

Parallel trade is an unacceptable risk to patient safety

The recent class 1 recalls of counterfeit medicines from the Medicines and Healthcare Products Regulatory Agency have worrying implications for all of us, as Jim Thomson explains

It gives those few people who campaign for safe medicines for patients no comfort to be proved right. For some time now I have been vocal about the patient safety risks of parallel trade in medicines. In return, I have faced the threat of being sued for suggesting that there might be a link between parallel trade and counterfeit medicines entering the legitimate supply chain. Now, however, we are seeing an extremely dangerous chain of events unfolding...



Last year, the World Health Organization (WHO), which had previously estimated the presence of counterfeits in the developed world at 10%, downgraded that estimate to 1%.¹

To put the revised estimate into perspective, it came hot on the heels of several evidence-based statements issued from other independent, international organisations — like the World Customs Organisation (including that by Kunio Mikuriya, Deputy Head of the World Customs Organisation, at the Organisation for Economic Co-operation and Development in Paris, in 2005)² and the EC, warning of a dramatic increase in counterfeiting. The reality is that seizures of counterfeit medicines at EU borders increased by 384% year on year between 2005 to 2006.³

So, at face value, the WHO statement would seem to imply that the counterfeiters have unilaterally decided to ignore the most profitable markets in favour of the less developed world. This is stretching credibility to the point that one could play a tune on it. I am sure that I was not alone as I watched and waited for counterfeiters to begin turning up with increasing regularity. It wasn't a long wait.

In May and June we saw the Medicines and Healthcare products Regulatory Agency (MHRA) issue four Class 1 recalls of counterfeit medicines.⁴ Some batches had, it seems, reached patients. According to the senior MHRA person who rang me to ask me to help inform patients of the risks, all counterfeiters had entered the legitimate supply chain via 'parallel

distribution' — a term that was new to me. Apparently, it isn't the same thing as parallel trade, although I am at a loss to see any discernable difference. So, for the sake of clarity in my arguments here I shall make *no* distinction between parallel distribution and parallel trade.

I fully expected the MHRA to take a proactive stance and call for the immediate suspension of parallel trade in medicines. I fully expected the European trade group of the parallel traders (EAEPCC) to do likewise. However, bearing in mind that the latter spent the last year claiming that parallel traders ADD a layer of security to the supply chain, perhaps I was being a little optimistic.

The Head of the Intelligence Unit and Head of the Enforcement Group at the MHRA reported last year that there is 'no evidence' to show that parallel trade has been the route for introducing counterfeit medicines into the legitimate UK supply chain.⁵ This is palpable nonsense. In the last ten years counterfeiters have entered the legitimate supply chain on 10 occasions, and now, in four of those cases — 40% of all the occasions — they entered via parallel importation.⁴ I have vociferously warned that parallel trade in pharmaceuticals was effectively an open invitation to counterfeiters to try their hand in the UK. Perhaps the MHRA might now care to revise its opinion?

Unsurprisingly, the EAEPCC agree with the MHRA. In an editorial in the May issue of *In-pharmatechnologist.com* featuring an interview with Heinz Kobelt, the secretary general of the EAEPCC, he is reported as

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comparing the argument in favour of ending parallel trade, with one in favour of banning cars — on the basis that they both cause accidents.⁶ Of course, it is perfectly true that the incidence of car accidents doesn't lead to prohibiting cars. However, to qualify to drive a car, one has to pass a rather more stringent test than is the case when one obtains a parallel trade licence. In addition, statistically, if one causes a road traffic accident, one stands a much better chance of losing one's licence and going to jail, than one does if caught with counterfeit medicines.

In any event, both the MHRA and EAEPCC have completely missed the point. The issue here is not about statistics, nor is it about a trade group — even one with what the MHRA might call 'single sector gains' — 'defending the business interests of its members.'⁵ The issue here is patient safety. The MHRA is responsible for ensuring the safety of the medicines supply chain and, clearly, it can't do that job under the present circumstances. Forty per cent of the counterfeit incidents in the last ten years have been as a result of parallel imports.⁴ Therefore, as the national regulator, it has a duty to put in place a

regulatory framework that it CAN effectively regulate. That is its job.

At the end of May, the UK regulator would have found itself increasingly isolated in its position on parallel trade. In a cathartic two weeks for the UK medicines distribution system, we saw four separate class 1 recalls, with medicines reaching patients and therefore putting them in clear danger. Indeed, who can now predict what the coming days and weeks will bring — both at home and in Europe?

What is crystal clear is that the MHRA must take immediate action to rationalise the supply chain to the point that it is safe — in short, it must do its job. Sadly, it is much more likely that it, and the likes of the EAEPCC, will continue to defend a shoddily regulated trading practice, which is rapidly becoming indefensible on any basis. I don't much care for statistics. I am a patient. We are all patients — including those people with mental health problems

who, in May, could have received fake Zyprexa ... those stroke and serious cardiovascular patients who could have received fake Plavix ... and those cancer patients who could have received fake Casodex. Here is a message to the MHRA. All of these people depend on you to protect them from counterfeit medicines. It is time for action, not smoke and mirrors.

I happened to be in Rome when these counterfeits began surfacing. Indeed, as I was reading the statements of the MHRA and EAEPCC, I heard a siren outside my hotel and went over to the window to check that the place wasn't burning down. I needn't have bothered. Clearly, Nero was fully occupied elsewhere. ❀

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References

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