

Results of a survey carried out by ASOP EU and the EAEP conducted amongst countries responsible for the administration, governance and public facing activities of the Falsified Medicines Directive and specifically the EU Common Logo.





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I read with interest and support wholeheartedly this report launched by the Alliance for Safe Online Pharmacy (ASOP EU) and the European Association of E-Pharmacies (EAEP) on the EU Common Logo. It's been just over a decade ago since EU Member States commenced applying the safety measures of the Falsified Medicines Directive (FMD)¹. One of the clear aims of the FMD was to instruct each Member State to create a register of all pharmacies who legitimately operate online via a website in order for patients to know if the website is a genuine one. A simple click on a logo – referred to as the EU Common Logo – would route the person through to the pharmacy with licensure, telephone and address confirmation details.



Petar Vitanov Member of the European Parliament Under Article 85D of the FMD, this legally obliges each Member State to carry out public facing information campaigns. Why is this aspect so important? A public facing campaign² carried out by ASOP EU provides very good evidence that this type of education is effective. This activity comprised an educational Google Adwords campaign which ran in five countries and revealed much useful behavioural data. Most significantly, it revealed that all types of medicines were being bought, and from similar genders and age groups. Of vital importance was that, once the respondent was informed about the scourge of falsified medicines online via illicit websites, then no less than nine out of 10 respondents said that they would seek out an authentic online pharmacy or offline physical pharmacy.

This survey sets out to pick up from previous useful communication, meetings and a published report with Member States and to examine latest activities in this respect. Based on the responses, I can only applaud this initiative by ASOP EU and the EAEP. I would hope that it serves to catalyse the coming together of those national departments charged with administering the Common Logo and adherence to Article 85D. This will further improve the patient knowledge of the EU Common Logo, which is clearly still very much needed. Only by sharing good practices of this worldwide challenge from falsified medicines, can we make bigger strides to inform and protect the EU citizen.





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In collaboration with the European Association of E-Pharmacies (EAEP) and the Alliance for Safe Online Pharmacy in the EU (ASOP EU) the two organisations constructed a survey to better understand the current status of the activities surrounding an important aspect of the Falsified Medicines Directive (FMD) under Article 85D, which legally obliges each Member State to provide information campaigns to inform the public about the meaning of a falsified medicine as well the EU Common Logo. Both organisations firmly believe that given the rising scourge of falsified medicines (where criminals have stepped up their illegal activities), it is essential that the public is made more aware of websites that sell medicines illegally as well as understanding how they can access authentic medicines via the Internet.

- Many EU / EEA countries and Serbia were contacted and in total 12 responded which has enabled a useful collection of data pertaining to nine EU Member States and two EEA Member States and Serbia, namely those that replied to the ASOP EU / EAEP inquiry for data.
- It revealed that there is total awareness of the Falsified Medicines Directive Article 85D.
- 11 of the 12 country respondents regarded this Article as of high or medium importance.
- All respondents operating under the Falsified Medicines Directive had a public facing website (see page 17).
- Six of the 12 country respondents had heard of the Top-Level Domain name operated by the National Association of Boards of Pharmacy and many expressed an interest in knowing more about this patient safety initiative and six countries were interested to learn more about this programme.
- Nine of the countries had run public facing campaigns on the Common Logo and falsified medicines whilst three had not. When asked if they intended to run future campaigns five countries stated that they would be.
- To the question "What is your opinion on running information campaigns collectively with healthcare stakeholders to raise further awareness of the Common Logo?" then this revealed a good degree of interest, with nine countries saying they would like to explore this more.
- Only one country expected the Common Logo to be promoted with any specific efforts / activities from healthcare providers such as online pharmacies.
- In answering the final question "To what extent do you expect healthcare providers such as online pharmacies to promote the EU Common Logo among customers and patients?" then seven countries had a high to medium expectation.





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Conclusions and recommendations

It was encouraging to note that all respondents regarded that it was a high or medium priority to publicise the meaning of the Common Logo and falsified medicines. However, whilst nine of the respondents had run campaigns in the past, many now had reverted to static website pages as part of the agency website and so there was little evidence of contemporary active outreach campaigns. Nonetheless, it is promising that respondents stated that they were keen to collaborate and run campaigns collectively. Based on the input collected, the following recommendations were made:

Recommendation 1: Design a collective outreach "generic" campaign by Member States whereby the text and images could be translated and transposed and thus used across Europe, as this would be beneficial to patients.

Recommendation 2: When designing such a campaign, set up a workshop with EAEP and ASOP EU to examine the success of such a campaign among customers/patients, whilst ensuring that stakeholders such as pharmacies are consulted around the proposed content.

Recommendation 3: Create a community of interested parties to enable further Member State collaboration on the important topic of falsified medicines and educational approaches.

Falsified Medicines Directive: The Directive aims to prevent falsified medicines entering the legal supply chain and reaching patients. It introduces harmonised safety and strengthened control measures across Europe by applying new measures, such as the EU Common Logo for online pharmacies.

EU Common Logo: The common logo for legally operating online pharmacies/retailers in EU countries was first introduced by Directive 2011/62/EU (Falsified Medicines Directive) as one of the measures to fight against falsified medicines. The logo consists of a national flag in the middle left side of the logo which corresponds to the EU country where the pharmacy or retailer is registered or authorised. Only national flags of EU countries or those of Norway, Iceland and Liechtenstein feature.

Top-Level Domain name DotPharmacy: The National Association of Boards of Pharmacy (NABP) has launched the .pharmacy generic Top-Level Domain (gTLD) merchandising accreditation programme to provide consumers around the world a means for identifying safe, legal, and ethical pharmacies and related resources. The .pharmacy generic Top-Level Domain (gTLD) is implemented and common practice in both the US and Canada.





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Methodology Results Conclusion Over the second half of the year 2023, EU / EEA countries and Serbia were contacted to complete a short survey to better understand the current status of the activities surrounding an important aspect of the Falsified Medicines Directive (FMD).

This Directive requires each Member State to make medicines available "at a distance" and as such enables pharmacies in accordance with their laws, to at least make available medicines of an "over the Counter" (OTC) category available via the Internet.

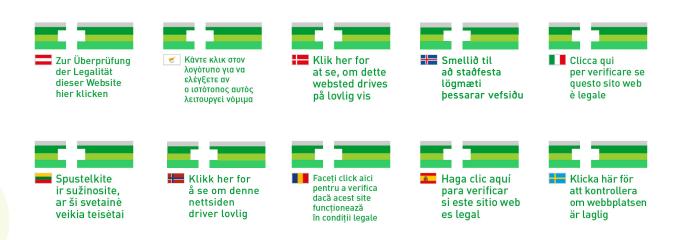
In doing so, a pharmacy that wishes to sell medicines online has to register with the national governing body and display on each website page depicting a medicine, an "EU Common Logo" (see Figure 1). This can be clicked on and routes through to a national register which helps ensure that the patient is dealing with a legitimate licensed pharmacy.



Article 85D of the FMD states "Without prejudice to the competences of the Member States, the Commission shall, in cooperation with the Agency and Member State authorities, conduct or promote information campaigns aimed at the general public on the dangers of falsified medicinal products. Those campaigns shall raise consumer awareness of the risks related to medicinal products supplied illegally at a distance to the public by means of information society services and of the functioning of the Common Logo, the Member States' websites and the Agency's website."

Figure 1.

The purpose of the survey was to ascertain important aspects of country activities in respect of this article and, in addition, sought to explore potential opportunities for private / public partnerships to further raise awareness and share good practices.







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A series of 10 questions with an introduction (see appendix) were designed with the aim to assess the country's knowledge around the Common Logo, the responsibilities of those responsible for carrying out the governance of the Common Logo, awareness campaigns (past, present or future) around the meaning of the Common Logo and falsified medicines, complementary safety digital devices, like the Top-Level Domain name DotPharmacy (.pharmacy), and questions around the expectations of e-pharmacies and / or healthcare stakeholders running collaborative awareness campaigns.

The survey period for gathering responses was from July to November 2023.

Invitations were sent to the appropriate department within the country to complete the survey which on average took about four minutes.

The questions

- 1. Please state which Member State you represent
- 2. Are you aware of Article 85D of the Falsified Medicines Directive (promotion of information campaigns on the dangers of falsified medicinal products and the meaning of the Common Logo)?
- 3. Do you have a competent authority website set that describes the Common Logo?
 - If yes, please would you give the website address that leads us closest to the page and this information (such as the official register of online pharmacies in your country).
- 4. In your view, what is the importance given to the implementation of Article 85D of the Falsified Medicines Directive in your country in the past years?
- 5. Are you aware of the Top-Level Domain .pharmacy that is run by the non-profit National Association of Boards of Pharmacy? This patient safety initiative is proving extremely useful in directing patients to a website selling authentic medicines. An Internet suffix like .pharmacy is a Top-Level Domain which cannot be copied or corrupted.
 - If you would like to learn more about this patient safety initiative, as it provides a safe secure place for patients to go to buy their medicines that cannot be scammed, please add your email address and we will send further information thank you.
- 6. Has your agency run any public facing campaigns about the Common Logo and falsified medicines in the past?
 - If yes, please provide essential details (web address, link to material etc).





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- 7. Do you intend to run any public facing campaigns in the future? If yes, please explain when and how.
- 8. May we ask if you expect any specific efforts / activities from healthcare providers such as online pharmacies to promote the EU Common Logo?
 - If yes, please describe what specific efforts / activities you would like to see.
- 9. What is your opinion on running information campaigns collectively with healthcare stakeholders to raise further awareness of the Common Logo?
- 10. To what extent do you expect healthcare providers such as online pharmacies to promote the EU Common Logo among customers and patients?

Many thanks for completing this important survey. Once the above survey is collated, we will produce a report for the benefit of sharing good practice. If you would like to receive a copy plus a potential invitation to attend a virtual meeting to further share experiences, please add your contact details below.





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The results were collected over a 5-month period of 2023 in the following volumes.



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Question 1.

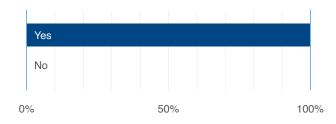
A total of 12 responses were received from nine Member States and two EEA Member States* and Serbia**.

These were: Austria, Belgium, Cyprus, Denmark, Iceland*, Italy, Lithuania, Norway*, Romania, Serbia**, Spain and Sweden.

Question 2.

Are you aware of Article 85D of the Falsified Medicines Directive?

Promotion of information campaigns on the dangers of falsified medicinal products and the meaning of the Common Logo.

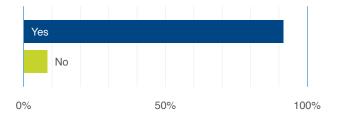


It is encouraging to note that all respondents say they are aware of Article 85D which provides a legally binding obligation to inform the general public on the dangers of falsified medicinal products as well as explaining the meaning and relevance of the Common Logo.

Question 3.

Do you have a competent authority website set that describes the Common Logo?

Links to the respective competent authority websites can be found on pages 11 and 17.



^{**}Not in the EEA





^{*}EEA countries

Question 4.

In your view, what is the importance given to the implementation of Article 85D of the Falsified Medicines Directive in your country in the past years?

It can be seen that only one country gave this question as "low" which was Serbia.

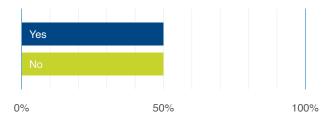
High importance: Seven countries

Medium importance: Four countries

Low importance: One country*

Question 5.

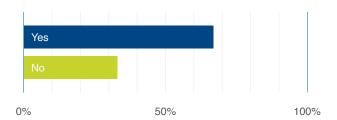
Are you aware of the Top-Level Domain .pharmacy that is run by the non-profit National Association of Boards of Pharmacy?



This patient safety initiative is proving extremely useful in directing patients to a website selling authentic medicines. An Internet suffix like .pharmacy is a Top-Level Domain which cannot be copied or corrupted. Six countries, notably Belgium, Italy, Iceland, Serbia, Spain and Sweden expressed an interest to learn more.

Question 6.

Has your agency run any public facing campaigns about the Common Logo and falsified medicines in the past?



^{*}Serbia is not obliged to implement the FMD, hence this result.





Competent authority websites with public facing educational messages



























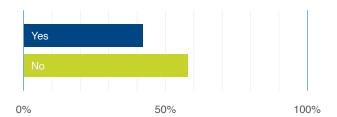






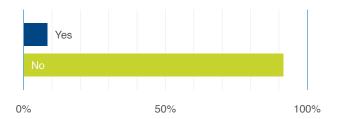
Question 7.

Do you intend to run any public facing campaigns in the future?



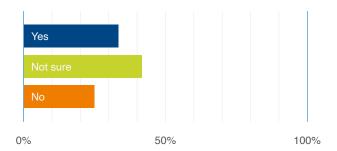
Question 8.

May we ask if you expect any specific efforts / activities from healthcare providers such as online pharmacies to promote the EU Common Logo?



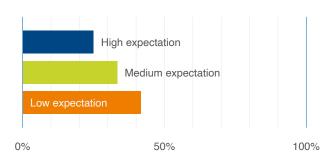
Question 9.

What is your opinion on running information campaigns collectively with healthcare stakeholders to raise further awareness of the Common Logo?



Question 10.

To what extent do you expect healthcare providers such as online pharmacies to promote the EU Common Logo among customers and patients?







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We hope that this report will enable a dialogue to be set up to encourage Member States to provide more information to the public on the subject of the Common Logo and the meaning of falsified medicines. This topic is becoming more important and it is alarming to note that over 36,000 websites are currently selling falsified medicines to a largely unsuspecting public. The Covid epidemic also highlighted how criminals took the opportunity to sell all types of falsified health related products.

This is one of the major reasons why ASOP EU commissioned a recent important report entitled "Unlocking the Benefits of Online Access to Prescription Medicines Across the EU" which clearly provided evidence that patients would benefit from having the choice to access/obtain their medicines online. In addition it is logical to propose that the sooner all Members States allow prescriptions to be obtained online (currently only 8 allow this), then the sooner the EU citizen will have a safe and secure place to obtain their Prescription as well as their OTC medicines.

However, It was encouraging to note that all respondents stated that publicising the meaning of the Common Logo and falsified medicines was of high or medium importance. And it is promising that respondents stated that they were keen to collaborate and run campaigns collectively.

Based on the input collected, the following recommendations were made by ASOP EU and EAEP:

Recommendation 1

Design a collective outreach "generic" campaign by Member States whereby the text and images could be translated and transposed and thus used across Europe, as this would be beneficial to patients.

Recommendation 2

When designing such a campaign, set up a workshop with EAEP and ASOP EU to examine the success of such a campaign among customers/patients, whilst ensuring that stakeholders such as pharmacies are consulted around the proposed content.

Recommendation 3

Create a community of interested parties to enable further Member State collaboration on the important topic of falsified medicines and educational approaches.





Appendix Questionnaire

Introduction

As a non-profit patient safety organisation committed to enable patients and consumers to buy their medicines safely online, the Alliance for Safe Online Pharmacy (ASOP) in the EU wishes to share best practices and cooperate with EU Member States regarding the EU Common Logo for the online sale of medicines. By contacting those who are responsible for the administration and good governance of the Common Logo which is described in the Falsified Medicines Directive under Article 85D and in light of the revision of EU Pharmaceutical legislation, it will help all Member States in their patient safety endeavours. By completing this survey, you will be sharing your country's initiative to help raise awareness of the issue of falsified medicines which is a growing online threat due to websites that are selling falsified, substandard, or unlicensed medicines to a largely unwitting public. The information from the survey can be used to foster cooperation between Member States and so enhance already proven communication platforms, be they via social media or website campaigns.

ASOP EU has supported the above patient safety initiative in the past and you will find a previous report which usefully lists Member States public facing awareness campaigns at https://buysaferx.pharmacy/wp-content/uploads/2020/04/A3A4-Fighting-Fakes-by-Member-States-Booklet.pdf.



The newest report will be co-signed with the European Association of E-Pharmacies (EAEP), the organisation representing the online pharmacy sector in Europe, which supports the EU Common Logo and is committed to the fight against illegal internet offers and counterfeits drugs. To know more please visit the dedicated EAEP website at https://www.eaep.com/en/safety.



The survey

There are just 10 questions to be answered and so the survey should not take more than 10 minutes. We would like to construct a similar survey as can be found here and so all Member States and those interested in the subject can be appraised of the latest situation and so best practices can also be shared.





Appendix Questionnaire

- 1. Please state which Member State you represent
- 2. Are you aware of Article 85D of the Falsified Medicines Directive (promotion of information campaigns on the dangers of falsified medicinal products and the meaning of the Common Logo)?
 - a. Yes
 - b. No
- 3. Do you have a competent authority website set that describes the Common Logo?
 - a. Yes
 - b. No

If yes, please would you give the website address that leads us closest to the page and this information (such as the official register of online pharmacies in your country).

- 4. In your view, what is the importance given to the implementation of Article 85D of the Falsified Medicines Directive in your country in the past years?
- 5. Are you aware of the Top-Level Domain .pharmacy that is run by the non-profit National Association of Boards of Pharmacy? This patient safety initiative is proving extremely useful in directing patients to a website selling authentic medicines. An Internet suffix like .pharmacy is a Top-Level Domain which cannot be copied or corrupted.
 - a. Yes
 - b. No

If you would like to learn more about this patient safety initiative, as it provides a safe secure place for patients to go to buy their medicines that cannot be scammed, please add your email address and we will send further information - thank you.

- 6. Have you run any public facing campaigns about the Common Logo and falsified medicines in the past?
 - a. Yes
 - b. No

If yes, please provide essential details (web address, link to material etc).

- 7. Do you intend to run any public facing campaigns in the future?
 - a. Yes
 - b. No

If yes, please explain when and how.





Appendix Questionnaire

- 8. May we ask if you expect any specific efforts / activities from healthcare providers such as online pharmacies to promote the EU Common Logo?
 - a. Yes
 - b. No

If yes, please describe what specific efforts / activities you would like to see.

- 9. What is your opinion on running information campaigns collectively with healthcare stakeholders to raise further awareness of the Common Logo?
- 10. To what extent do you expect healthcare providers such as online pharmacies to promote the EU Common Logo among customers and patients?

Many thanks for completing this important survey. Once the above survey is collated, we will produce a report for the benefit of sharing best practice. If you would like to receive a copy plus a potential invitation to attend a virtual meeting to further share experiences, please add your contact details below.

Name:

Role:

Member State:

Email address:





References

- Falsified Medicines Directive https://health.ec.europa.eu/medicinal-products/falsified-medicines_en
- ASOP EU and EAASM data on file

Competent **Authority Websites**

Austria https://www.basg.gv.at/konsumentinnen/arzneimittel-im-internet/versandapotheken

https://www.famhp.be/en/human_use/medicines/medicines/distribution_delivery/ Belgium

pharmacy_public/website_pharmacy/registrepharmacies

Cyprus https://www.moh.gov.cy/moh/phs/phs.nsf/

All/23DFAFA481BB9FEAC225857D0030E9B2?Open

Denmark https://laegemiddelstyrelsen.dk/en/pharmacies/buying-and-selling-medicines-online/

Iceland https://www.lyfjastofnun.is/leyfisskyld-starfsemi/apotek/listi-yfir-netapotek/

Italy https://www.salute.gov.it/portale/temi/p2_5.jsp?area=farmaci&menu=online

Lithuania https://www.vvkt.lt/index.php?1883680634

https://legemiddelverket.no/tilvirkning-import-og-salg/apotekdrift/registreringsordning-Norway

for-netthandel-med-legemidler

Romania https://www.ms.ro/ro/informatii-de-interes-public/pacienti/registrul-farmaciilor-online/

Spain https://distafarma.aemps.es/farmacom/faces/inicio.xhtml

Sweden https://www.lakemedelsverket.se/sv/handel-med-lakemedel/distans--och-e-handel



Austria



Belgium



Cyprus



Denmark



Iceland





Lithuania



Norway



Romania



Spain



Sweden









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