

Dealing with the EU counterfeit threat

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Medicines counterfeiting is a global threat to public health. This is most obvious in sub-Saharan Africa and Asia; Europe, by contrast, is relatively secure. EU citizens can normally be confident that medicines supplied by pharmacists will be safe and effective. As yet there have been no recorded deaths resulting from medicines counterfeiting in the EU, albeit that if these were to occur they may be difficult to identify.

However, there is an undeniable danger from medicines counterfeiting in Western Europe. Information from the Medicines and Healthcare products Regulatory Agency, for example, shows that presently there are some 20 individuals being prosecuted for counterfeiting-related offences in the UK alone. The agency is currently investigating a further 25 cases, three of which involve counterfeits that have entered the legal supply chain.

Our relative security does not mean that current patterns of medicines discounting, trading and supply in the EU cannot or should not be reformed. The School of Pharmacy's new report "Trick or treat?", published earlier this week, explores the extent to which medicines counterfeiting is a threat to public interests. In the wider context of European pharmaceutical sector policy as a whole it also outlines a range of political, economic, regulatory and commercial responses that may be needed to promote better health and better pharmaceutical care in the decade ahead.

Criminal sanctions

One way to contain any criminal activity is to increase the sanctions for those who are caught. The World Health Organization (which is in the process of establishing the International Medicines Products Anti-Counterfeiting Taskforce) has recommended strengthening the law, so that any person or company found making, purchasing or supplying counterfeit medicines can be made to pay a higher penalty.

We support such action. However, alone it is unlikely to address the root causes of what appears to be a growing hazard in Europe. And simply policing the situation more firmly will not enable European society to find ways forward in relation to broader questions, eg. appropriately supporting public engagement and choice in relation to health and medicines use, facilitating the ongoing discovery of new medicines, and creating a knowledge-based economy able to compete with the US, China and India as this century progresses. We argue the medicines counterfeiting hazard is linked to all these areas. An effective precautionary approach will require extensive European reforms.

For example, the parallel importing of medicines across the EU's internal borders is not a criminal enterprise. To the extent that it

exploits patented medicine price differences imposed by different member states to gain savings it is seen by some commentators as ethically and economically desirable. But our analysis questions this view: it suggests that dependence on parallel trading and related practices is creating an undesirable culture in much of European pharmacy, while also weakening the overall European economy.

This is partly because at the margins of the complicated medicines trading system which has grown up in Europe in the past 40 years (and most notably in circumstances where relatively small scale operators act as both parallel traders and secondary wholesalers) there are opportunities for both error and on occasions the deliberate insertion of fake products into the legitimate supply chain. It is also because evidence available from independent studies funded by agencies such as the UK Economic and Social Research Council shows that the overall impact of pharmaceutical parallel trading on the UK economy (and the UK is by far Europe's largest user of PI medicines) is in fact negative. The total cost of the trade outweighs the savings it may make for the NHS and other benefits generated. This is no foundation for pharmacy to build its future upon.

We do not in "Trick or treat?" explore the controversy that has surrounded Pfizer's recent attempts to increase its control over the distribution of its medicines in the UK, through seeking to use a wholesaler as its distribution agent and establishing more direct relationships with its pharmacy customers. But it is relevant to note that if the professional focus of pharmacy is to move more towards improving clinical outcomes (in addition to supplying medicines efficiently) such developments could in time prove beneficial for pharmacy as well as the public.

If a culture has been created that legitimises spending excessive amounts of professional time and effort on activities such as buying drugs as cheaply as possible from (in effect) any supplier, then patient services are likely to suffer. Despite recent developments in the UK in the context of generic medicines supply, Europe as a whole should seek to increase further the integrity and transparency of its medicines supply chain.

This ought logically to be with a view not only to further insuring against the dangers of counterfeit medicines being given to patients, but also to protecting public interests in maintaining a strong, research-based industry alongside appropriately funded pharmacy services. Without a viable knowledge-based economy, with robust intellectual property laws and a respect for innovators' rights to profit exclusively from their products, neither Europe's economy nor its health care systems will in future be able to prosper.

Pharmacy opportunities for service improvement are also being created and threatened by the expansion of internet use. It is, of course, desirable that more people are seeking information about their health and health care options, and are more prepared than in the past to question professional judgements and seek alternative advice. But where enhanced autonomy leads to self purchase of potentially toxic and on sometimes fake medicines, increased risks must also be recognised and managed.

One important reason for Europe's past pharmaceutical security has been that the citizen's of countries such as the UK have had comprehensive access to treatments. Unlike many relatively poor Americans they have not had to pay for medicines out of their own pockets. But as Europe expands eastwards and its social environment becomes in some ways harsher this situation may be changing. For instance, Karol Sikora has recently speculated (*The Observer*, November 5) that British cancer patients, because of judgements by the National Institute for Health and Clinical Excellence and other NHS restraints, are turning to the internet to purchase medicines they believe may benefit them. If trends like this are real and sustained the risks of harm from both fake and genuine medicines will inevitably rise.

Towards solutions

Better regulation, shortened and more direct medicines supply lines and enhanced public information about, trust in and use of pharmacists and the research pharmaceutical companies that create new treatments are all part of the possible solution to the problems. Europe to date has not been a leader in seeking to adapt its regulatory environment to meet the 21st century public's requirements for safe, convenient and innovative medicines and information supply. But it is to be hoped that constructive partnerships between pharmacists, pharmaceutical producers and other stakeholders in medicines supply and use will in time lead to a better understanding of the relationships between problems (such as medicines counterfeiting), challenges (such as adequate funding for European medicines research) and fundamental goals (such as assuring better global public health).

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