

Collection of examples of illegal conduct in relation to the online provision of medicines¹

1. Purpose of this document and context

This document intends to specifically address and complement the information already provided in our position paper on the DSA with regard to illegal practices affecting the online provision of medicines (both non-prescription medicines and medicines subject to prescription). The examples showcased in this document cover cases reported by PGEU members or found in public sources. Several of them relate to cases which were investigated or are currently investigated by the national competent authorities. Kindly be aware that this does not intend to be an exhaustive list of illegal practices and should be considered only as a mere internal collection of cases for the purposes of illustrating the increasing availability of unsafe medicines and health products as well as the risks posed to patient safety and public health by the illegal or inappropriate supply of medicines over the internet.

Furthermore, it should be noted that in some cases these illegal practices are hard to detect (for instance omnibus order of medicines) or it proves difficult to identify the seller or its location which hinders first their detection and then their legal pursuit by the competent authorities. Even when the identity and location of the offender is known the fact that the websites are located in a different Member State from the one where the illegal practice takes place makes very difficult for the authorities of the country of destination to pursue them. This means many of them may remain uncovered and unpunished. The lack of coordination between Member States or the lack of response by operators established in a different Member State may deter public authorities from pursuing such illegal practices in a cross-border context. Therefore, attempts to enact cross-border sanctions are hugely burdensome, costly and in most cases not successful.

Another important aspect is the asymmetry of information between consumers and the providers of medicines. Consumers are usually not able to assess whether a medicine is illegal or unsafe, and therefore this prevents them for identifying any risks and, eventually, submit a complaint before the relevant authorities.

2. Non-exhaustive overview of illegal practices affecting online supply of medicines to the public

2.1. General overview

Illegal practices affecting the online supply of medicines to European consumers could be broadly classified as follows.

- Online provision of non-authorised medicines (for instance an online actor based in Member State A provides a medicine authorised in this country to a consumer based in Member State B where such a medicine has not been authorised).
- Online provision of counterfeit medicines (usually from non-official websites)
- Online sale of medicines from non-authorised providers (e.g. illegal websites operating without a licence to sell medicines). This includes online provision of prescription-only-

¹ By 'medicines' and unless further specified in a particular case, we refer to non-prescription medicines, prescription medicines and medical devices.

medicines through non authorized agents (for instance, through online platforms or social media platforms either by companies or individuals).

- Online provision of prescription medicines or non-prescription medicines without complying with applicable standards (e.g. without obtaining a doctor prescription or exceeding permissible quantities of NPMs or without complying storage conditions, such as temperature standards)
- Illegal provision of POMs (in most Member States the online provision of medicines subject to prescription is forbidden, therefore their online provision is only allowed between Member States where this practice is allowed).
- Data protection breaches by the online operator (GDPR).

2.2. Concrete examples of illegal conduct in respect of the online supply of medicines

In this section we are covering a wide range of illegal practices that have occurred within the EU over the last 4 years.

Online provision of prescription medicines or non-prescription medicines without complying with applicable standards

In 2019, the **Italian consumer organization** conducted mystery-shopping on online pharmacies which has resulted in the delivery of over-the-counter medicines to Italian citizens of medicines with a packaging which does not comply with the packaging rules of the Community Code. Indeed, the packs and package leaflets of such OTCs were not displayed in Italian which is a mandatory requirement for medicines to be sold in Italy.

Also in 2019, the **Dutch consumer organisation** published the results of a mystery-shopping conducted in the Netherlands which revealed that a number of online websites (based in EU and non-EU countries) were supplying prescription medicines to Dutch customers in breach of the law. The research targeted 12 online websites and 20 prescription medicines were ordered and delivered without a doctor prescription which is contrary to Dutch law. Such medicines included antibiotics, sleeping pills, sedatives, and cancer drugs. The study showed that almost all medicines supplied contained a different quantity of active ingredient than the stated on the packaging².

Protecting public health also means ensuring the availability of and access to medicines. It is worth noting that in a context of shortages of medicines, online sales can prevent patients from having access to medicines they need. Indeed, during the COVID-19 pandemic, the **French government** imposed a temporary ban on online sales of paracetamol, ibuprofen and aspirin in order to prevent people to acquire large quantities of these products which were getting scarce (Article 6 of arrêté du 23 mars 2020).

In a number of EU countries there is a lack of quality control measures in place to ensure appropriate internet sale of medicines³ and in some countries there are even no restrictions on the number of

² <https://www.consumentenbond.nl/nieuws/2019/kinderlijk-eenvoudig-zware-medicijnen-bestellen-zonder-doktersrecept>

³ European Community Pharmacy Sector Facts & Figures 2016-2017 PGEU

items to be purchased online. This caused a death in **Germany**, where a patient who ordered online multiple packs of a potentially dangerous medicine committed suicide⁴.

Even in those countries where quality control mechanisms are in place, it is quite common that patients receive packs which are not meant for them, either because the internet pharmacy has packed the wrong medicines into the concerned parcel or because a pack was intended for another patient. In Germany, for instance, in some cases cold-chain medicines were sent via ordinary mail without special package.

In June 2018, the **UK General Pharmaceutical Council (GPC)**, expressed its concerns about easy online access of certain medicines in the United Kingdom⁵. The regulator stated that it was aware of situations where patients have been put at risk because of **the inappropriate sale and supply of medicines on the internet**. The GPC also called on online pharmacy owners to make appropriate checks, such as the identity of the patient, and to identify possible risks to patients, such as identifying multiple orders to the same address.

With regard to medicines prescribed by healthcare professionals established outside the UK, the GPC also identified some patients were not properly informed about indemnity and regulatory arrangements that apply to those prescribers. In particular, the regulator listed the following four medicines categories as not being suitable to be supplied online unless additional action is taken to ensure they are appropriate for the patients: (i) antimicrobials; (ii) opiates and sedatives; (iii) medicines or medical products for chronic conditions (including asthma and diabetes) and mental health conditions; and (iv) Non-surgical cosmetic medicinal products (such as Botox, Dysport or Vistabel).

Furthermore, in 2017, the **UK health regulator, the Care Quality Commission (CQC)**⁶, carried out various inspections of some companies that provide online primary care which raised significant concerns about patient safety. For instance, on 29 June 2017, an inspection report by CQC concluded that Pharmacy2U's online clinic does not provide "safe, effective or well-led" services. For instance, the CQC found that care in relation to asthma was not being delivered in line with current evidence-based guidance and standards.

Online provision of non-authorised medicines (including counterfeit) or supply of medicines by non-authorised providers

Several recent investigations of illegal conduct by online operators targeting Italian consumers have shown the vulnerability of consumers vis-à-vis deceptive and misleading practices concerning medicines sold online. This includes misleading advertising of prescription-only medicines claiming beneficial effects in the treatment of Covid-19, without holding a marketing authorisation, as well as the finding of fake pharmacy websites, which operated in the Italian market without the necessary

⁴ The pharmacist selling the medicine to such patient was convicted afterwards by a professional court, though the court held that it was difficult for the pharmacist to discover the danger, because "omnibus orders" by one person for multiple patients seems to be quite common, to save postage costs.

⁵ <https://www.chemistanddruggist.co.uk/news/stop-selling-opiates-asthma-inhalers-gphc-online-pharmacies>

⁶ The Care Quality Commission is an executive non-departmental public body of the [Department of Health and Social Care](#) of the [United Kingdom](#). It was established in 2009 to regulate and inspect health and social care services in England.

authorization to sell medicines online⁷. Indeed, in April 2020, **Italy's competition and consumer protection authority** (AGCM) required search engines and browsers to remove fake pharmacy websites from their search results. They identified 60 illegal pharmacies, which offered prescription-only drugs without authorization while claiming beneficial effects in the treatment of COVID-19⁸. The AGCM also opened two investigations into e-commerce platforms Amazon, Wish and eBay for allowing individual market players the online supply of coronavirus-related products (including sanitizing/disinfectant products, respiratory tract protection masks and other health and hygiene products) at exorbitant prices and by providing misleading descriptions about their preventative or curative effects as it considered this could constitute unfair commercial practices⁹. In December 2020, the AGCM adopted a decision by imposing *ex ante* obligations to eBay, Wish and Amazon to stop making available such products on their websites and preventing similar practices in the future¹⁰. Indeed, the AGCM considered these platforms to be liable for the illicit conduct committed by traders on their websites and, via a settlement proceeding with the authority, Amazon and eBay committed to verify all products sold on their platforms. Given the AGCM was satisfied with the cooperation offered and commitments agreed by the online platforms no fines were imposed.

In addition, in March 2021, the AGCM fined Vova online marketplace with EUR 3 million as it held it liable for the unfair commercial practices committed by traders using its platform in respect of the promotion and supply of masks and antibody kits for self-diagnosis of covid-19 in Spring 2020. The AGCM concluded, firstly, that Vova failed to provide clear and comprehensible information on the identities of the sellers of the products. It also stressed the antibody test for the rapid diagnosis of covid-19 lacked the required CE-marking. The antitrust authority concluded Vova was responsible for the traders' unfair and aggressive methods of promotion and sale capable of misleading consumers and endangering their health and safety¹¹.

In 2019, the **Spanish Agency of Medicinal Products** received 700 notifications of illegal websites selling medicines¹². Often, the websites are hosted on servers outside Spain (France, United States) which hinders the effectiveness of the Agency's actions. Also, in Spain, in February 2020, a **police investigation** resulted in 47 people arrested for being involved in the import, manipulation and supply of medicines without complying the applicable safety measures. This criminal organisation imported drugs in large quantities (70.000) from Malaysia, always falsely declared as food supplements and natural plants to circumvent customs controls and subsequently marketed as 100% natural invigorators. These products, once manipulated, were intended to be sold in premises such as gyms, herbalists or sex shops, and through the Internet. After various analyses, it became clear that these

⁷ https://www.agcm.it/media/comunicati-stampa/2020/3/PS11733-PS11735?utm_source=POLITICO.EU&utm_campaign=c8f57c279a-EMAIL_CAMPAIGN_2020_03_31_04_58&utm_medium=email&utm_term=0_10959edeb5-c8f57c279a-190547999&utm_source=POLITICO.EU&utm_campaign=4245772282-EMAIL_CAMPAIGN_2020_04_21_12_02&utm_medium=email&utm_term=0_10959edeb5-4245772282-190359449

⁸ <https://www.agcm.it/media/comunicati-stampa/2020/4/PS11746>

⁹ See press releases announcing the launching of the investigations at [AGCM - Autorita' Garante della Concorrenza e del Mercato](#) and [AGCM - Autorita' Garante della Concorrenza e del Mercato](#)

¹⁰ [AGCM - Autorita' Garante della Concorrenza e del Mercato](#)

¹¹ See case number PS11752 in the AGCM journal: [AGCM - Autorita' Garante della Concorrenza e del Mercato](#)

¹² [MEMORIA 2019 \(aemps.gob.es\)](#)

were in fact powerful drugs such as Tadalafil and Sildenafil, vasodilators intended for the treatment of erectile dysfunction. As a result, the Spanish Medicines Agency blocked 59 websites and withdrew from the market certain products declared to be "natural", the content of which would not correspond to their composition and could be highly dangerous for the health of consumer¹³.

Illegal practices regarding the online provision of medicines have also been identified in other EU countries including **France, Greece, Denmark and Bulgaria**. For instance, in France some individuals used big platforms to sell their prescription medicines. In Denmark, several foreign websites giving the wrong impression of being Danish pharmacies offered medicines prescribed at an online consultation at the website, such online consultation is forbidden in Denmark. In Bulgaria, big online social media platforms such as Facebook are used by individuals to offer and deliver to patients by postal services prescription medicines, including drugs containing narcotic substances or powerful sedatives. Some medicines distributed through Internet are not authorised in Bulgaria. Ongoing police investigations encounter difficulties to establish the identity and/or geographical location of the sellers.

In Greece, during the past years, several reports were issued by **Hellenic Drug Authority (EOF)** notifying various illegal practices performed by several e-shops and internet platforms. Various illegal medicines, either containing unlicensed substances¹⁴ or authorised medicinal active substances without being declared on the label¹⁵ (such as corticosteroids or sildenafil) or indeed containing prohibited substances (such as sibutramine¹⁶) were found to be available on these websites. Furthermore, certain medicinal products that are very strictly regulated in Greece, for patient safety reasons, such as those containing Codeine, are found to be sold by e-pharmacies to Greek consumers without complying with the said regulations.

Patient safety has been put at risk also in relation to the online sale of slim pills in the UK. In August 2016, the **UK Medicines Agency (MHRA)** launched a 'FakeMeds' campaign with warning of the dangers of buying dodgy diet pills online. This followed an investigation conducted by MHRA which led to the seizure of over 240,000 doses of unlicensed slimming pills in 2015, and the closure of over 2,000 unauthorised online retailers. Research carried out by MHRA in 2016 showed that although shoppers believe themselves to be "internet-savvy", 79% of the public are unaware of the issue of fake medical products. Through the campaign, MHRA intended to raise awareness that many of the slim pills available on the internet are not licensed medicines, meaning that their contents are unknown and untested, and, therefore, such pills may contain dangerous substances that can have devastating consequences for people's health.

As an example, the MHRA detected that some of the slimming products which claimed to be herbal contained sibutramine – a medicine which was withdrawn from sale due to serious side effects including strokes and heart attacks. Similarly, there are countless 'herbal' erectile dysfunction medications available online that could put your health at risk.

¹³ Spanish Internal Affairs Ministry website: [Detenidas 47 personas en 15 provincias españolas por la importación, manipulación y venta de medicamentos sin control sanitario - Noticias - Ministerio del Interior](#)

¹⁴ See EOF report about an unlicensed substance [Εθνικός Οργανισμός Φαρμάκων - Αρχική \(eof.gr\)](#)

¹⁵ See EOF report about a herbal cream containing non-declared medicinal substances: [Εθνικός Οργανισμός Φαρμάκων - Αρχική \(eof.gr\)](#)

¹⁶ See EOF report about slimming product containing sibutramine: [Εθνικός Οργανισμός Φαρμάκων - Αρχική \(eof.gr\)](#)

Illegal sale of POMs online

A UK prescribing platform provides POMs to French patients, through the website of an authorised British pharmacy. This illegal practice was brought to the attention of the **French Health Ministry** but it is unknown whether any action has been taken in this regard. The online sale of POMs is forbidden in France.

In other countries such as **Spain**, various cases of online provision of prescription medicines have also been detected despite this also constitutes an illegal practice in this country. The most recent case was the arrestation in October 2020 of a German citizen resident in Singapore for his involvement the distribution of illegal medicines in Spain (among other European countries) via the Internet using illegal online pharmacies whose web hosts had been located in different countries by the criminal organisation. In Spain, he introduced drugs for erectile dysfunction, while in other countries around the world he also introduced antibiotics, cancer drugs, alleged Covid-19 drugs and HIV drugs. This person was part of a criminal organisation which was dismantled in 2018 by Spanish authorities¹⁷. As a result of this previous investigation 500,000 doses of 62 different types of illegal medicines not authorised for sale on the Internet in Spain were seized, as they were not subject to any health control and did not have a prescription.

Data protection breaches

During the 2017 inspection as mentioned in the section above, CQC found that **patient data was not adequately protected** by the Pharmacy2U.¹⁸ Indeed, the CQC outlined as an area of improvement was that there were no formal protocols in place for identifying and verifying the patient's identity, and there could still be doubt about the identity of the patient requesting a prescription.

Finally, in July 2020, the **Polish Ministry of Health** lodged a complaint before the Polish Data Protection Authority about a potential breach of data protection rules as it found that Amazon US had access to personal and health data through access to e-prescription records used and processed by a pharmacy chain operating in this country. This has allegedly created the risk that such an online platform was able to profile patients on the basis of such sensitive data. The Data Protection Authorities and the Pharmaceutical Inspectorate Authorities are currently involved in this case^{19, 20, 21, 22}.

¹⁷ http://www.interior.gob.es/prensa/noticias/-/asset_publisher/GHU8Ap6ztgsg/content/id/12491363

¹⁸ <https://www.chemistanddruggist.co.uk/news/pharmacy2u-clinic-not-safe-or-well-led-finds-cqc?cid=ENL-CDNEW-DAILYB-LN-TOPSTORY-2017-0705>

¹⁹ Complaint before the Polish Data Protection Authority: <https://uodo.gov.pl/pl/138/1581>

²⁰ Press release (EN) https://www.reddit.com/r/europe/comments/hijm14/gdpr_polish_pharmacy_chain_gemini_caught/

²¹ MP question to the MoH <http://www.sejm.gov.pl/Sejm9.nsf/InterpelacjaTresc.xsp?key=BRCC3T&view=5>

²² Reply from the MoH to the MP question
<http://orka2.sejm.gov.pl/INT9.nsf/klucz/ATTBS2HTU/%24FILE/i08532-o1.pdf>