS are still not yet fully using the system effectively. According to EMVO data from September 2023, 26% of the medicines with safety features are not checked out of the repository system when dispensed ('decommissioned'), putting them in breach of the EU legislation ([12]). Two main problems with the EMVS are set out in the bullet points below.

- Some pharmacists admit that they do not decommission medicinal products when dispensing them to patients. They argue that verification, i.e. scanning the UI, triggers high numbers of alerts for medicinal products that could possibly be false alerts. This causes delays, interrupts workflows, and fuels patient dissatisfaction.
- Single-pack verification is considered an excessive burden in hospital pharmacies due to the large number of products handled in this setting. Verification is time-consuming. The Member State Expert Group on safety features issued a working paper in 2018 in which it proposes bulk verification using 'aggregated codes' or 'consolidated codes'. The use of these codes allows a speedier and more efficient process of decommissioning of packages of the same content and origin.

The system was designed to prevent falsified medicinal products from reaching patients. Wholesalers can verify the packs at their disposal if they have suspicions. Wholesalers are not obliged to verify all packs systematically (i.e. those received from the marketing authorisation holder, manufacturer or a designated wholesaler do not need to be verified). This is to avoid a disproportionate burden for wholesalers.

Based on these considerations, it is not possible at this stage to draw clear conclusions on the actual ability of the EMVS to effectively detect all falsified medicinal products throughout the

([12]) 'Decommissioning of a unique identifier' means the operation changing the active status of a unique identifier stored in the repositories system referred to in Article 31 of the Delegated Regulation to a status preventing any further successful verification of the authenticity of that unique identifier.

supply chain. However, evidence shows that the few cases of falsification in the legal supply chain were promptly addressed when they were detected.

4.5. Reporting mechanism

The reporting system is based on two alert mechanisms for falsified medicinal products, described in the two paragraphs below.

1. EMVS automated code-scanning alerts: the objective agreed in the EMVO is to reach an alert rate of less than 0.05%. According to the EMVO's report of March 2024, in seven countries (including Northern Ireland ([13]), the alert rate is between 0.16% and 1.17% (Lichtenstein). According to the EMVO, the three main causes of this are: (i) mistakes in the data uploaded by the marketing authorisation holder to the European hub; (ii) scanner issues; and (iii) double decommissioning. This is however a noticeable improvement compared to the initial phase of the implementation.
2. User notifications of suspicious packages: a lack of clarity in Articles 18, 24 and 30 of the Delegated Regulation on terms and responsibilities result in little use of this option.

Many automated alerts are not subsequently confirmed in the form of falsified medicinal products. To avoid a situation in which many products are not provided to patients because of technical issues creating false alerts, the EMVO promoted a 'stabilisation period' at the start if the system which was extended several times.

During these stabilisation periods, even if a product raised an alert, the persons authorised/entitled to supply medicinal products to the public could dispense that product to patients upon careful control of the packaging. It was introduced to avoid disruptions in the supply chain due to alerts caused by missing or incorrectly uploaded data, scanning products not in the scope of FMD, procedural mistakes etc.

Based on EMVO's monitoring report of March 2024, six Member States still allow to dispense medicine packs that raise alerts in the system. As a result, some Member States ([14]) set up parallel national alert-management systems.

NMVOs systematically investigate alerts emanating from automated code scanning with the support of the NCAs. The follow-up on these alerts as suspected and/or confirmed cases, does not follow the same procedures in each Member State. Moreover, users rarely notify suspicious packages on their own initiative.

([13]) Which in the meantime left the system with the Windsor Framework, Joint Declaration No 1/2023 of the Union and the United Kingdom in the Joint Committee established by the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community of 24 March 2023 (OJ L 102, 17.4.2023, p. 87) see at: https://commission.europa.eu/strategy-and-policy/relations-non-eu-countries/relations-united-kingdom/eu-uk-withdrawal-agreement/protocol-ireland-and-northern-ireland_en.

([14]) As an example, Estonia already developed a national alert system.

4.6. Perceptions held by both stakeholders and NCAs

The Falsified Medicines Directive introduced harmonised European-wide rules to fight medicine falsifications and ensure that patients receive safe medicines.

The Delegated Regulation provides authorities with the tools they need to rigorously control the trade in medicines under its scope. Its provisions received a positive opinion from the NCAs.

Supply-chain operators recognise the need for harmonised rules across the EU and the interconnected repositories system. It is to be welcomed that EU rules will end divergent national requirements and make it easier to monitor the movement of products across the EU/EEA.

However, all the NCAs that responded to the survey conducted for the purpose of the Study considered that the supply chain in their region was already safe before the EU legislation was in place. The same is true for wholesalers and pharmacists ([15]).

4.7. Conclusions

The purpose of the legislation was and remain to avoid that falsified medicinal products reach patients. The measures adopted aimed to balance the risks posed by falsified medicines with the administrative burden of preventing them.
However, the incomplete implementation of the measures makes it impossible to properly and firmly assess the effect that they have had.

For this reason, and based on figures regularly provided by the EMVO, the Commission has urged the Member States to comply with their obligations under the legislation and to ensure that the stakeholders involved comply as well.

The Commission has been liaising with Member States to first and foremost to increase: (i) the number of stakeholders connected to the repository system (i.e. pharmacies, wholesalers, persons authorised/entitled to supply medicinal products to the public); and (ii) the decommissioning rates.

Regular exchanges with the Member States are ongoing to monitor progress towards full compliance, both bilaterally and in the Expert Group set for the purpose of the implementation of the legislation and through regular data reporting. As a result of this, there has been significant progress in 2023 with regards to the connection of community pharmacies.

([15]) Outside of the scope of this report on falsified medicinal products, manufacturers and marketing authorisation holders that were consulted promote the transformation of the verification system into a ‘track and trace system’. Some NCAs support this idea in the hope that such a system could serve to monitor, prevent and mitigate shortages of medicines. The information that is currently generated by the system does not provide an overview of stocks and volumes of medicinal products, and it does not provide the location of the medicinal packs. The system was not designed with that purpose. Interoperability with other systems outside the scope of the Falsified Medicines Directive and its Delegated Regulation could be analysed as need be.

The Commission has also urged the NCAs to allocate sufficient resources to appropriately supervise the system at national level.

The Commission is also closely monitoring the work of the EMVO to ensure that it delivers on its tasks.
Thus, although significant progress has been noted since 2023, the Commission is actively monitoring the following challenges and engaging with the national authorities and stakeholders to address them:

- in a limited number of countries, low level of connection of hospital pharmacies;
- decommissioning rates;
- technical issues triggering considerable numbers of false alerts that consequently discourage stakeholders from using the system;
- diverging views between EMVO members, which can prevent strategic decisions from being taken; and
- the lack of guidance for the suitability of ATDs.

5. OVERALL CONCLUSIONS AND NEXT STEPS

It is critical that the measures in the Falsified Medicines Directive and Delegated Regulation are fully implemented to reach their full potential.

The measures introduced by the Falsified Medicines Directive and Delegated Regulation have already had two main positive results:

- they make it more difficult to introduce illegal products into the legal supply chain, so illegal products stay in the illegal circuit; and
- they generate data for investigators that make it possible to detect suspicious packages and track falsifying activities.

So far, most cases of falsifications have been detected in the illegal supply chain (including illegal websites or websites not authorised to provide medicinal products).

Even when falsified medicinal products were identified in the legal supply chain, the national authorities, in collaboration with the supply-chain operators, promptly addressed the matter to remove the products from the legal supply chain.

Considering that this EU legislation is still in the process of being implemented in all the EU/EEA countries, and given that confirmed and suspected cases of falsification are not reported centrally at EU level, it is currently not possible to make a complete and firm assessment of the impact of the Falsified Medicines Directive and Delegated Regulation.

The Commission will, in cooperation with the NCAs and the supply-chain operators, further identify actions to address the remaining challenges and achieve full implementation, such as:

- Collaborating closely with Greece and Italy to make sure they comply with the EU legislation by 9 February 2025,
- Continuing to check compliance by working bilaterally with the Member States, and leveraging the Member State Expert Group on safety features for them to exchange

best practices and take a strategic approach to solve current challenges with the system,

- Identify areas where the development of possible additional guidance documents could facilitate a common EU-wide approach to implementation e.g. in relation to the anti-tampering device and the follow-up of suspected packs,
- Collaborating with EMVO to explore the most effective actions to address the number of false alerts that remains above the desired level, and
- Continuing to participate to the EMVO Board meeting to encourage appropriate implementation of the Delegated Regulation by the stakeholder organisations represented in the board, and to encourage a collective and cohesive strategic approach supporting the functioning of the system.