



Response from Celesio Pharmacies.

Public Consultation in preparation of a legal proposal to combat counterfeit medicines for human use

Key ideas for better protection of patients against the risk of counterfeit medicines.

INTRODUCTION

Celesio Pharmacies today operates 2273 pharmacies in 7 EU countries and is a division of the Celesio healthcare Group which is represented in 16 European countries. Its three divisions, Celesio Wholesale, Celesio Pharmacies and Celesio Solutions cover the entire spectrum of pharmaceutical distribution and pharmaceutical-related services. Celesio pharmacies division now incorporates Europe's largest legitimate mail order pharmacy, Doc Morris.

Celesio's pharmacies serve more than 500,000 customers daily, and these pharmacies dispense over 11.5 million prescriptions each month in 7 EU member states

Across the EU Celesio pharmacies employs over 22,000 staff, of which over 4000 are professional pharmacists, and due to its geographic spread, it has accumulated a wealth of market knowledge and expertise.

Celesio Pharmacies strive to deliver quality healthcare to its customers on a daily basis. We firmly believe that Pharmacy is a much under-utilised part of the primary care network. Celesio remains a willing participant in any future primary healthcare strategies which aims to improve the health of EU citizens.

Celesio pharmacies division welcomes the opportunity to respond to this current consultation combating counterfeit medicines.

Summary

Celesio Pharmacies division acknowledges the Commission's efforts to combat counterfeit medicines. As supply chain integrity is a complex issue, Celesio Pharmacies shares the Commission's view that a range of measures are necessary to deal effectively with this problem. These will include regulatory, legal (including punitive measures), and process driven solutions.

In this submission Celesio pharmacies division will concentrate specifically on the issues of community pharmacy practice and related pharmaceutical activities, and how this trading environment can provide solutions to the counterfeit problem.

Scope and Proportionality

Celesio Pharmacies Division as a leading community pharmacy retailer is pleased to play its part in an effective public-private partnership with national governments, who together deliver an efficient and successful public private pharmaceutical service to EU consumers.

Our pharmacies form a part of the extensive network of approx 125,000 pharmacies across the EU. We have estimated that these 125,000 EU pharmacies dispense approximately 25 billion pharmaceutical products each year. It is true to say that one counterfeit is too many, however, reported counterfeits in the legitimate supply chain account for an infinitesimally minute proportion (yet significant) of the actual number of products dispensed.

Community Pharmacy's role

Preliminary EU discussions around anti-counterfeiting activity should in the first instance give due regard to how an effective system can be delivered, given the diverse nature of EU member state health care markets. One must also take account of the fact that the Commission can only effectively deal with the legitimate supply chain, and efforts to deal with illegitimate internet pharmacy originating from outside the EU, will require some imaginative and innovative measures. These measures do not currently exist.

Community pharmacies have a direct interface with the end user of pharmaceuticals and are, by default, the last step in the legitimate supply chain. This is highly relevant because it is the final opportunity to check that the product is legitimate. Registered community pharmacies in each member state are part of a regulated profession and subject to strict regulation.

Celesio pharmacies takes note of the original Commission consultation document dated 11.3.08 and would immediately point out that the document does not feature community pharmacy to any great extent. The proposal document concentrates heavily on other players in the supply chain. It is right that the majority of emphasis should reside with manufacturers. We would also argue that to create an effective solution, the Commission must consider all steps and suppliers in the supply chain including the impact on, and the possible involvement of, community pharmacy

Celesio pharmacies can speak with some authority on counterfeiting in the legitimate supply chain. We, through our colleagues in Celesio Wholesale division are part of the WHO IMPACT WG, representing GIRP, The Association of full line European wholesalers. In addition, we are close to completing a

process of implementing an extensive anti-counterfeit programme across all of our divisions.

Focus on health and consumers

Although awareness already exists within the EU Commission, Celesio pharmacies division wishes to highlight to the Commission that some players may wish to use the issue of counterfeits in the supply chain as a vehicle to achieve other economic aims. In response to this, the Commission must keep the issues of patient safety and the best interests of the EU consumers as its main priority.

For the Commission to successfully achieve its aims any new measures must be proportionate, effective and not add additional burden or have unnecessary impact on interrelated business activities.

Special nature of medicines

Celesio acknowledges that there are economic as well as health issues at stake when dealing with counterfeit medicines; however Celesio Pharmacies insists that all players, including governments and industry, must take account of the “special nature of medicines” in relation to counterfeits. Direct comparisons with other commodities are not useful. This difference is particularly important when considering effective anti-counterfeit medicines legislation.

Unlike other counterfeit commodities - Counterfeit medicines can potentially kill. Therefore the legal consequences for those found guilty of committing pharmaceutical counterfeiting crimes, should we suggest, better reflect the serious nature of their crime by imposing harsher penalties. Similarly, suitable fines should be high enough so as to act as a real deterrent.

EU import and export controls contain a loophole in that no license is required for importation intended for use outside of the EU. This is now recognised but what about stricter penalties for diversion and similar activities?

In addition, medicines and pharmaceuticals are an important part of people lives. Once again, Celesio Pharmacies would remind all industry players to be cautious, and not to over estimate the dangers: which could affect the general public's overall confidence in medicines.

Celesio pharmacies position can be summarized thus:

- No one method alone will protect the public from counterfeits. To effectively deal with a multi step supply chain one must employ a range of measures at different levels within the supply chain.
- No counterfeit medicines have to-date been reported in the legitimate EU Mail Order pharmacy business, i.e. mail order by licensed pharmacies.
- It will not be possible to protect the public from medicines which are available from *illegitimate* suppliers on the internet. In this instance we can only create awareness of the dangers of medicines from *illegitimate* internet pharmacy.
- A set of clear definitions is required for terms like: legitimate and illegitimate supply chain; internet pharmacy, legitimate mail order¹. These terms are being used by some industry players to create unnecessary confusion among the public, and we recommend that full and justifiable recognition is now necessary for the established and highly valued part of the legitimate pharmaceutical supply chain.

¹ See suggested definitions in appendix.

- Once these definitions are prepared and accepted by all players more effective legislative measures will become possible.
- Protection from counterfeits in the legitimate supply chain is only possible by ensuring that a range of measures are put in place to protect the integrity of the **legitimate** supply chain.
- Many supply chain industries, e.g. automotive, airline, and foodstuff have all developed systems to ensure the integrity of their supply chains. These methods include processes such as mass serialisation, track and trace, RFID and many more. In many cases these initiatives are seen as an integral part of branding by manufacturers. The necessary technologies already exist. What is now required is the political will to make the necessary changes.
- Celesio pharmacies consider that a key point in the supply chain which can guarantee effectiveness is an authentication step just before the customer receives their medicines from a pharmacist. Intervention at this step also safeguards against any breakdown earlier in the supply chain. This method is also independent of how many steps exist in the supply legitimate chain.
- Mass serialisation should be considered as a key protective measure. This will allow one stage authentication in pharmacies. This should be part of new product licensing requirements (EMA or National Medicines Boards) thereby compelling the pharma industry to include a unique identifier on each pack. Initially this should involve only those products which are of known high-risk of counterfeiting. This system would be acceptable to Celesio pharmacies if agreement can be reached on the use and control of data generated by such a process, and provided that the introduction of such a system is resource neutral.

- End user product authentication models, such as that proposed by Aegate, and a similar project currently at pre-pilot stage being conducted by EFPIA, should be considered as possible tools to protect the consumer against counterfeit medicines, but only as part of a broader process.
- Product Integrity, security tags, etc are all good ideas but the introduction of such changes will have knock-on effects. For this reason we suggest that a comprehensive impact assessment is carried out before any changes are imposed.
- Whilst original pack dispensing (OPD) is common place in some EU member states, countries like the UK and Ireland still open packs and cut tablets so as to exactly meet prescriber needs. In these countries no common agreement exists on a monthly pack – both 28 and 30 pack sizes exist.
- We would argue that the costs to the Pharma industry of implementing such a system should be measured against the savings in terms of effective batch recalls, reduced morbidity, and brand integrity. In this context funding for this activity by the industry should be part of annual brand building budgets.
- A central EU database of wholesalers and strict control of API manufacturers under GMP must be considered as key process.
- The commission should in addition consider the introduction of an anti-counterfeit directive which would include steps to create severe punitive measures (the severity of which should be far in excess of existing low level fines etc) for breeches of counterfeit regulations.
- In regard to mail order it is very important to clearly distinguish between legitimate mail order and illegitimate internet pharmacies (please refer also to the definitions in the appendix). While legitimate mail order is offered and rendered by registered pharmacies with a licensed presence in the member states, internet pharmacies are unregulated businesses

which can have their presence anywhere. Unlike registered pharmacies with (pure) internet pharmacies nobody can be held directly responsible and there is no control by professional authorities or any other official body, nor are they subject to specific laws and regulations.

In conclusion, it is right to create proportionate awareness of this key issue and to implement measured regulatory reform. One must seek to clarify the important difference between the legitimate supply chain and other supply channels e.g. illegitimate internet supply.

However, one must then balance this legitimate need to “create awareness” against the potential harm that could be done to the public's confidence in their medicines.

Any major changes to this finely balanced supply chain, e.g. regulatory or the introduction of IT processes should be preceded by an impact assessment study to establish effectiveness, and any peripheral implications that might arise.

There is much groundwork to be done and agreement to be reached before the Commission can effectively deal with the area of anti-counterfeiting. Celesio Pharmacies believes that real and effective opportunities exist, which, if tested, supported and developed by all players, could bring about real benefits for all EU citizens.

Appendix

Definitions

Legitimate Mail-Order / Internet Pharmacies: Difference between mail-order and internet pharmacies.

Legitimate mail order pharmacy is a commercial activity carried out in accordance with member state rules. These rules legally ensure that the highest probity is guaranteed, and customer health is treated with the same respect as it is in a traditional pharmacy.

Legitimate mail order pharmacies are registered pharmacies with an online presence. As they must employ registered pharmacists, who are legally obliged to care for their customers and patients, their primary focus is always the welfare of the patient.

Legitimate Mail order pharmacies – such as Doc Morris use and develop market leading IT and have successfully put in place patient safety standards based on best practice. Many of these high quality patient management systems are still not available in traditional pharmacies.

Legitimate mail order pharmacies require the customer to supply a legal prescription in order to get their Rx (Prescription drugs) medicines.

Illegitimate internet pharmacies have no regard for patient health and they operate outside the law, and as such are criminal activities.

Illegitimate internet pharmacies are not subject to any kind of regulation or control, and most notably have no link to a registered

pharmacy. No presence and supervision of a pharmacist is required. Therefore these internet “pharmacies” are not pharmacies at all, and the use of the term pharmacy is misleading, and should be questioned. This form of dangerous trade is not effectively legislated against in member states, and is notoriously difficult to police. People will continue to use the internet to purchase medicines which they could not normally receive with consulting a doctor and receiving a prescription.

Illegitimate internet pharmacies are a major source of counterfeit medicines because it is totally unregulated.

Possible definitions of legitimate mail order pharmacy;

1. **Legitimate Mail order of Prescription medicines** can be defined as the delivery of prescription medicines on foot of a valid and legal prescription from a registered pharmacy* to the end customer using an existing postal service, or via a third party logistic company, to the individual customers delivery address notified to the dispensing pharmacy.

The delivery of pharmaceuticals to remote, (non customer) or a commercial pick up point, which does not hold a pharmacy license, under this definition is not mail order.

Mail order trading is the dispensing of pharmaceuticals via mail order.

2. **Legitimate Mail order of OTC (non prescription medicines)**

products can be defined as the sale and delivery of OTC (non prescription medicines) pharmaceuticals from a registered pharmacy* to end customers; using an existing postal service or via a third party transportation company, to the individual delivery address notified to the pharmacy.

The delivery of pharmaceuticals to remote, (non customer) or a commercial pick up point, which does not hold a pharmacy license, under this definition is not mail order.

Mail order trading is the dispensing of pharmaceuticals via mail order.

*Registered Pharmacy. A building or premises licensed by a national pharmaceutical society or pharmaceutical chamber. The license permits the legal holding and dispensing of pharmaceutical products under the supervision of a qualified pharmacist,

[The definition of a registered pharmacy may change depending on member state]

END.