

January 2018

Fighting Fakes by Member States

Falsified Medicines and the Common Logo
– raising public awareness



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 in the EU and the European Alliance for Access to Safe Medicines.

In cooperation with EU Member States who kindly provided supportive
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Words of encouragement from the European Commission

In recent correspondence with Commissioner Andriukaitis drawing attention
 to the collaborative actions between ASOP and the Member States personnel
 directly involved in the implementation of the Common Logo, it was positive to
 receive these words of encouragement:

*“ I support the efforts which aim at fighting falsified medicines
 available online and increase awareness on the EU logo to
 be displayed on legal online pharmacies ”*

Commissioner Vytenis Andriukaitis – European Commission
 Directorate-General for Health and Food Safety



Foreword

Lynda Scammell

The Internet has brought many positive benefits for consumers – easier access to a wide range of goods and services. This has extended to medicines and medical devices – countless websites operate to supply a diverse choice of medicines and medical devices which can be delivered to your door by clicking a button and providing credit card details.

There is legal provision for the online supply of medicines but many thousands / millions of these sites operate illegally – offering prescription medicines without a prescription and / or supplying falsified or unauthorised medicines and counterfeit / non-compliant medical devices.

Why do people take the risk? Whilst some research has taken place as to understand this market place, much more is needed to comprehend the motivations of the consumer prepared to take a risk with their own health.

The MHRA has embarked on a sustained public awareness campaign – named FakeMeds#. We looked closely at the buying of all the types of medicines and health-related substances (such as slimming pills) and segmented the potential target audiences demographically. This has enabled us to hone the educational and safety messages and to reach the right people via various media such as Facebook and Twitter.

We are very supportive of the activities of ASOP Global and ASOP EU along with other organisations working tirelessly to inform the public about how to purchase medicines safely.

This report helps to disseminate useful information and enhance the expansive collaboration that is needed between all interested parties in efforts to combat this growing and dangerous crime effectively.

Lynda Scammell
Senior Policy & Relationship Manager
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Medicines and Healthcare Products and Regulatory Agency (MHRA)

Contents

- 3 **WORDS OF ENCOURAGEMENT** - Commissioner Vytenis Andriukaitis – DG Sante
- 4 **FOREWORD** - Lynda Scammell – MHRA
- 5 **CONTENTS**
- 6 **EXECUTIVE SUMMARY**
 - Purpose of the report
 - The Falsified Medicines Directive
 - Complementary measure Top level Domain Name .pharmacy
 - Demand vs Supply equation
 - Educating the Public about the Common Logo and Falsified Medicines
 - How does the logo work?
 - The extent to which Member States are fulfilling their obligations under Article 85d
- 8 **OVERVIEW OF MEMBER STATE PUBLIC AWARENESS RAISING ACTIVITY**
- 10 **LIST OF REGISTERS OF ONLINE MEDICINE RETAILERS**
- 13 **MEMBER STATE** – Public awareness raising campaigns
- 24 **ORGANISATIONS PUBLISHING AND CHAMPIONING THE FIGHT AGAINST FALSIFIED MEDICINES**
- 26 **CONCLUSION AND CALL TO ACTION**
- 26 **CONTACT US**



Executive summary

Purpose of Report

The purpose of this report is to highlight best practice amongst Member States and not-for-profit organisations that have an objective to educate the public from the growing threat of illegally operating websites selling medicines and related healthcare products. This is a phenomenon that is now well documented and well known amongst those actors that make it their business to do so but unfortunately the knowledge by those who most need it – the public is woefully lacking.

The Falsified Medicines Directive

The introduction of the safety features of the Falsified Medicines Directive (FMD) will undoubtedly enhance the security of the supply chain in what is commonly cited as the “legitimate” supply chain and can be characterised by a flow of product from manufacturer, to wholesaler (or distributor) to community and hospital pharmacy. After February 2019, each prescription pack will have a uniquely identifiable data matrix that will be required to be verified at point of dispensing and an anti-tampering device, thus the pharmacist will know the integrity and authenticity of the pack being dispensed. However, this part of the directive does not tackle the “illegitimate” supply chain – that of criminals selling falsified medicines – usually without the need for a prescription over the Internet.

Nevertheless, written in to the Directive is the requirement for each Member State to make medicines available “at a distance” and as such obliges sellers of medicines in accordance with their laws, to at least make available medicines of an “over the Counter” (OTC) category available via the Internet.

It does not however and importantly oblige Member States to change their laws to allow prescription only medicines to be sold at a distance.

The phrase “at a distance means” via the Internet. Such online sales of medicinal products are allowed in the EU but on the condition that the legitimate retailer displays a logo, often referred to as the Common Logo. Legally operating online pharmacies in the EU may only sell medicinal products that comply with the legislation of the Member State of destination.

The government Member State body that governs this, varies from Member State to Member State but the

responsibility normally resides with the national medical regulatory agency.

These bodies are responsible for the registration process of those entities wanting to sell medicines over the Internet and also inspections, to ensure that such pharmacists or retailers are operating legally and displaying the logo in accordance with the Directive. The logo is encrypted to enable a visitor to the site to click on the logo which then routes through to a list of registered sellers (normally pharmacies). The visitor is therefore able to check the validity of the website. Whilst this in principle will help to secure the supply chain, the logo is vulnerable to criminal “copying and pasting” on to websites that could be operating illegally.

Complementary measure Top Level Domain Name .pharmacy

As a complementary measure, the National Association of Boards of Pharmacy (a non-profit organisation comprised of state pharmacy regulators in the US, Canada, Australia, New Zealand and other countries) have acquired the top level domain name¹¹ .pharmacy from ICANN (Internet Corporation for Assigned Names and Numbers). Pharmacies wanting to offer the protection and gain the credibility of using a verified top level domain name .pharmacy have to pass stringent regulatory criteria. Thus if a visitor searches on the web and finds a .pharmacy website, they can be assured it is genuine and that it is selling medicines in accordance with the in-country laws. Although this initiative may be complementary to a common EU logo, it does not replace it.

Demand vs Supply equation

We can characterise the supply chains that exist on the Internet as being “demand led” and “supply generated”. As such those concerned with tackling the demand side regard the education of the public as paramount – after all it is the public that are going online and creating the demand.

Conversely the supply side is all about finding the source or the suppliers; the criminals who are supplying the public with falsified medicines. This side of the equation is focused on by law enforcement bodies. The Pangea operations spearheaded by Interpol, is a good example of a key activity to address the criminal activity relating to illegally operating websites selling medicines.¹²

Educating the Public about the Common Logo and Falsified Medicines

Within the Falsified Medicines Directive under Article 85d there is a section relating to the legal obligation by Member States and the DG Health and Food Safety of the European Commission to inform the public about the purpose of the Common Logo and the dangers relating to falsified medicines:

Article 85d

“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.”

In support of Article 85d, DG Health and Food Safety provided each Member State with a communication tool kit¹³



How does the logo work?

The Common Logo links to the website of the national competent authority listing all legally operating online pharmacies/retailers. National websites are listed with the European Medicines Agency¹⁴. By simply clicking on the logo the visitor will be routed to the national list of registered online sellers of medicines.

Look out for the logo

To stay safe when buying medicines online, **look out for the logo**. The logo is clickable and will appear on the websites of all online medicine retailers in the EU that are registered with their national regulatory authority.



Clicking on the logo will take you to the register of online retailers of the country where the retailer is established and registered, corresponding to the flag displayed on the logo. Once there, **check that the retailer is listed**.

Do not continue with your purchase if the retailer is not on the list.

The national flag and the text are an integral part of the logo. Only national flags of an EU Member State, as well as those of Norway, Iceland and Liechtenstein can be displayed. A logo that displays the EU flag, for example, is not authentic.

The extent to which Member States are fulfilling their obligations under Article 85d

This report sets out to chart the extent to which Member States (MS) are informing the public about the dangers of falsified medicines and the relevance of the Common Logo. As such it is simply a “snap shot” in time. The FMD obliged MSs to implement the Common Logo on July 1st 2015. Thus far such public facing campaigns appear to be variable across the EU countries and therefore from a patient safety perspective, it is hoped to see continual progress by MSs and the Commission to further inform the public.

REFERENCES

¹⁰NABP and VIPPS

¹¹National Association of Boards of Pharmacy (NABP) <https://nabp.pharmacy/study-examines-consumer-educational-initiatives-raising-awareness-about-internet-drug-outlets-includes-nabp-data/>

¹²Interpol and Pangea Operations - <https://www.interpol.int/en/Crime-areas/Pharmaceutical-crime/Operations/Operation-Pangea>

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¹³EU logo for online sale of medicines http://ec.europa.eu/health/human-use/eu-logo_en

¹⁴European medicines Agency – provides a list national competent authorities in the EU and EAA regions http://www.ema.europa.eu/ema/index.jsp?curl=/pages/regulation/general/general_content_000630.jsp

Overview of Member State public awareness raising activity

Country	Competent authority website set up with campaign material	Public facing campaigns running now or in the past	Future campaigns planned	Measurement of campaigns and awareness of common logo and falsified medicines
Austria	Yes	Yes	Yes	Not known
Belgium	Yes	Yes	Not Known	No
Bulgaria	Yes	Not known	Not known	Not known
Croatia	Yes	Yes	Yes	Not known
Cyprus	Yes	Yes	Not known	Not known
Czech Republic	Yes	Yes	Yes	Yes
Denmark	Yes	No	Yes	No
Estonia	Yes	Yes	No	No
Finland	Yes	Not known	Not known	Not known
France	Yes	Yes	Yes	Not known
Germany	Yes	Not known	Not known	Not known
Greece	No	Not known	Not known	Not known
Hungary	Yes	Yes	Not known	Not known
Ireland	Yes	No	No	No
Italy	Yes	Yes	Yes	Yes
Latvia	Yes	Not known	Not known	Not known

Country	Competent authority website set up with campaign material	Public facing campaigns running now or in the past	Future campaigns planned	Measurement of campaigns and awareness of common logo and falsified medicines
Lithuania	Yes	Not known	Not known	Not known
Luxembourg	No*	Not known	Not known	Not known
Malta	Yes	Yes	Yes	No
Netherlands	Yes	Yes	No	No
Poland	Yes	Yes	Yes	Yes
Portugal	Yes	No	No	No
Romania	No*	Not known	Not known	Not known
Slovakia	Yes	No	No	No
Slovenia	Yes	Not known	Not known	Not known
Spain	Yes	Yes	Yes	Yes
Sweden	Yes	No	No	No
UK	Yes	Yes	Yes	Yes
EAA Member States				
Iceland	No*	No	No	No
Liechtenstein	No*	No	No	No
Norway	Yes**	Yes**	Yes**	No
Other countries active on Falsified medicines				
Serbia	Yes	Yes	Yes	Yes

REFERENCES

*To be made available shortly

**Information on falsified medicines can be found here <https://legemiddelverket.no/bivirkninger-og-sikkerhet/rad-til-pasienter/nettapotek>

List of registers of online medicine retailers


EU Member State	Register of online retailers ¹⁵
 Austria	https://versandapotheeken.basg.gv.at (DE)
 Belgium	https://www.fagg.be/nl (NL) https://www.afmps.be/fr (FR)
 Bulgaria	https://bit.ly/2VLKwPd (BG)
 Croatia	https://bit.ly/2Uxlabl (HR)
 Cyprus	https://bit.ly/2UP2J1L (EL) https://bit.ly/2UNWhYV (EN)
 Czech Republic	http://www.sukl.eu (EN)
 Denmark	https://bit.ly/2UxJ07W (DK) https://bit.ly/2UUu8iZ (EN)
 Estonia	http://rkav.sm.ee (ET/EN)
 Finland	https://bit.ly/2xzZJhM (FI)
 France	www.ordre.pharmacien.fr (FR)
 Germany	http://www.dimdi.de (DE)

EU Member State	Register of online retailers ¹⁵
 Greece	To be made available shortly
 Hungary	https://bit.ly/3ataReV (HU)
 Ireland	https://bit.ly/3aw0irC (EN)
 Italy	http://www.salute.gov.it (IT) https://bit.ly/3bGRcIM (IT)
 Latvia	https://bit.ly/2UMlvqu (LV) https://bit.ly/2Jq5kdj (EN)
 Lithuania	http://www.vvkt.lt (LT)
 Luxembourg	To be made available shortly
 Malta	http://medicinesauthority.gov.mt (EN)
 Netherlands	http://www.aanbiedersmedicijnen.nl (NL)
 Poland	https://bit.ly/3dM3ktw (PL)
 Portugal	https://www.infarmed.pt (PT)

REFERENCES

¹⁵ European medicines Agency – provides a list national competent authorities in the EU and EAA regions http://www.ema.europa.eu/ema/index.jsp?curl=/pages/regulation/general/general_content_000630.jsp

List of registers of online medicine retailers

EU Member State	Register of online retailers ¹⁵
 Romania	To be made available shortly
 Slovakia	https://bit.ly/2Jza4Nv (SK)
 Slovenia	https://bit.ly/2WYTOxy (SI)
 Spain	www.distafarma.aemps.es (ES)
 Sweden	https://bit.ly/2UyzhOo (SE)
 United Kingdom	www.gov.uk/mhra (EN)
EEA Member States	
 Iceland	https://bit.ly/2wG3RwJ (IS)
 Liechtenstein	To be made available shortly
 Norway	https://bit.ly/2w2n0bl (NO)

Member State – public awareness raising campaigns

Austria

In Austria, a recent thesis¹⁶ *Fraudulent Online Pharmacies and the Public Awareness of Falsified Medicines in Austria* summarises very well the current situation.

The Ministry of Health commissioned a survey on the subject of online sales of medicines in Austria which revealed that 70 percent of the respondents felt that online pharmacies was a positive step forward. The former Austrian minister of health, Sabine Oberhauser stated that the low level of knowledge about the legal possibilities of buying medicines over the Internet in combination with **the positive attitude towards the online sales of OTCs shows that education in this area is an urgent and pressing matter.**¹⁷

In 2015, together with the Federal Office for Safety in Health Care (BASG), the Austrian Ministry of Health commenced an information

campaign amongst the public, called 'Buying medicines on the Internet? Do you really know what you get? (dt. Medi-kamente im Internet kaufen? Wissen Sie wirklich, was Sie bekommen?). With information folders, and advertisements in daily media and on the homepage of the official web-site of the Health Ministry, the public was informed about the legal possibilities to Online pharmacies in Austria to acquire medicines over the Internet but also about the dangers associated with buying online¹⁸. Moreover, the Austrian Federal Criminal Police Office introduced the campaign 'on the safe side' (dt. Auf der sicheren Seite), which should increase the public awareness through extensive online advertising. This organisation has established the website www.auf-der-sicheren-seite.at where information about the legal situation and news related to this topic can be found.¹⁹

Belgium

On 1st July 2015, the Belgium Federal Agency for Medicines and Health Products announced the launch of the Common Logo with a press release from the FAMHP concerning the Common logo (see https://www.fagg-afmps.be/fr/news/news_logo_eu_pharmacie_en_ligne).

Currently, the Belgian agency is running a campaign entitled "Médicaments par internet? Ne surfez pas avec votre santé!" / "Geneesmiddelen via internet? Surf niet met uw gezondheid!".

The campaign is disseminated via leaflets and through the specific website www.geneesmiddelen-via-internet.be / www.medicaments-par-internet.be. In terms of measuring the impact of the campaign, the number of leaflets distributed can be monitored. In 2018 the FAMHP should host the specific website relating to the campaigns (which is not the case currently). At that point in time the behaviour of the visitors in terms of which pages are most popular and volume of visits etc will be measured.

REFERENCES

- ¹⁶ Sarah Gradl - *Fraudulent Online Pharmacies and the Public Awareness of Falsified Medicines in Austria 2016*
- ¹⁷ BMSG. (2015, June 23). *Online-Versand für rezeptfreie Medikamente startet*. Retrieved from Bundesamt für Sicherheit im Gesundheitswesen - AGES Medizinmarktaufsicht: <http://www.basg.gv.at/news-center/news/news-detail/article/online-versand-fuer-rezeptfreie-medikamente-startet-1098/>
- ¹⁸ Sucker-Sket, K. (2015, June 25). *Startschuss für legalen OTC-Versand*. *Deutsche Apotheker Zeitung*.
- ¹⁹ Bundeskriminalamt. (2015, June 01). *Start der Aufklärungskampagne "Auf der sicheren Seite"*. Retrieved from Bundesministerium für Inneres: http://www.bmi.gv.at/cms/bk/_news/start.aspx?id=6E744B6D36356D365951453D&page=0&view=1

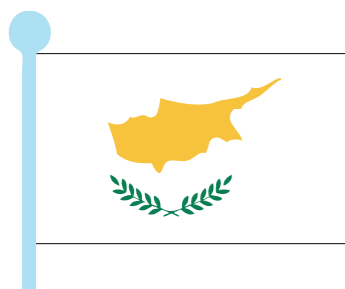


Croatia

It is reported that there is a growing trend in the sale of counterfeit products over the Internet in Croatia, with approximately 80,000 websites and 7000 facebook pages involved. Currently in Croatia a campaign entitled "Stop counterfeiting and piracy" is running on TV and facebook: <https://www.facebook.com/stopkrivotvorinamaipiratstvu.hr/> and <http://www.stop-krivotvorinama-ipiratstvu.hr/hr/index.html> (official web site of the campaign).

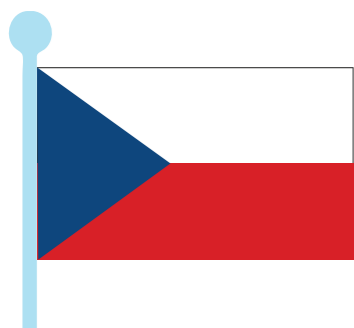
In 2016 there was a consultation process between stakeholders on the development of a new legal act which would regulate activities by Internet pharmacies and the implementation of the Common Logo. This is still being developed and so there are no pharmacies currently registered and so it is still illegal to sell medicines to the public "at a distance" over the Internet.

In terms of measurement there is a poll running currently which is revealing that 74.29% of the people surveyed have not heard about falsified medicines.



Cyprus

A presentation to the consumers association has been made. In addition a TV and radio campaign is planned as well publicising the results of Pangea X. At present there are no pharmacies registered to sell medicines via an Internet website.



Czech Republic

The campaign by the State Institute for Drug Control named "Dangerous drugs" ("Nebezpečné léky") was launched in March 2010 on the website www.nebezpecneleky.cz. The main objective of the campaign is to warn the general public of falsified and illegal medicinal products often offered on the internet and in other public accessible places. The website also contains information about falsified and illegal medicinal products' seizures made within the Czech Republic and from all over the world. The "Dangerous Drugs" campaign has been continued in 2017. In 2018 there are plans to redesign the website www.nebezpecneleky.cz next year (2018).

This campaign is regularly run via facebook and its effectiveness is measured on an annual basis by

the opinion poll called "Sources and use of information in the field of pharmaceuticals". Within this survey is a question which is focused on motivations to do with buying medicinal products on the Internet and information about the uptake by the public of illegal offers.

Videos and posters of the campaign can be accessed here

- <http://www.nebezpecneleky.cz/video-a-plakaty>
Posters – Danger of active substances in falsified and illegal drugs:
- <http://www.nebezpecneleky.cz/plakaty-nebezpecni-ucinnych-latek-v-padelcich-a-nelegalnich>

Manual for the correct/legal shopping on the internet:

- <http://www.nebezpecneleky.cz/manual-spravneho-nakupovani-leku-na-internetu>

Czech Republic cont'd

Brochure for patients:

- <http://www.nebezpecneleky.cz/informace-pro-pacienty>

Brochure for pharmacists:

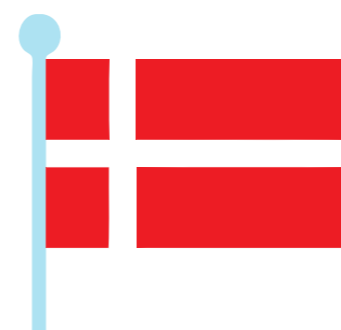
- <http://www.nebezpecneleky.cz/informace-pro-lekarniky>

Brochure for doctors:

- <http://www.nebezpecneleky.cz/informace-pro-lekare>
The State Institute for Drug Control registers pharmacies that sell medicines over the internet within the Czech Republic and also abroad.

From the total number of registered pharmacies (2786 to date 13.9.2017) 154 pharmacies have been registered with an online buying website within the Czech Republic and 50 pharmacies that can sell online abroad.

There is also an information portal for the public to access www.olecich.cz, where an article has been published with information on the common logo: <http://www.olecich.cz/lekarny-s-internetovymi-nabidkami-leku-musi-mit-logo-lekaren>.



Denmark

Two campaigns are planned for 2017 but not specifically for the Common Logo. The campaigns are of a more general nature about the dangers of buying falsified medicines.

One will use GIFs (Graphics Interchange Format) to be circulated on the internet and social media. The content is currently being developed. The other will be an interactive role playing comic for young adults.

Denmark has 112 authorisations for online sales out of approximately 3800 retail/pharmacy licensed premises.

Some online retailers have expressed a wish to use the Common Logo in Apps and the technical implications of this are being analysed. In Denmark medicines are divided in to three categories:

1. Prescription only medicines, which may only be sold by pharmacies
2. Over the counter medicines which may only be sold by pharmacies
3. Over the counter medicines, which may be sold by anyone authorised to sell medicines

All three categories of medicines may be sold via the internet.

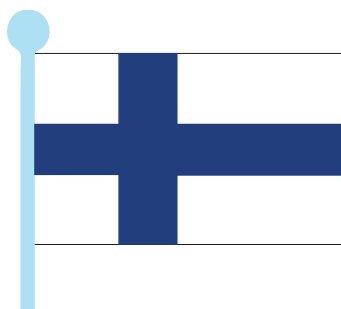


Estonia

Prescription and Over the Counter medicines can be sold at a distance and so via the Internet (prescription medicines require a digitally created prescription in the national prescription data base within the Estonian e-Health system). Certain products cannot be sold at a distance e.g. anabolic steroids, narcotic and psychotropic substances, cells and tissues, etc.

A communication campaign took place in 2015 which comprised a number of actions including a flyer on the agency website. In addition the flyer was printed and posted to a random sample of the public and it was also circulated via social e-media. Banners were also displayed at bus stops and run in local internet portals and articles appeared in the press.

No market research is currently planned.

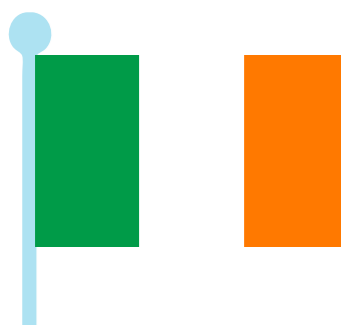


Finland

In Finland to operate a pharmacy business requires a licence from the Finnish Medicines Agency (pharmacy licence), details of which are defined in the Medicines Act 395/1987.

There are approximately 600 pharmacies with around 200 subsidiary pharmacies in Finland (the Agency may authorise a licensed pharmacist to operate up to three subsidiary pharmacies only).

To date there are around 100 online pharmacies (it is required to have a pharmacy license to provide pharmacy services also via an online pharmacy service).

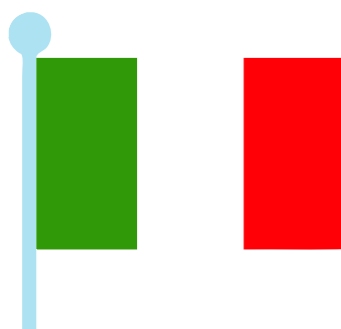


Ireland

There are currently no public facing campaigns planned to be run in Ireland.

Prescription medicines cannot be sold via the Internet in Ireland.

Currently 2.5% of pharmacies have applied to register their website to sell medicines at a distance via the Internet.



Italy

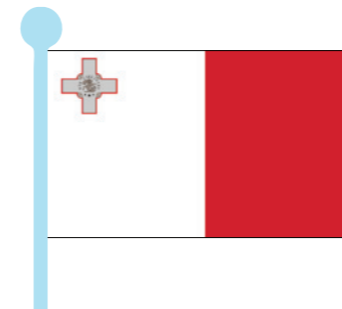
Spearheaded by the Italian, Portugal, Spain and UK medical agencies in 2016, the Fakeshare communication project was launched. A number of public facing campaigns have been run and more recently a series of facebook videos have been launched in cooperation with wholesalers/ pharmacists' associations (see <http://www.socialfarma.it/fakeshare-aifa>)

During 2017 the Fakeshare public facing activities will be continued. The Italian medical agency has plans to keep performing ad hoc surveys in 2018, most likely targeting specific categories (e.g. pharmacists, health professionals) through professional associations, instead of Internet users, as these have already been continuously evaluated since 2012. This is also in line with the long term

goals of the Fakeshare project, that was originally designed with the goal of creating an "avalanche effect" with respect to the other stakeholders planning to campaign on the same theme.

In fact many positive results have been generated e.g. all professional associations developing campaigns in the field used the Fakeshare models/language/messages. In addition professional healthcare bodies regularly used the panel of expert Fakeshare speakers. Further developmental work on key performance indicators is under way.

In respect of the number of pharmacies that have registered to sell medicines via the Internet using a legal pharmacy website to sell OTC medicines, then almost 500 out of the 18,000 Italian pharmacies (and 3000 OTC retailers) have achieved this.



Malta

There are no public facing campaigns which are currently running at the moment, however an information public campaign is planned for end 2017 / beginning 2018 via a published information leaflet and a video.

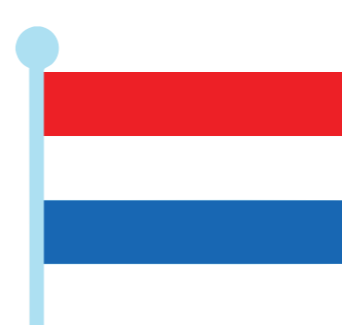
A series of campaigns have been implemented in the past years on purchases of medicines over the Internet, the common logo. and Internet pharmacies. These campaigns have included public and healthcare professionals, public talks and seminars including phone-

in radio programmes. In addition, an educational leaflet was sent to each household in Malta as well as information leaflets being distributed to all pharmacies.

Some of the information is available through <http://www.medicinesauthority.gov.mt/falsifiedmedicines?l=1>

Effectiveness of campaigns are measured through questionnaires with the public/patients and during management meetings.

No pharmacies are as yet established in Malta as Internet pharmacies.



Netherlands

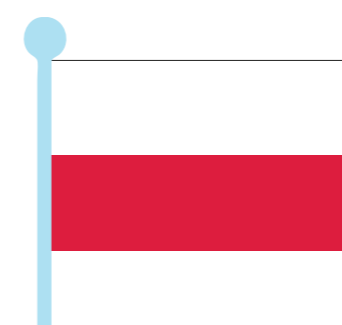
In 2008 a public health awareness raising campaign was initiated along with a policy decision which comprised four major components, namely: quality assurance and signaling, damage and scope of issue, enforcement and awareness.

This was the first Dutch campaign to be run on falsified medicines (then called counterfeit medicines) for the public and also health professionals.

In 2016 an investigation was carried out in to purchasing behaviour, motives, risk perception and information needs of online buyers of medicines. This revealed that 1 in 10 of the population had bought a medicine online with 3.8% of people considering that they might buy a medicine online. 1.6% of medicines were being purchased outside of the Dutch healthcare system. The research covered the age 20-30 years old and revealed that women buy as much medicine as men but unregulated medicines are bought

more frequently by men. The types of medicines include painkillers, slimming products, sex-related medicines and/or sleep or calming medicines. They were doing this for ease of purchase mainly via Internet websites or secondary platform market websites. They were often found using search engines.

38% of purchases were bought via non-Dutch websites. People liked the anonymity of the process. The number of purchases per person was low but the order might be large. Trust and satisfaction as to the service was noted by respondents. From this research it was decided to embark on a campaign to the public that would highlight the potential risks and possible actions to buy more safely online. The target audience was those orientating to buy medicines online. The campaign material comprised a website using a quiz theme called "Real or Fake" (<http://www.echt-of-nep.nl>) with choices to be made by the visitor to the website. Consumers were led to the educational website by a Google AdWords campaign.



Poland

Articles on falsified medicines were published in the Polish press during 2016. During 2015 research revealed that one in three people believed that they could distinguish the difference between a fake and a genuine medicine. This was regarded as an important finding and led to the development of a major

educational campaign that will feature TV and radio advertising during the latter part of 2107. This will be run alongside an educational website and Facebook profile. In addition prominent influencers from the scientific community as well as public figures will be used to attract attention to this important health issue. Market research is planned to measure the effectiveness of the campaigns.



Portugal

There are no public awareness campaigns running and none are planned for 2017. The public can obtain information about the Internet and medicines on the Portugal Medicines Agency website.

<http://www.infarmed.pt/web/infarmed/venda-de-medicamentos-pela-internet>

Portugal has 2806 authorised pharmacies and 1106 registered non-prescription retailers. Since 2007, pharmacies and medicine retailers have been allowed to sell via the internet, phone or home-deliver medicines to the patients, but on a local level only.

Currently 747 pharmacies and only 27 medicine retailers are selling medicines via the internet. There has not been a significant increase in these numbers since the introduction of the Common Logo.

To this date no pharmacy or Non Prescription Medicine Retailer has requested the common Logo to INFARMED, I.P.

Portuguese pharmacies and Non Prescription Retail stores are therefore only selling online to local customers, as it is not permitted by law for medicines to be sent via a courier.

Slovakia

The Slovakian Medical Agency (SIDC) currently does not have any public awareness campaigns running.

However, the agency website exhibits all of the important information regarding this issue (list of online retailers, instructions for pharmacists, recommendations for patients as to how to buy medicines online safely), and these can be found online: http://www.sukl.sk/sk/inspekcia/lekarenstvo/internetovy-vydaj-liekov-a-zdravotnickych-pomocok?page_id=3425

Due to the media interest regarding falsified medicines the SIDC regularly publishes articles, "How to buy medicines online safely" in various professional journals.

The law No. 362/2011 Coll. on medicinal products within the meaning of § 22 allows the supply of medicinal products or medical devices by the internet.

Currently Slovakia has approximately 62 registered online pharmacies.



Spain

During 2016, a new public facing collaborative initiative commenced called the Fakeshare campaign. This was launched by the Spanish Agency of Medicines and Medical Device (AEMPS) jointly with the Italian Medicines Agency (AIFA), the Medicines & Healthcare Products Regulatory Agency (MHRA) and the National Authority for Medicines and Health Products (INFARMED), in order to warn Spanish users and consumers about the risk of buying medicines from illegal websites. In addition, the Agency has constructed educational material based on that which was provided by the Commission on the Agency website. Additional campaign material can be found here:

<https://distafarma.aemps.es/farmacom/faces/templates/estaticas/campania.xhtml>

<https://www.aemps.gob.es/informa/campannas/medillegales/home.htm>

The Agency has also been collaborating with ASOP EU to optimise a Google AdWord sponsored campaign.

During 2016, the number of advertisements selling medicines, hosted by online marketplaces has increased. However, close collaboration by the Agency with Internet Service Providers who host

these sites has proved successful as once alerted to illegal activity took swift and corrective actions.

The Agency has also put in place a number of cross border initiatives. This helps to ensure that sharing of information between national authorities takes place efficiently in order to apprehend illegal activity and to take appropriate law enforcement actions.

In terms of market research within Fakeshare's project, there are 2 surveys including questions about previous campaigns. From its results, it seems that the impact of public information and communication campaigns is less than expected. Without prejudice to the relevance of the media, we have noticed an increasing interest of specialised press in the issues around the Common Logo and there are articles which appear periodically about this.

As of June 2017 the situation in Spain of online selling of non-prescription medicines over the Internet is the following: 426 pharmacies out of a total of approximately 22000, have notified the activity and have already inserted the logo on their web pages and are listed in the competent authorities website. It seems the main problem for these pharmacies is ensuring appropriate transport conditions, especially for medicinal products that must be kept under 25C.

Sweden

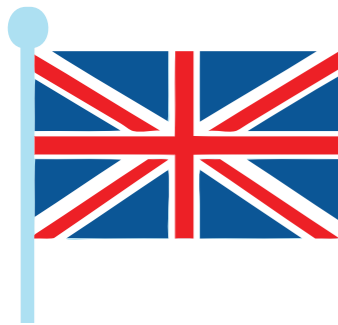
Selling prescription medicines online has been allowed in Sweden for more than ten years and it is gaining in popularity. All pharmacy chains in Sweden are now offering this as an option and electronic prescriptions combined with secure and efficient online identification systems makes it easy to order your medicines from your Smart phone or computer.

The Swedish medical authorities are not currently focusing attention on the Common Logo. But instead use their involvement and subsequent publicity around the criminal findings through the Pangea operations. For instance in 2017, the public was informed about

the wide-spread use and increase seen of online buying of Tramadol, classed in Sweden as a narcotic, without a prescription.

In 2018, the public will be informed about the dangers of buying medicines in the wrong way, through the media by highlighting cases discovered through the Pangea operations.

For example, cannabinoid, thyroid and melanotan/tanning products with the investigations and subsequent prosecutions. In addition, the focus on medicinal products classified as narcotics will continue.



United Kingdom

The Medicines and Healthcare Products Regulatory Agency (MHRA) since the implementation date of the Common Logo and prior to this, has over the last two years, run a number of public facing awareness campaigns. The reason for this is a growing issue of falsified, unlicensed and counterfeit medicines and medical devices that are being illegally distributed in to the UK. This is being fuelled by the evolution of Internet and e-commerce activities.

The MHRA therefore believes that it is essential to educate the public about falsified medicines and the Common Logo, in order to change behaviour. Sustained communication to create awareness of the issues with those who are creating the demand is seen as of paramount importance to change behaviour and thus produce, an effective defence against the rising tide of the illegal trade of medicines.



The campaigns that were run 2016/17 reached over 30 million people and over 25% (3.5 million) of the segmented target audience (18-30 UK-wide). There was a 10% increase in the target audience acknowledging the issue of falsified medical products sold online, with a 39% increase in target audience perception that they can be affected by the sale of falsified medical products online. 25% of the target audience were aware of the campaign and the key messages via unprompted awareness and recollection questioning.

Campaign engagement was strong, with dwell time on webpages averaging one minute or more than the benchmark Government campaign webpage.

Use of the distance selling Common Logo scheme by online consumers has also significantly increased (+60%) over the course of the campaign. There are now over 100,000 online shoppers per month using the scheme to verify retail registration.

The UK plan over the period 2017-2018 is to create substantial awareness across clearly defined target audiences. These will include 18-30 year olds with a bias to middle/lower socio-economic groups, (most at risk) and also intermediary healthcare professionals.

The campaign components will aim to educate people so that they can recognise signs of falsification, avoid illegitimate online retailers and to increase reporting of falsified products.

To enable an optimisation of the campaign, market research was carried out in two phases. The first being desk research where data was reviewed from:

- Within Agency (e.g. product seizure figures)
- From public sources (e.g. via Office of National Statistics)
- From key stakeholders (e.g. trade associations)

This enabled an understanding of current levels of falsification; identified most 'at risk' consumers/target audiences; specific health risks and medical products that the campaign should focus on.

The second phase comprised qualitative research using in-depth interviews with historic online consumers of our prioritised medical products.

This enabled an understanding of what drives consumers online, their customer buying process, and how to tackle this behaviour.

This led to a campaign approach that involves running clear waves of activity targeting prioritised product groups: slimming pills, condoms, STI self-test kits, sports supplements (sold as medicines), erectile dysfunction and smart drugs, anti-depressants, sleeping medication, dental equipment, anti-psychotic/ anxiety medication and tanning products.

First wave: slimming pills



In order to gain exposure, a network of more than 100 key stakeholders who regularly share content with their members and across their own channels was used.

Examples include:

- Other Government departments, including all of those in the health family like PHE
- Healthcare professionals and associations, such as the General Pharmaceutical Council (GPhC) and Royal Societies



- Celebrities (who may have experienced the negative effects of falsified medical products themselves), whom are very influential to our audience
- Product specific influencers e.g. eating disorder charities or manufacturers of legitimate sports supplements

Thus an integrated communications campaign could be launched via a media sell-in, social media networks and partnerships, digital and internal communications.

EAA Member States



Iceland

Currently there are no public facing campaigns running at this time with no campaigns planned for the immediate future. There is a very low usage of the Internet for the dispensing or acquisition of either prescription or OTC medicines in Iceland. The situation will however be monitored closely and appropriate action taken when required.



Liechtenstein

Liechtenstein is in the process of implementing the Falsified Medicines Directive and as such is in the process of implementing directive 2011/62/EU and the licence agreement with the Commission is signed. The Commission Implementing Regulation (EU) No 699/2014 is still in the process of being included in the EEA acquis. No pharmacies are currently registered to sell medicines at a distance. At present there are no plans for communicating to the public on this subject. Monitoring of pharmacies that register to sell medicines over the Internet will be the responsibility of the agency.



Norway

The Norwegian Medicines Agency has signed the licence agreement with the European Commission and will implement the Common logo along with a Medicines Agency website section dedicated to this in 2018. A public awareness campaign is also planned for 2018.



Serbia

In collaboration with the Medicines and Medical Devices Agency of Serbia (ALIMS) and Italian Medicines Agency (AIFA), the EDQM and the Council of Europe have made a comprehensive educational web based teaching programme that is available to all Member States and interested parties.

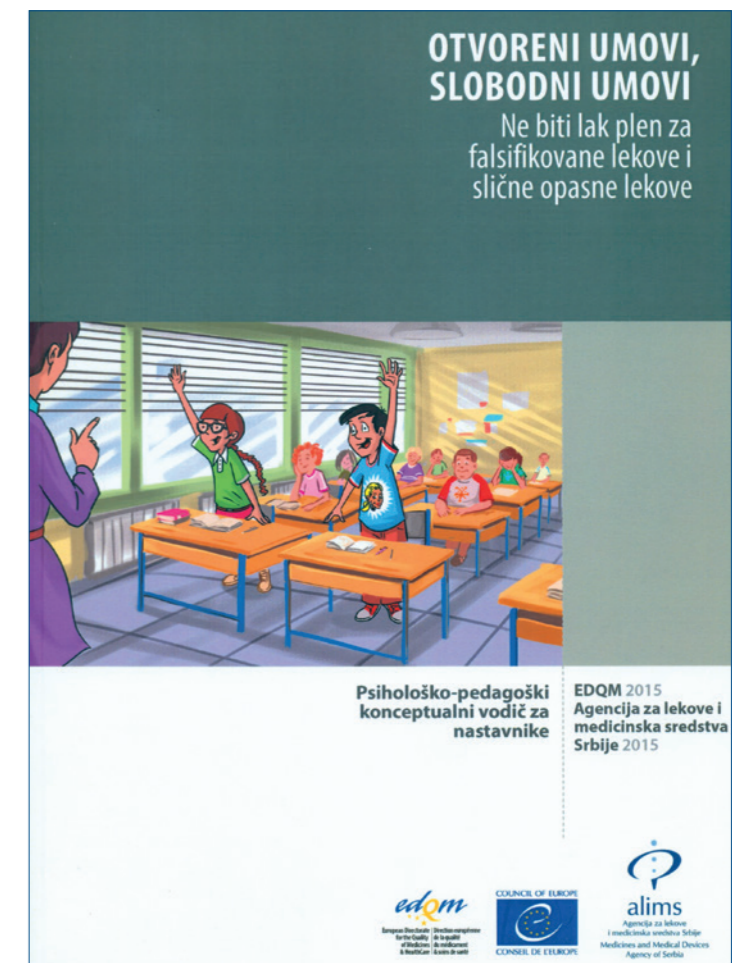
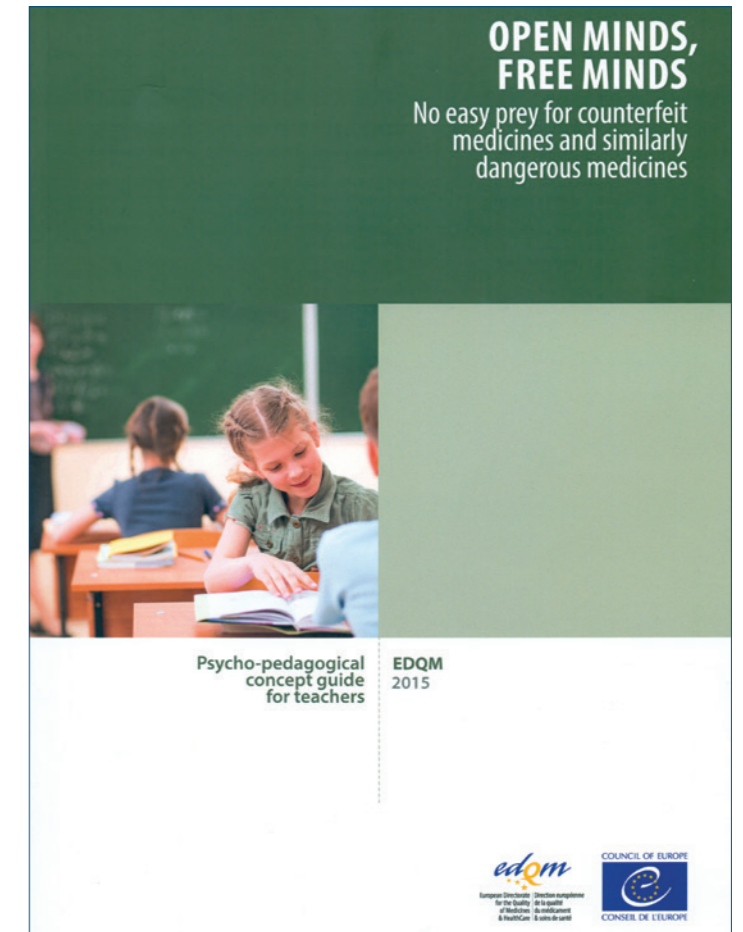
Called "Open Minds, Free Minds" the content was developed by 6 consultants involving experts from psychiatry, IT and the arts from Serbia and Italy. Aimed at age groups 8-11 and 12-15, the content is scientifically based and involves an interactive story where the reader can choose different routes to an end point so, in essence, the student chooses their own adventure.

The programme is now available in Armenia, France, Switzerland, Denmark and Poland. It is ready for the 2017 schools and festivals around Serbia and in the region such as Montenegro, Bosnia and Herzegovina, Croatia. The programme will encompass practical lectures, social networks, and use all media. Direct feedback has been collected from those that have been exposed to the programme and has helped to develop the thinking further.



Psycho-pedagogical guide for teachers.

"Open Minds, Free Minds" is scientifically based content which involves an interactive story where the reader can choose different routes to an end point and so the student can choose their own adventure.



Organisations publicising and championing the fight against falsified medicines

The following not for profit organisations have run or are currently running public facing awareness campaigns.



ASOP EU

Of particular note is the ASOP EU campaign which is running 5 Google AdWord grant campaigns in France, Germany, Italy, Spain and the UK. The current combined "impression rate" (this is the number of times per day that the Google advertisement appears on page one of a research results page, the visitor having used a key word such as "pharmacy Online"), is over 35,000 per day with over 1000 visitors per day clicking on the advertisement to obtain more information about the subject. The interim published report of the Italian campaign can be found here <http://buysaferx.pharmacy/wp-content/uploads/2017/03/Fighting-Fakes-by-Raising-Public-Awareness.pdf>



ASOP GLOBAL

The Alliance for Safe Online Pharmacies is a global non-profit organisation, based in Washington, DC, working in the US, Europe, Canada, and Asia to make the internet safer for patients through its four workstreams namely: Education, Influence, Research and Collaboration. A particular challenge has been educating the public and politicians about the risks involved in allowing US citizens to buy medicines via the Internet which the US Administration had tabled in Congress.



CSIP

The Center for Safe Internet Pharmacies comprises an active group of over 12 significant Internet Intermediaries. Together they have created a Principles of Participation <https://safemedsonline.org/who-we-are/principles-participation/> which sets out a detailed plan of voluntary actions to exhibit a best practice approach to the issue of selling medicines online. They are very active in raising awareness and many of these examples can be found here. <https://safemedsonline.org/protecting-consumers/education-campaign/>



EAASM

The European Alliance for Access to Safe Medicines have played a pivotal role in the creation of the educational material and websites to inform the public about falsified medicines. A ground breaking project called "Counterfeiting the Counterfeiter" ran in Germany where a 9 week campaign saw the website being ranked as the third most visited pharmacy site. The use of Google Pay-per-click AdWords, email advertising and banner advertising was used to attract would-be buyers of medicines.

From this important work the latest educational websites currently running in France, Germany, Italy, Spain and the UK were developed. The report can be found here <http://eaasm.eu/cache/downloads/av3r9l87z4wg4ocs8w84gogs0/CtC%20report%202012.pdf>



EUROPEAN MEDICAL ASSOCIATION

The European Medical Association was created in 1990 by doctors from 12 member states, and was established as an "international foundation pursuing a scientific aim" according to the Belgian law dating 25/10/1919. It is a unique, independent non-profit organisation, which offers every European Community doctor the opportunity to: join a European network of doctors, add a European dimension to their professional and social life and actively influence the development of European healthcare. In terms of collaboration with ASOP EU and the EAASM, plans are under way. As an example an educational leaflet for patients informing them about the dangers associated with falsified medicines is being progressed. This has the potential to be effective in raising awareness across the EMA network and thus enhance patient safety greatly.



FIGHT THE FAKES

Fight the Fakes is a global movement of international organisations representing doctors, nurses, pharmacists, research institutes, NGOs and foundations, academic institutions, coalitions for consumer protection, product development partnerships, pharmaceutical wholesalers, the research-based and generics pharmaceutical industry and civil engagement networks who commit to sharing information on the negative impact that fake medicines have on people around the globe. By signing up to Fight the Fakes, partners commit to spreading the word via their networks around the world – potentially reaching millions of people who have a professional role to play in protecting both patients, the public and health systems from fake medicines.

The campaign website www.fightthefakes.org provides information materials and social media tools (follow @FightTheFakes) to be shared by partners that explains that fake medicines is a crime against patients and a public health threat.



FMEDS

The FMEDS® Program aims to establish education and information tools focused on consumers.

We help consumers to protect their health by empowering them to avoid falsified medicines, and seek help if they believe that they have consumed some.

The goals of the FMEDS® Program are to:

- Obtain information rapidly and directly from consumers upon detection of falsified medicines,
- Provide an assistance to victims from FMEDS®-certified health professionals,
- Contribute to the dissemination of such information rapidly to the populations concerned,
- Educate consumers about the risks of falsified medicines and how to avoid them.



FONDATION CHIRAC

Founded in 2008 by President Chirac, the Fondation spends most of its resources on advocacy campaigns and the creation of programmes that unify and mobilise other actors on the world stage in reaching out for peace and a better world in every respect.

Part of this vision includes combatting and highlighting the current scourge of criminal activity in producing for the unwitting

public, fake medicines. Of particular merit, available for viewing by the public, is a powerful short film on this subject entitled Pharmacide (<https://www.youtube.com/watch?v=khR5EGCG0Q8>)

Fondation Chirac is also extremely active in furthering the goals of the MEDICRIME Convention; the first international treaty to criminalise acts of falsification of medicines.



IRACM

The International Institute of Research Against Counterfeit Medicines has run many public facing awareness campaigns. Recently they launched a France-wide awareness campaign about the hidden side of illegal e-pharmacies <http://www.iracm.com/wp-content/uploads/2016/11/en-press-release.pdf>

IRACM has also produced an interactive video that aims to make the viewer and in particular teenagers and students think about a situation to which little thought is often given: whether the website is safe or not. IRACM will also be proposing interactive games to sensitise teenagers about the risks of buying online fake medicines and also a serious game to educate about the hidden face of organised crime in this scourge.



LEGITSCRIPT

LegitScript is a trusted provider of tools and services that determines for credit card networks, search engines and regulators which Internet pharmacies, supplement sellers and other online merchants are operating legally.

LegitScript's customised "sweep" software platform monitors client platforms to identify problematic merchants, including rogue online pharmacies and sellers of dangerous health products.

LegitScript plays a key role in helping to keep patients safe. It is therefore a highly effective intelligence gathering and enabling organisation for all interested parties who are collaborating and acting to combat the illegal sales of medicines across the Internet.



NABP

The National Association of Boards of Pharmacy (NABP) has undertaken a multi-year public awareness campaign in the United States and Canada, including online banner ads, display posters, and two television and radio public service announcements (PSAs), with a third in production. The US TV PSA, available on the .Pharmacy Program website at <https://www.safe.pharmacy/buying-safely/pharmacy-on-your-tv/>, received more than 34,000 airings and nearly 2 million impressions.

Conclusion and Call to Action

Clearly as part of the Falsified Medicines Directive under Article 85d there is a legal obligation to raise public awareness about falsified medicines and the meaning of the Common Logo...

“

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..... ”

This is a clear call to action for Member States and DG Sante to raise public awareness. This report further highlights that need. The private organisations such as ASOP Global and ASOP EU are already facilitating a close and collaborative bond to help support the implementation of Article 85d. This collaboration is encompassing many face to face sharing best practice meetings with Member States with the aspiration to accelerate campaigns to help ensure the public become better educated as to how to buy medicines safely via genuine pharmacies using the Internet.

We hope that this report further encourages all Member States to become even more involved in the implementation of the Common Logo and raising public awareness about this critical issue of falsified medicines.

It is of paramount importance that the unwitting public is not duped in to buying medicines that may be unlicensed in the country of receipt, may contain too much, too little or no active ingredient at all or indeed may contain substances that can seriously harm the buyer.

For sure fake healthcare products/ medicines are illegal and dangerous, can cause patient harm and even death²⁰ ²¹. They also undermine the trust in public health systems as patients taking themselves out of their national health systems may be storing up future negative health outcomes.

We therefore call upon Member States, the Commission, the Parliament and all interested parties to continue to build on the many initiatives that raise public awareness which in turn will help to combat this growing threat to public health.

Contact us

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²⁰ Student who died after taking "toxic" slimming pills <http://www.telegraph.co.uk/news/uknews/law-and-order/11758216/Eloise-Parry-inquest-Student-who-died-after-taking-toxic-slimming-pills-sent-heart-breaking-final-text.html>

²¹ State of the Internet: NABP Position Paper on the Continued Proliferation of Rogue Internet Drug Outlets

