Buying Medicinal Products

Over The Internet And Internet Pharmacies

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- 1. EU Legislation on internet pharmacies.

Article 85c(3) of Directive 2001/83/EC as amended provides that a common logo recognisable throughout the European Union should be established, which will enable the identification of the Member State where the person offering medicinal products for sale at a distance to the public by means of information society services, from now on referred to as internet pharmacies for short, is established.

Therefore the European Commission issued regulations on the design of a common logo to identify such internet pharmacies established in any EU member State. The verification of the authenticity of the common logo is done via a hyperlink between the logo on the internet pharmacy and the list of authorised or notified internet pharmacies found on the website of the regulatory competent authority in the member state where that internet pharmacy is established.

The EU legislation further obliges persons offering medicinal products for sale at a distance to the public by means of information society services (internet pharmacies) who are established in the EU to supply their customers with those products which are authorised in the member state of their client.

2. National legislation on internet pharmacies and on buying medicinal products over the internet.

The establishment of pharmacies is regulated by the Medicines Act, Chapter 458 of the Laws of Malta and Subsidiary Legislation 458.16 (Pharmacy Licence Regulations). This legislation caters for the establishment of physical community pharmacies but does not provide for the establishment of internet pharmacies. In fact there are no internet pharmacies established in Malta to-date.

Click here to access the Medicines Act and Subsidiary Legislation 458.16 (Pharmacy Licence Regulations).

However people in Malta can buy medicinal products from internet pharmacies as long as these medicinal products are strictly for personal use and are not passed on to other individuals. Prescription medicinal products should only be obtained upon the availability of a valid prescription. Internet pharmacies legislation may vary between member states within the EU as do the medicinal products classification with regards to the requirement of a prescription or not. If an internet pharmacy is established in the EU it is obliged to supply you with the medicinal products which is authorised in Malta (Click here for that Malta Medicines List) and dispense them against a prescription according to how they are classified in Malta i.e. whether they should be subject to a prescription or not locally.

However beware as buying medicinal products over the internet brings about with it an increased risk to one's health if the source from which one is sourcing his or her medicinal products is not regulated in the country where that internet pharmacy is established. Therefore if you are reading this, you are encouraged to continue to read the following information on this webpage, as the Medicines Authority believes it would equip you to

make better choices and decisions for yourself when it comes to buying medicinal products over the internet.

3. How would I know if an internet pharmacy established within the EU and in which I am interested to buy from, is genuine or not?

As from June 2015 all internet pharmacies established in any member states of the European Union should have the EU logo readily recognisable on each page of its webpage. The EU logo would have the same design, shape and size all throughout the EU with the national flag of the member state where that internet pharmacy is established inserted in the white rectangle in the middle (left side) of the EU common logo.

4. The EU Common Logo for Internet Pharmacies

The EU common logo should look like the following:



Currently in Malta there are no established internet pharmacies as the law does not provide for their establishment.

5. How can I use the EU Common Logo?

Upon clicking on the EU common logo you should be directed to the page of the website of the competent authority in that member state where the internet pharmacy which you are interested in is established. You should be taken to a specific page where the internet pharmacies which are allowed to operate in that member states are listed. In this way you would be able to know whether you are dealing with a genuine internet pharmacy established in the European Union or not.

6. What if there is something quite not right with a specific internet pharmacy?

Therefore if:

- the internet pharmacy you are interested in does not have this EU logo,
- or the EU logo shown on its website is not exactly as the one shown here,
- or if upon clicking it does not direct you to the webpage of the competent authority where that internet pharmacy is established,
- or if the name of that internet pharmacy is not listed on the webpage of that competent authority,

Then **do not** proceed to buy, as that would not be a regulated internet pharmacy and hence not a trusted and probably not a genuine internet pharmacy.

The above applies only to internet pharmacies established in the European Union.

7. Possible other indicators which would help me determine whether I am dealing with a probably genuine and legal internet pharmacy if not established in the European Union.

Apart from the above you should consider posing the below questions to yourself and think about the following remarks before proceeding further with your internet purchases, as these could help you identify whether you are probably dealing with a genuine source:

✓ Is the physical address concealed? If it is concealed the likelihood is that you are not dealing with a genuine internet pharmacy;

- ✓ Is the name and website of its regulator listed so that you can verify with the respective competent authority website whether the site is genuine or not?
- ✓ Consider buying only from countries which regulate internet pharmacies;
- ✓ Check the regulator's website of the internet pharmacy where it is established to check whether that internet pharmacy is notified or not;
- ✓ Does it supplies POMs without a prescription? If yes probably it is an unregulated pharmacy and certainly not a source to be trusted as it puts its sales above the health of its customers;
- ✓ Does it offer medicines at excessively cheap prices? Beware of internet pharmacies which offer their medicines at unreasonably low prices. Genuine medicines are subjected to high standards and requirements in order to assure their quality, safety and efficacy and therefore there is a limit of how much they can be offered at cheap prices;
- ✓ If in doubt, don't take chances with your health.

8. Risks related to medicinal products supplied illegally to the public by means of information society services (internet pharmacies).

Falsified medicines are medicines that are deliberately and fraudulently mislabelled with respect to their content or identity and/or source.

Use of falsified medicines can result in treatment failure or even death. Both branded and generic products are subject to falsification, sometimes also referred to as counterfeiting. All kinds of medicines have been falsified, from medicines for the treatment of life-threatening conditions to inexpensive generic versions of painkillers and antihistamines.

More people are turning to purchasing medicines over the internet with some even buying prescription only medicine without a prescription. WHO estimated that between 50-90% of all medicines sold on websites which conceal their address are fake – a gamble not worth taking.1, 2

So what are the real risks and facts when buying medicinal products over the internet from illegal or unregulated sources?

- It is a known fact that illegal or unregulated internet sources supply counterfeit medicinal products. Counterfeit medicines can contain harmful ingredients. In some cases found abroad counterfeit medicines contained harmful substances such as such as rat poison, boric acid and lead based road paints.
- They can also contain too little or too much active ingredient some contain no active ingredient at all.4
- Fake drugs can cause harm to patients and sometimes lead to death.

• It is often produced in unhygienic surroundings by people who have no appropriate qualificationss.

References

1.WHO and IMPACT factsheet. Counterfeit drugs kill! Last accessed on 13.10.09 from http://www.gphf.org/images/downloads/impactbrochure.pdf

2.In-PharmaTechnologist News. Last accessed 08.10.08 from http://www.in-pharmatechnologist.com/Industry-Drivers/The-globaldisaster-of-fakeinternet-pharmacies

3. Solomon, S. BC Woman killed by fake drugs bought online. National Review of Medicine. 2007;

- 4. http://www.who.int/medicines/services/counterfeit/impact/ImpactF S/en/index.html
- 5. European Alliance for Access to Safe#Medicines: The Counterfeiting Superhighway, 2008, Medicom.

In the UK, following a study carried out in March 2011, a report was launched that revealed the findings of a unique investigation into the danger to unsuspecting members of the public of bypassing the healthcare system and falling for email offers advertising Prescription Only Medicines.

The findings showed that SPAM emails promoting Prescription Only Medicines not only encourages a culture of self-diagnosis and self-medication for conditions that should be checked by a doctor, but also puts people's health and potentially lives at risk.

The investigation revealed a multitude of dangers:

Health – products containing banned, untested, or undeclared ingredients, products containing too much or too little active ingredient, with no information supplied on dosage or side effects, together with allowing Prescription Only Medicines to be sold without a proper consultation or prescription provided.

Financial — potential for credit card cloning and other fraudulent activities, as well as products being sold at a much higher price than they would cost from a high street pharmacy.

Personal – viruses were contracted from spam emails and the website they advertised, infecting PCs in an attempt to copy contact details for further 'spamming'.

9. The Medicines Authority initiative on information regarding internet pharmacies and buying over the internet.

The Medicines Authority has been actively involving itself in disseminating information on internet pharmacies and safe buying of medicine over the internet. Apart from involving itself in diverse programmes over the local media, the Medicines Authority launched two campaigns which part of these campaigns were addressed and provided information on internet pharmacies and buying of medicinal products over the internet. The following is a link to the material used and disseminated in these campaigns:

http://www.medicinesauthority.gov.mt/informationleafletsmedicines?l=1

10. The European Medicines Agency and Internet Pharmacies

The European Medicines Agency (EMA) have set up a website providing information on the EU Common Logo to be used by internet pharmacies established in the EU and with background information on the risks related to medicinal products supplied illegally to the public by internet pharmacies. The webpage also provides information on the European Union legislation applicable to falsified medicinal products as well as hyperlinks to the EU Member States' websites pages where internet pharmacies established in their respective territory are listed.

This webpage of the European Medicines Agency can be accessed through the following hyperlink:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_con_tent_000186.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac058002d4e8

The EU Commission has also a webpage dedicated to the 'EU Logo for online sale of medicines', which can be accessed through this link:

http://ec.europa.eu/health/human-use/eu-logo/index en.htm

11. Some information / educational videos on internet pharmacies

The following hyperlinks connect to some interesting educational videos on the risks associated with buying medicines over the internet from illegal sources or un-trusted sources:

http://www.pfizerlife.co.uk/live-well/health-news/real-danger/

http://www.safemedsonline.org/protecting-consumers/education-campaign/

http://www.safemedsonline.org/2012/12/csip-announces-winners-of-tongal-psa-video-contest/

Other similar videos can be found through the following link:

http://safeonlinerx.com/public-awareness/

12. Internet Pharmacies established in Malta



Currently there is no person offering medicinal products for sale at a distance to the public by means of information society services (internet pharmacies) established in Malta.