



Discounted or Dangerous

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Forewords

Jim Thomson

When I was a child, my parents were frequently dismayed when school report cards arrived on the doormat. They knew that every entry would contain the same phrase, "James must try harder."

Discounted or Dangerous (DOD) is one of two reports the European Alliance for Access to Safe Medicines (EAASM) is publishing simultaneously. It highlights the abject standards in three Member States where online pharmacy is supposedly not allowed (but seems rife) and the barely-better standards in two where the activity is legal. The sister publication, *Counterfeiting the Counterfeiter*, complements this report by demonstrating just how easy it is to attract the public to an illegitimate website, and how much money can be made by criminals preying on vulnerable patients.

As an alliance dedicated to patient safety, we would rather that it had not been necessary to undertake either of these projects, but the harsh reality is that in much of Europe (and globally) the internet remains the pharmaceutical Wild West. Unregulated at worst and under-regulated at best, the internet facilitates easy pickings for major criminals and, regardless of the fact that it should not be so, an online trading environment that does not meet the high standards of equivalent community pharmacy. For example, a so-called "online consultation" is an extremely flawed mechanism, wide open to potential abuse both from the "pharmacy" and the (necessarily anonymised) patient. It compromises the face-to-face relationship and trust between patient and healthcare and, effectively, subverts the traditional role of the pharmacist.

As each piece of this research was completed and collated, the team became ever-more incredulous at the parlous state of online patient safety. In the three Member States where online pharmacy is supposedly prohibited (France, Spain and Italy) we surveyed 177 websites. Not a single one displayed a consistent URL. The report details why this is a significant risk marker. In Germany and the UK, which fared rather better, there remained alarming discoveries to be made. For example, in Germany, over 30% of websites surveyed did not require a prescription, whilst in the UK, 75% did not have a named pharmacist on the website (a legal requirement).

At the point of purchase, a whole new series of ingredients enter this lamentable mix. These are the internet intermediaries, who play a part in the websites being found, the payments being processed and the purchases being delivered. There is at least a simple duty of care on their part to trade only with legitimate and legal pharmacies but the reality is that each continues to play its part. Whilst search engines are taking action to limit access to advertising, it is still very easy to buy "medicine" either from legitimate (but still, as this report clearly shows under-regulated) or illicit sources, to have the payment processed and the purchases delivered to one's door.

That can't be right and urgent action is required to make tangible improvements in the interests of all European patients. There is a familiar ring to European online pharmacy's report card. It reads "must try harder."



Jim Thomson
Chair, EAASM

Forewords

John Chave

The next few years will bring unprecedented improvements in the safety of the medicines supply chain in Europe. As a result of the Falsified Medicines Directive (FMD), it will become extremely difficult for falsified medicines to penetrate the legitimate supply and reach the hands of patients. And the use of new technology to authenticate medicines in the pharmacy – as mandated by the Directive – will create new opportunities for pharmacists further to ensure medication safety on the basis of new technology.

Europe's pharmacists are at the heart of these developments and their role is set to become even more central to patient care. The mission of community pharmacists is patient safety, and we are ready to play our part in the implementation of the new Directive. But it is when we look at the distribution of medicines via the internet that the picture is less clear. It is vital that those supplying medicines in the online environment aspire to and meet the high standards promoted and achieved by traditional pharmacists. There must be no concession, no weakening of controls, just because a pharmacy trades online.

In publishing this piece of research, the EAASM has shone a spotlight on the online status quo in several EU Member States. It does not make pleasant reading. The situation in the countries where internet sale of medicines is permitted and controlled, is poor enough. However, perhaps more surprisingly, in those countries where it is forbidden, unregulated online sale of medicines appears to be alive and flourishing. The research findings in these countries make for truly disturbing reading.

The Pharmaceutical Group of the European Union (PGEU) is determined to see the very highest standards whenever medicines are dispensed, both on and offline. It is not acceptable that unscrupulous traders can prey on unsuspecting patients whilst pretending to be legitimate regulated pharmacies. The EAASM's work in this area does its constituents – European patients – a great service. It also benefits all of us involved in healthcare provision, by bringing to light very important issues surrounding the whole area of online medicines supply. It is essential not only that we learn from this report, but also that all stakeholders work together to ensure that, regardless of how a patient obtains a medicine, safety is assured.



John Chave
Secretary General
The Pharmaceutical Group of the European Union

Contents

FOREWORDS

Jim Thomson	3
John Chave	4

THE EAASM AND FALSIFIED MEDICINES 6

Falsified medicines – what are they and why are they dangerous?	7
Where do falsified medicines come from?	7
What is an online pharmacy?	7
What makes online pharmacies attractive?	8
Why do criminals use the internet to sell falsified medicines?	9

AN INTRODUCTION TO THE DISCOUNTED OR DANGEROUS PROJECT 10

COMPARATIVE RESULTS 12

Consistent URL	12
Telephone number	13
Country name	13
Prescription required	14
Online consultation	15
Named pharmacist	16
Bulk discounts	16

THE ENVIRONMENT FOR ONLINE PHARMACIES: GERMANY 17

DoD findings: Germany	18
-----------------------	----

THE ENVIRONMENT FOR ONLINE PHARMACIES: UK 19

DoD findings: UK	19
------------------	----

THE ENVIRONMENT FOR ONLINE PHARMACIES: FRANCE 20

DoD findings: France	20
----------------------	----

THE ENVIRONMENT FOR ONLINE PHARMACIES: ITALY 21

DoD findings: Italy	21
---------------------	----

THE ENVIRONMENT FOR ONLINE PHARMACIES: SPAIN 22

DoD findings: Spain	22
---------------------	----

THE WAY FORWARD: RECOMMENDATIONS 23

Accountability of search engines/banks/credit card providers	23
An online information repository	24
European icon	24
Physical address	24
Online review and regular audits	25

REFERENCES 26

The EAASM and Falsified Medicines

The EAASM is an independent, pan-European initiative dedicated to protecting patient safety by ensuring access to safe and legitimate medicines. The Alliance was formed by a cross-section of European patient safety stakeholders from a variety of backgrounds. Its key activities include campaigning for the safer use of unlicensed or off-label medicines and also the exclusion of counterfeit and substandard medicines from the supply chain, raising public awareness around such issues, and promoting effective legislation and enforcement in relation to falsified medicines.

In May 2011, the EAASM held a conference on the Falsified Medicines Directive (FMD), which brought together key opinion leaders from throughout the medicine supply chain. During the conference a mutual understanding was gained of how the FMD will affect the medicines supply chain and how all can work together in the interests of patient safety. As of 1st July 2011 the FMD has been transposed into national law by each Member State of the European Union. The new legislation backed by the EAASM aims to ensure that medicines are safe and that the trade in medicines is rigorously controlled in order to improve the protection of public health. Following the execution of this new legislation each pack of medicine will have to carry a unique identifying code that can be authenticated at pharmacy level. This unique code will be linked to a common database and will verify if that medicine has come from a genuine manufacturer. In addition, the special feature carrying the code can hold other information that would enable healthcare providers and patients to access useful information on their medication and condition. Other measures that will be implemented include:¹

- ★ a common, EU-wide logo to identify legal online pharmacies. This would make it easier to distinguish between legal and illegal online pharmacies throughout the European Union
- ★ strengthened record-keeping requirements for wholesale distributors
- ★ tougher rules on the controls and inspections of producers of active pharmaceutical ingredients.

In one of the largest investigations of its kind, new research '*Cracking Counterfeit Europe*' commissioned by Pfizer revealed an enormous black market economy generated by falsified medicines, as Europeans risk their health by purchasing medicines online from illicit sources. Until now, estimates of the scale of the hidden falsified medicines market have been vague. However, the research (undertaken across 14 European countries) now values it at more than €10.5 billion per year.²

The WHO believes that more than 50% of medicines offered by websites that conceal their physical addresses are falsified.³ Research conducted in 2008 by the EAASM (*Counterfeiting Superhighway*) puts this percentage higher, at 62%. In the same year, a customs operation in the EU netted more than 34 million illegal tablets in just 8 weeks.

Among the products which were intercepted were antibiotics, anti-cancer, anti-malaria and anti-cholesterol medicines, as well as painkillers and erectile dysfunction medicines.⁴

The conclusions and recommendations section of this report is a call for action to make the online environment harder for counterfeiters to operate within and therefore safer for consumers.

Falsified medicines – what are they and why are they dangerous?

"Falsified Medicines" is the new terminology that is contained in the FMD (the term 'falsified' is used to distinguish the issue from intellectual property violations, so-called 'counterfeits'). It refers to products that are part of the broader phenomenon of substandard pharmaceuticals, products whose composition and ingredients do not meet the correct licensed specifications and which can consequently be ineffective and often dangerous to the patient. The difference with falsified medicines or counterfeits is that they are deliberately and fraudulently mislabelled with respect to identity and/or source. These medicines are a major threat to public health and safety. As falsifications become more sophisticated, the risk that falsified medicines reach patients in the EU increases every year. Falsified medicines represent a serious threat to global health and call for a comprehensive strategy both at European and international level. Falsified medicines can apply to both branded and generic products. They usually contain substandard or falsified ingredients, no ingredients, or ingredients including active substances in the wrong dosage thus posing an important threat to public health.⁵

Where do falsified medicines come from?

The issue of falsified medicines is now a truly global phenomenon, at first thought to only affect developing countries, now known to impact upon the developed world.⁶ Medicines are often manufactured illegally in back street 'laboratories' in central and far eastern countries such as China and India before being sold globally online. In such countries legislation or enforcement are inadequate and counterfeiters face extremely low risks of being detected or punished, making counterfeiting attractive to criminals.⁷ Developed countries such as the UK and other European countries serve as transit points and end-user markets.⁶ Falsified medicines represent a significant danger to patient health and it should also be noted that there is a rapidly growing trend by consumers to buy medicines online, where falsified medicines are readily available.^{6,8}

What is an online pharmacy?

It is important to distinguish between legitimate and illegitimate trade over the internet. For example, through a legitimate online pharmacy a consumer may now legally purchase medicines with a verified prescription from a doctor in certain countries. When used appropriately, legitimate online pharmacies offer a convenient, discreet and fast delivery service for medicines and healthcare products. A legally registered online pharmacy should request personal details, credit card information and require the consumer to provide a prescription for any prescription-only medicine (POM). In countries where online pharmacy is legal websites should be registered with an independent regulatory body.

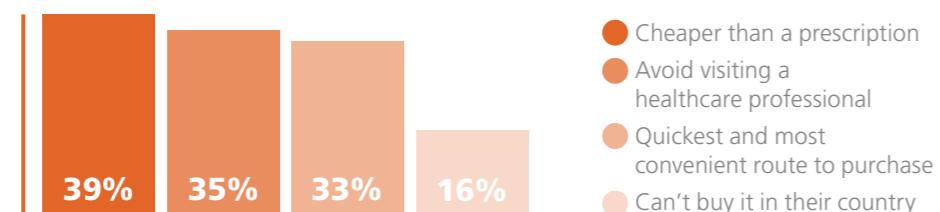
What makes online pharmacies attractive?

The prices of medicines sold via internet pharmacies are typically lower than those of similar products available in high street pharmacies, mainly because owners need not pay for so many overheads. Illegitimate internet sites often sell products in bulk, a fact that may entice online purchasers. In the results section of this report the scale of this issue will be demonstrated, particularly in member states where online pharmacy is not legal. Internet pharmacies therefore offer certain specific benefits over the high street equivalent, but they are at the same time fraught with potential dangers. However, patients should be aware that prescription medicines when prescribed and dispensed within the legitimate supply chain are never done so in bulk and therefore sources offering these discounts are likely to be illicit.

Online pharmacies also offer a high level of convenience, particularly for people with limited mobility, as items are typically delivered direct to the customer's home. Registered online pharmacies can provide convenient access to healthcare products, as well as advice, for people who are perhaps elderly, disabled, live in remote areas or work long/unsociable hours. They therefore offer significant advantages for people who cannot easily travel to a medical centre or high street pharmacy. They also offer a means for patients to purchase POM's that aren't available in their country. Online consultations can be offered, meaning that patients can obtain a prescription without visiting a doctor. However, there are serious concerns that this process removes the need for a patient to be seen, physically, by a doctor, a process that offers a greater degree of safety. Without a proper diagnosis, disease symptoms can be left untreated and lead to other more serious long-term complications. Online consultations can result in patients gaining access to unnecessary repeat prescriptions. Furthermore, persons seeking access to a particular medicine may be capable of manipulating the online consultation procedure which, as evidenced in the EAASM *Counterfeiting Superhighway* report, may in fact amount to little more than a "rubber-stamping".⁹

Finally, online pharmacies offer a means of maintaining a high level of privacy. Perhaps a patient does not wish to inform friends, family, employer or even a doctor about a suspected condition, or may wish to avoid potential forms of embarrassment, particularly if looking to purchase erectile dysfunction medicines. They may not understand that erectile dysfunction can be a very important early warning sign of cardiovascular disease, or be masking diabetes. Patients may also be keen to avoid a formal diagnosis of other stigmatised conditions, such as mental illness.

Reasons why people would buy POM online without prescription (% of people surveyed)²



Why do criminals use the internet to sell falsified medicines?

The internet is a technical tool with global reach, which allows criminals to remain relatively hidden and anonymous, whilst freeing themselves from the dangers of working from 'brick and mortar' establishments.¹⁰

As these criminals are able to hide their identity, consumers are more exposed to – and have more opportunities to knowingly or unknowingly purchase – falsified medicines, irrespective of where they reside.

Moreover, unscrupulous salespeople can easily display an image of a genuine product on a website, but then ship falsified medicines to the consumers once a purchase is made. This is in contrast to high street pharmacies, in which consumers can see and handle the product that they are purchasing. These pharmacies are generally managed by a professional pharmacist and professional checks are in place to ensure their integrity and reassure patients of their quality and safety. Falsified medicines can often be very difficult to identify visually and may require a lab test to confirm that they contain the wrong chemical composition or active therapeutic components.



An introduction to the Discounted or Dangerous project

The growing prevalence of internet usage in recent years has been accompanied by a rising trend towards the use of online pharmacies. While such online pharmacies provide benefits such as convenience and anonymity, they also carry numerous risks due to the largely unregulated nature of the internet. The objective

of this report is to review online pharmacies, their structure and their practices, against pre-determined criteria.

The criteria that have been selected for this project (Table 1) are a list of practical guidelines that have been set out by the EAASM.

Table 1

Criteria	Description
Consistent URL	Does the website operate from one web address only or are there multiple web addresses leading to the same website?
Physical address	Does the website display the address of the pharmacy operating the website?
Telephone	Does the website have a pharmacist available to answer questions?
Country	Does the website display a county name which indicates where it is situated? Is the pharmacy registered in the country in which it intends to sell medicines?
Registration	In countries where online pharmacy is legal, is the website registered by a local regulatory body?
Working link	In countries where online pharmacy is legal, does the website display the relevant stamp of approval and does this stamp link to the website of the regulatory body?
Named pharmacist	Does the website have a pharmacist available to answer questions?
Prescription required	Is a prescription required for the purchase of POMs?
Online consultation	Does the website offer patients an online consultation? Registered pharmacies are required to check that a medicine is suitable for a patient before selling it
Bulk discount	Does the website sell prescription medicines in bulk? Are discounts offered when these are purchased?
Safety/Security policies easy to find	Are safety and security policies easily located?
Product information	Is adequate product information offered to the patient including information on how to store the drug, dosage, drug interactions and side effects

The criteria represent a set of values and requirements that should be expected by the general public from online pharmacies. These criteria should be fulfilled if these establishments are to operate to the highest possible standard and offer the type of quality care to which citizens of the European Union are entitled.

It is essential to bear in mind that, although for the most part, the criteria are applicable across the Member States, there may be variances where policies and/or regulatory environments differ. Furthermore, all the information supplied based on the predetermined criteria was accurate at the time of the data-gathering process.

The report will seek to offer an audit of these internet pharmacies and identify whether and, if so, where, guidelines could be introduced and recommendations made to relevant European stakeholders in order to make the online environment for the purchase of medicinal products safer for consumers within the European Union/Economic Area. It will furthermore offer an insight into how legitimate online pharmacies might be able to support the pharmaceutical supply chain.

Using these criteria as a basis, the report has been focused on five major markets within

the European Union: the UK, Germany, France, Spain and Italy. These represent the largest countries in the EU in terms of population and host some of the most mature markets. However, whilst regulatory frameworks within the five are similar, their approach to the pharmacy sector as a whole and the online pharmacy sector in particular varies. For example, France, Spain and Italy do not permit the sale of prescription medicinal products through internet-based pharmacies. However, it must be highlighted that, whilst such sales are illegal within these countries, this does not necessarily prevent the consumer from purchasing products from an online pharmacy based in another EU/EEA Member State or even from a country outside of these geographical areas.

Finally, it is important to stress that the report is not in any way intended to comment on the legitimacy or illegitimacy of any given site. As such, some sites with low scores may be entirely legal, whereas those with higher scores may not necessarily enjoy the same status. Neither is this report designed to give precedence to one site over another, nor to determine the value of any of the sites surveyed as a vehicle for the purchase of prescription medicinal products.



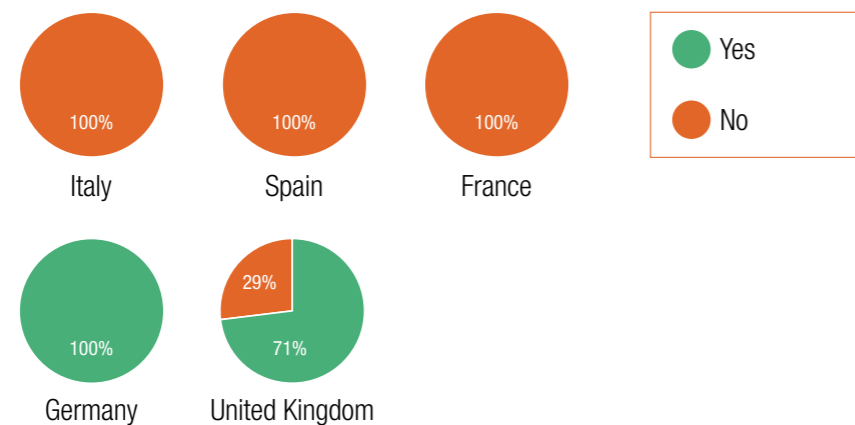
Comparative results

The results of the DoD survey of online pharmacies in the five largest European markets shows a clear divide, with regard to the reliability and safety of these internet establishments, between those EU Member States in which regulated online pharmacies are permitted and those in which they are prohibited. The results indicate that consumers in France, Italy and Spain are far more at risk of dealing with fraudulent establishments and receiving questionable products than those who reside in Germany or the UK. (Refer to Table 1 for the list of set criteria which each pharmacy was marked against).

Consistent URL

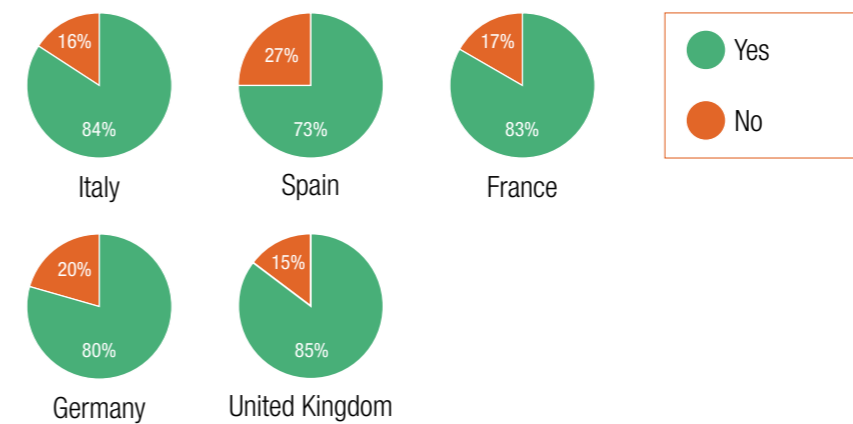
With roughly the same number of online pharmacies surveyed in Italy (57), Spain (60) and France (60) serious questions were raised about their actual existence. For example, across all three countries, no single online pharmacy surveyed could display a consistent URL. This means that criminals would be able to close down the site and open another in a nominal amount of time. It also gives them the capability of operating from several sites at once, which reflects on both their consistency and reliability. This raises immediate questions about the legitimacy of medicines available from these sources.

By contrast, 59 online pharmacies in the UK had a consistent URL, compared with 24 that did not. In Germany, all 54 internet-based pharmacies possessed a consistent URL.



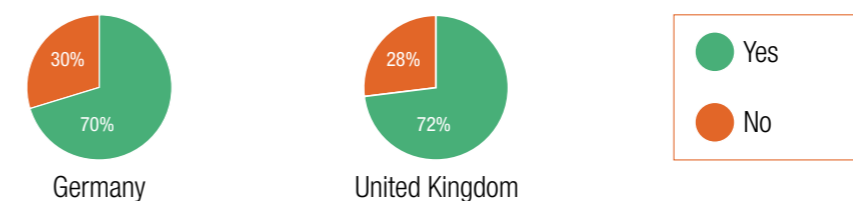
Telephone number

In Germany 43 websites displayed a telephone number and 11 did not, and in the UK, 71 displayed a number whilst 12 did not. Of the pharmacies which displayed a telephone number and claimed to be based in the country which they are licensed to sell medicines in, a stratified sample of 30% were contacted. Of the German numbers contacted, 17% of the sample did not verify themselves as the pharmacy in question. The score for the UK pharmacies contacted was even worse, with 35% of the sample not verifying themselves as the pharmacy in question. A proportion of these numbers were invalid and one pharmacy questioned where the number had been obtained from. From a consumer and patient safety perspective, and for verification purposes, contact via telephone is a distinct advantage. This is because it may provide a means through which a consumer can contact a healthcare professional and ascertain the legitimacy of a pharmacy – although this is by no means an iron cast guarantee.



Country name

German (38 yes/16 no) and UK (60 yes/23 no) sites displayed a country name, placing the online pharmacy in the Member State itself. As internet-based pharmacies are prohibited in Italy, France and Spain, where websites displayed a country name, indicating where the pharmacy was based, it was generally outside the EU – where regulatory rules might not be as rigorous as those within the Union.

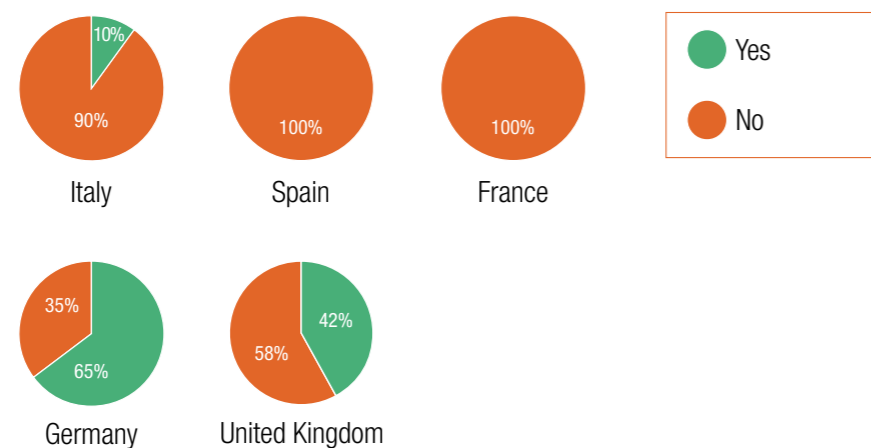


Prescription required

Perhaps more alarming are the comparative statistics relating to the safety of service and the dispensing of medicines. The purpose of requiring a prescription for the issuing of certain medicinal products is to safeguard patient health. However, of the online pharmacies surveyed in Spain and France, none required a prescription in order to obtain these types of restricted medicines. Of those surveyed in Italy, only 6 required a prescription.

The figures for the UK were marginally better, but even here only 35 of 83 online pharmacies surveyed demanded a prescription. Some of the online pharmacies that did not request a prescription required the patient to undergo an online consultation in order to gain one. However, it must be considered that a consultation for a POM requires input from a doctor (for the vast majority of medicines – pharmacists and nurses have only limited supplementary prescribing permissions). For an over the counter (OTC) medicine, a telephone consultation with a pharmacist is permissible, but is still not considered to be good practice. This suggests that even in a regulated market, establishments exist that are willing to exploit a loophole in the basic rules protecting patient health. It is essentially a loophole that leads to greater health insecurity, because nowhere does the regulation state that the doctor must physically see the patient. Online pharmacies are using an exemption introduced, for example, to enable people in remote areas to obtain medicines without visiting the doctors surgery. It was never intended to apply to the internet and is considered to be a major weakness in the legislation. In essence, all online pharmacy sites must have a doctor and doctors should be responsible for screening of online consultation submissions.

Germany's figures showed that 35 of 54 online pharmacies required a prescription. Whilst this looks significantly better than other EU countries, it must be stressed that over 30% still did not require a prescription.



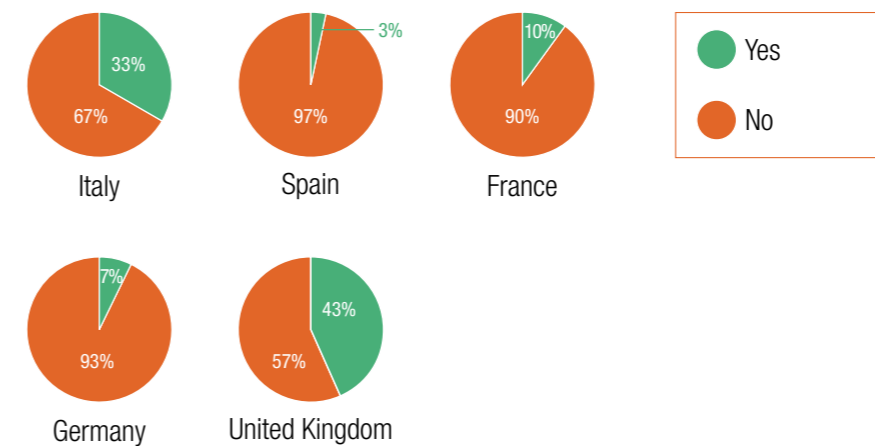
Online consultation

The other three mechanisms that should be employed by internet-based pharmacies with a view to both safeguarding patient health and guaranteeing peace of mind include: the provision of an online consultation service; offering easy access to safety and security policies; and the inclusion on the site of a named pharmacist.

With the exception of Spain, and somewhat surprisingly, the vast majority of online pharmacies in the other four Member States surveyed offered easy access to safety and security policies. The accuracy and authenticity of these policies were neither tested nor verified.

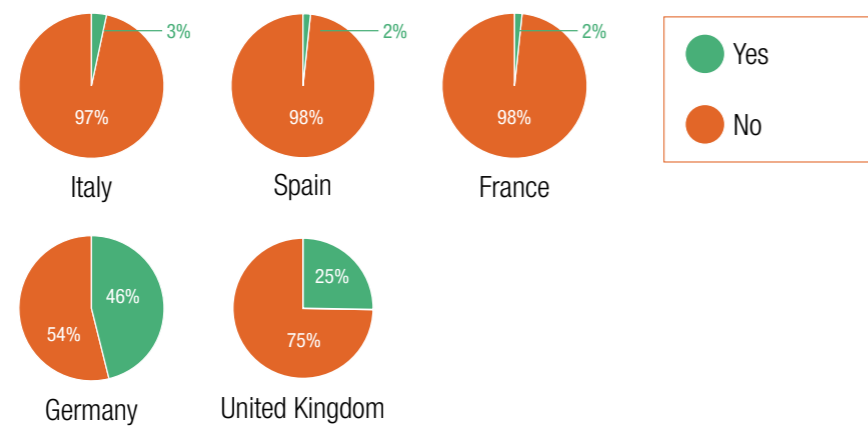
The online consultation process is clearly not working in all five countries polled, although the UK fared marginally better than the others. For example, in Italy, only 19 of the 57 pharmacies surveyed were able to offer this type of service, compared with 2 out of 60 in Spain and 6 out of 60 in France. Even in Germany, where internet-based medicines dispensing is permitted, only 4 of the 54 pharmacies under scrutiny offered the possibility of an online consultation. In the UK 36 of 83 pharmacies offered this type of service.

Essentially, the figures show that potentially harmful products are being ordered and taken without effective advice, leaving patients open to serious health dangers that may emanate not solely from the products themselves, but also to potential contra-indications. However, the online consultation process itself may be considered suspect, because there is clearly no guarantee that submissions are being scrutinised by a doctor. Furthermore, with no physical examination in place, a patient may fill in any details they wish, indicating that the online consultation process can be seen as providing a means to obtaining a medicine which might not be appropriate or required.



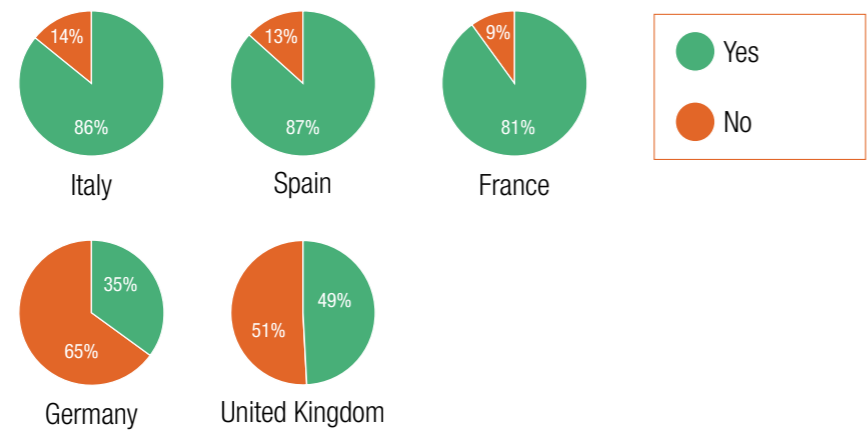
Named pharmacist

In the UK a named pharmacist was offered on a total of 21 out of 83 sites. It must be stressed that it is a legal requirement to have a Royal Pharmaceutical Society (RPS) registered pharmacist named on every legitimate site in the UK, indicating that the results are extremely concerning. The other four countries were far behind, with 2 out of 57 in Italy, 1 out of 60 in Spain, 1 out of 60 in France and 25 out of 54 in Germany providing a name. It must be noted that illegitimate online pharmacies can make up or forge a name of a pharmacist. In countries where online pharmacy is legal, a consumer wishing to verify the existence of a named pharmacist and confirm that they are associated with the website where their name is displayed, can do so by contacting the relevant regulatory body in their country (General Pharmaceutical Council [GPhC] in the UK and German Institute of Medical Documentation [DIMDI] in Germany). However, counterfeiters may be aware that the likelihood of this happening is very low.



Bulk discounts

Another interesting point is that in countries where online pharmacies are not permitted, internet-based traders selling into these Member States are more than happy to provide discounts for bulk purchases. This was the case for 49 of the 57 pharmacies polled for Italy, 52 of 60 in Spain and 54 of 60 in France. By contrast 41 of 83 offered this service in the UK and only 19 of 54 in Germany. Clearly the prospect of discounted medicines based on volume is an attractive one and may sway consumers who might otherwise not be tempted to shop online.



The environment for online pharmacies: Germany

Since enforcement of the Statutory Health Insurance (SHI) Modernisation Act in 2004, the structure of the German pharmaceutical sector has changed significantly. Online sales of medicines increased rapidly and, according to the Federal Association of German Mail Order (BWH), online trade volumes of pharmaceutical products increased by over 28% between 2006 and 2007.¹¹

Ongoing health reforms, many designed to cut the federal spend on pharmaceuticals, have meant that the amount of the patient co-payment for drugs has steadily increased. Moreover, many drugs have simply been removed from the reimbursement list altogether and must be paid for in full by the patient. This theme is likely to continue as a result of the introduction of the recently introduced healthcare finance law (AMNOG), which requires a drug to provide added benefit over existing therapies in order to qualify for reimbursement.

Internet-based pharmacies are now able to supply German consumers with both OTC and prescription medicines. The patient need only send an original prescription to the pharmacy, although in some cases it may be accepted as a scanned attachment to an email. Legitimate online pharmacies are required to operate a quality management system, which is intended to provide for efficient ordering and delivery.

In addition to national internet pharmacies, to which the same regulations apply as those for community pharmacies, pharmacies from other European countries may offer drugs in the German market in

accordance with the EU free movement of goods legislation.

DoD findings: Germany

Out of a total of 54 online pharmacies surveyed, only 10 were able to satisfy 12 or more of the criteria set out to make the online environment for the purchase of medicinal products safer for consumers. At the same time, 19 of the pharmacies surveyed satisfied less than half of these criteria, although only 6 websites did not display easily accessible safety and security policies.

19 of the pharmacies offered bulk discounts and 18 did not require the production of a prescription, in contravention of the law. Online consultations are only available for patients who supply a prescription. 16 were not able to display details of a physical address.

The DIMDI operates a Register of Mail Order Pharmacies, which contains the details of pharmacies officially authorised to carry out mail order trade. The register shows contact details, internet addresses associated with the pharmacy, information relating to the competent supervisory authority and the date of authorisation of the mail order permit required by law. DIMDI updates overviews of all the pharmacies registered on a weekly basis.

Registered pharmacies should display the DIMDI security logo on their website(s). Clicking on the logo will take the user to the details of the pharmacy listed in the register. Of the 54 websites surveyed, 32 displayed the relevant logo.



The environment for online pharmacies: UK

In the UK, it is estimated that approximately 440 million Euros each year is spent on POM's by people without a prescription.²

The distance selling of medicines is permitted in the UK, however pharmacy websites must display clearly the name of the owner of the business, the address of the pharmacy at which the business is conducted and, the name of the superintendent pharmacist. Furthermore, the site must provide information that would allow confirmation of the registration status of both the pharmacy and attached pharmacist(s). The specific circumstances relating to the make-up of the UK mean that in England, online pharmacies are not permitted to provide NHS services unless they have premises in England and are placed on the pharmaceutical list of their local Primary Care Trust (PCT). Prescription medicines on the NHS can only be dispensed against a properly obtained prescription, submitted by post. The NHS is in the process of developing a system that will allow doctors to forward prescriptions electronically to a community pharmacy selected by the patient, which will include online pharmacies.

Existing community pharmacies that are included on a PCT's pharmaceutical list do not need to apply additionally for a permit to undertake 'distance selling' in order to provide pharmaceutical services from their existing pharmacy via the internet. The permit is only required by a person or persons who want to establish a new pharmacy that is not already on the PCT pharmaceutical list and that cannot satisfy the 'necessary or expedient' test. This means that an existing pharmacy, operating

in accordance with the Medicines Act and NHS terms of service, can provide goods and services via the internet from its existing community-based establishment.

DoD findings: UK

Only 5 of the 80 pharmacies surveyed satisfied 14 or more of the 15 criteria set out in the project and 44 of them satisfied less than 50% of the criteria. Inconsistent URLs were attributed to 4 pharmacies surveyed and 11 of the pharmacies were not located in the UK – in fact at least 5 were located outside of the EU, in the USA, Canada or the Seychelles.

All legitimate online pharmacies in UK must be registered with the Care Quality Commission (CQC) and the GPhC. The GPhC has introduced a logo that participating online pharmacies should apply to their sites. Only pharmacies that offer professional services via the internet can use the GPhC pharmacy logo. It is intended to identify whether a website offering online sales of medicines or the provision of additional pharmacy services is connected to a registered pharmacy. By clicking on the logo, visitors are linked to a page on the Royal Pharmaceutical Society (RPS) website where they can make checks to ensure the site is a registered pharmacy. Out of the 80 websites surveyed, 26 of them displayed the GPhC logo. However, the logos in question can be easily copied and applied to illegitimate sites. One of the UK's largest pharmacy chains, Boots, did not display the GPhC logo, nor did it offer a named pharmacist.



The environment for online pharmacies: France

In the *Cracking Counterfeit Europe* research, commissioned by Pfizer, 14% of respondents in France admitted to buying medicines over the internet.² The figure is noteworthy in a country that actually prohibits web-based trading in medicinal products.

In 2011, the French Ministry of Foreign and European Affairs moved to discourage people from making such purchases. Together with the Fondation Chirac, the Ministry launched Pharmacide, a video warning against the dangers of consumption of drugs purchased through the internet. The aim was to inform consumers and patients that medicine is not just another commodity.

DoD findings: France

Despite these types of ongoing public awareness-raising activities, the figures from the DoD survey show that traders are by no means discouraged from selling drugs into France via the internet. What's more, whilst the law requires the presentation of a prescription for the provision of POMs, internet traders are clearly circumventing this. Of the 60 sites surveyed, none required evidence of a prescription. Only one displayed a named pharmacist and 6 offered the possibility of an online consultation. None of the sites were approved by the European Medicines Agency (EMA) and nor did any have a consistent URL, suggesting that the purchase of drugs online in France is, in effect, outside of normal controls.

Of the 60 sites surveyed, 27 were able to offer a physical address. Given the prohibition of internet-based sales in France, a handful of the addresses reported were located in other EU Member States, and the majority were further afield. Medicines that are imported into the EU may not be subjected to the same standard of regulatory controls in their countries of origin.

Of the 12 criteria set for France, the highest score achieved was only 7, by a single pharmacy out of 60. The majority, a total of 56, satisfied between 1 and 4 of the criteria set out. This suggests that consumers in France who look to purchase medicines over the internet are not guaranteed to receive an original and safe product.

It is noteworthy, however, that the sites surveyed scored highly on the provision of product information and easy access to safety and security policies. However, there is no guarantee either that the policies are authentic and applicable, or that the product information corresponds effectively to the medicine actually dispensed.

In contrast to the two countries in which online sales of medicines are permitted, Germany and the UK, the sites surveyed in France focused solely on drugs sales and did not offer other products likely to be found in a community pharmacy. Furthermore, almost all of the sites, 54, were able to offer bulk discounts, thereby making them more attractive to consumers who may otherwise have respected the legal ban.

The environment for online pharmacies: Italy

Neither internet pharmacies/e-commerce, nor sale of pharmaceuticals by email or mail order are allowed in Italy.¹² As the country does not permit online pharmacies to be established in its territory, or indeed to make sales into its territory, the survey results are alarming. Despite the apparent ban on internet pharmacies, the sale of medicines via the internet into Italy is clearly taking place, with 60 websites having been recorded as undertaking this type of trade.



DoD findings: Italy

As expected, due to the fact that an online pharmacy cannot be established legally in Italy, the internet pharmacies are mainly listed in a number of other countries, including: Cyprus, UK, Czech Republic and Latvia (all these countries are EU Member States); and Canada, US, India, the Bahamas and Mauritius. Only 16 of the 60 pharmacies surveyed indicated that they had a physical address.

In contrast to Germany, where internet-based pharmacies are permitted, only 5 out of the total 60 websites were not offering bulk discounts. This could be attributed to the fact that most of the sites offering online drug sales to Italy were located a considerable distance away. Again, in contrast to the German situation, only 6 of the sites selling into Italy required the presentation of a prescription. This may be indicative of the fact that the ban does not necessarily equate to a total prevention of a product coming onto the market, but often spurs on more covert, black market operations.

Despite just a couple of pharmacies claiming to be in Italy, a total of 19 offered consultation services during the purchasing process. At the same time, only 16 of the sites were able to offer easily accessible safety and security policies.

Overall the scores from Italy were extremely disappointing, pointing to the hypothesis that a total ban on online pharmacies may be encouraging black market trading in medicines. Of a total 13 criteria under consideration, no website scored 10 or above. The highest score came from the UK-based Chemist Direct, which, with 9 points out of 13, was deemed to have provided "thorough information". While the vast majority scored below half marks, 4 websites actually recorded a score of zero.

The environment for online pharmacies: Spain

In Spain the purchase of prescription medicines over the internet is a practice that is expressly banned by law. It follows, of course that internet pharmacies are therefore prohibited. The General Council of Official Colleges of Pharmacists suggests that the risk of counterfeit medicines is minimal, thanks to the country's pharmacy model, which is based on a linear chain of agents, including the pharmaceutical laboratory, the distribution warehouses and the community pharmacies.¹³ The role of the healthcare professional within the chain is to ensure a high level of health care at a reasonable cost to the patient.

DoD findings: Spain

A key entry route for counterfeit medicines is the internet, allowing criminal dealers to flout the exhaustive quality controls which are carried out as part of the authorisation process by regulatory bodies and through monitoring and reporting by manufacturers and healthcare professionals. The measured scores achieved by websites selling medicines in Spain are noticeably low, with none of the 57 sites surveyed scoring above half marks with regard to the 13 criteria laid down. One site scored a zero, 8 of the 57 sites scored 1 point and 26 scored 2. Whilst the legitimate supply chain appears to be secure, it would appear that a plethora of below-par internet pharmacies are profiting from Spanish trade in medicines.

Of all the sites surveyed, only one offered a named pharmacist, raising concerns over the safety and accuracy of information provision. Astonishingly none of the sites under review required the presentation

of a prescription and only 2 offered the possibility of online consultation. Despite these problematic issues, 32 of the sites had safety and security information that was easily accessible. An overwhelming number were able to offer bulk discounts: 52 of the 57 sites surveyed.

In line with the prohibition on internet sales of drugs in Spain, unlike in Italy, none of the pharmacy sites suggest that their drugs can be obtained on domestic soil, but offer a number of countries as their original source. These include: England (and separately, the UK), India, Andorra, Germany, Canada, Cyprus, US and "worldwide". Of the sites surveyed, 15 offered a physical address.

Two URLs linked to the same site and another took the reader to a "popular drugs broker" worldwide. Given the low scores experienced in the Spanish survey, the overall picture is one of insecurity and inaccuracy. In line with the findings in Italy, it appears that the prohibition of internet sales of drugs has not in fact worked, but has instead driven black market trade in medicinal products. The overall inconsistency regarding the provision of accurate information, together with the arms-length location of the websites – placing them beyond Spanish Law, could point to a possible route into the country for falsified products.

The way forward: recommendations

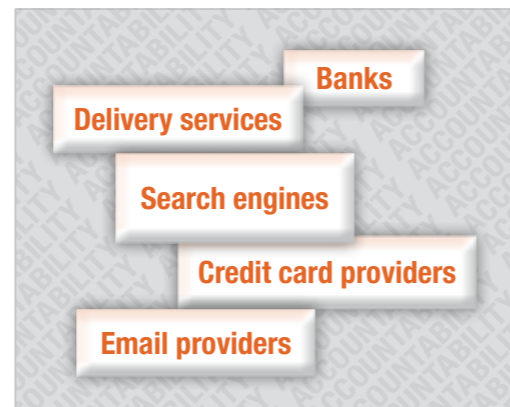
There is a distinction to be made between legitimate online pharmacies and the illegal sale over the internet of potentially harmful, falsified medicines. Given the prospects of serious harm to human health from these products, often dispensed without adequate consultation or even the presentation of a proper prescription, it is up to healthcare stakeholders to seize the initiative and protect the consumer.

It was apparent during the debate of the European Parliament on information to patients in 2010/2011, that policing the internet is fraught with problems. This does not mean that certain defensive mechanisms cannot be put in place. One serious issue that needs to be addressed is the apparent lack of search engine accountability where counterfeit medicines are concerned.¹⁴

Accountability of search engines/banks/credit card providers

Services such as Google, Yahoo and MSN – along with other popular internet search engines – are making efforts to remove from paid-for search results web pages advertising illegal internet pharmacies. This is a tactic that has already proved to be successful in stopping people finding (accidentally or deliberately) websites related to other wrongful or unprincipled interests and activities. Action is needed to prevent illicit sites being returned by organic searches.

Buying medicines online requires the details of a valid credit card, a key part



of which is very often the full name and address of the cardholder. Illegitimate websites regularly use the main credit card servers to process transactions.

This offers banks and credit card companies the opportunity to identify and block transactions related to illegitimate websites. The websites have to apply to the banks and credit card companies for permission to use their payment services. Therefore a degree of responsibility – including a duty of care – should lie with the banks and credit card companies to accurately screen applications and detect illegitimate websites within the healthcare arena. If they are unwilling to tackle the issue, or are simply lax in their application of preventative measures, penalties could be applied to these institutions. Indeed, it may be time for regulators to look into the workings of credit card processing and merchant account companies.

An online information repository

In terms of more concrete measures to directly communicate with patients about the potential dangers of purchasing drugs online, it is imperative that their efforts to detect legitimate online pharmacies are made easier. For example, this could be facilitated by an online repository for legal web-based pharmacy information. This could contain a reference list to which patients could refer if they want to know whether the pharmacies are genuine and, by extension, whether the products they are buying are safe and legitimate. This will require support from health bodies and legitimate online pharmacies.

European icon

Several associations and other representative bodies have introduced (or are currently testing) schemes that help consumers distinguish genuine internet pharmacies from illegal online medicine traders. However, these efforts to prove reliability and legitimacy could be reinforced. Where medicines sold on specific sites have been approved by the EMA, it would help if this were indicated by an EMA icon. Work will need to be done, however, to ensure that such an icon cannot easily be reproduced by unscrupulous traders. Eventually it would be helpful to extend this protection to medicines approved by national medicines agencies, with each applying their own seal of authenticity.



Physical address

Legitimate online pharmacies should be compelled to display prominently on their websites, a physical address for their establishment and provide the name of a dispensing chemist. These measures are only aimed at subjecting web-based pharmacies to the same rules that apply to those in the community.

Online review and regular audits

Patients should have the ability to report a potentially bogus site for independent review to a professional body, a regulatory authority or the European Commission. Authorities and professional bodies could take action to verify the website and either report for closure or contact to advise on how to improve consumer information.

It is also a matter of urgency that online pharmacies be prevented from dispensing prescription medicines without the actual presentation of a prescription. Patients should be made aware of the dangers of receiving such products, particularly where they are not accompanied by medical advice from the dispensing pharmacist.

Finally, it is imperative that online pharmacies are subjected to regular scrutiny in order to ensure their legitimacy. Quarterly internet audits should be conducted and the results of such reporting passed onto appropriate Member-State health authorities, thereby ensuring that the online environment is effectively monitored.



This could be accompanied by randomised inspections as a part of on-going regulatory follow-up.

However, these mechanisms will not operate effectively without information being adequately conveyed to consumers. Such actions could take the form of a concerted awareness campaign supported by local, high street pharmacies in countries where online pharmacies are legal. This could also be driven by competent authorities, as with the efforts undertaken by the UK's Medicines and Healthcare Products Regulatory Agency (MHRA) and Sweden's Läkemedelsverket. Those institutions that currently register online pharmacies, such as the GPhC in the UK and DIMDI in Germany could also promote awareness to consumers and highlight their own role in assuring a legitimate online trade in medicines. The input of pharmaceutical companies would also be welcome, such as the highly successful advertising campaign against counterfeit medicines run by Pfizer. However, the actual contribution of pharmaceutical companies may be dependent on restrictions in the legislation of the various Member States.

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Notes

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