European Alliance for
Access to Safe Medicines

How effective

is the Medicines and Healthcare products Regulatory Agency in protecting patients?

The Medicines and Healthcare products Regulatory Agency (MHRA) is the government agency responsible for ensuring that medicines and medical devices are safe for UK patients to use. It is responsible (and accountable) for taking the necessary action to protect the public from counterfeit and substandard medicines. However, with a dramatic increase in the number of counterfeit medicines being seized by customs authorities across Europe (2.7 million pharmaceutical items seized in 2006 compared to 500,000 items in 2005[1]), I ask: are patients in the UK safe?

The recent BBC radio "Crossing Continents – Crossing Europe" documentary on pharmaceutical parallel trade was remarkable for two main reasons. The most striking and obvious was the difference – plainly evident even on radio – between the atmosphere inside a parallel trade facility, and that inside a pharmaceutical industry facility. The latter was silent, secure, it even sounded sterile. The former resembled a Kasbah. Instructions were shouted, a whole range of medicines (we were told) was stacked on shelves around various rooms, batches of medicines were being opened and re-packaged in a variety of locations but, we were assured, "the boys in Goods-in" were on top of things. It is hard to imagine that this is the picture that springs to mind when patients think about how life-saving medicines reach them.

The second reason that the radio programme was remarkable was for the way in which the MHRA, not only spurned the opportunity to call for a tightening of the rules on parallel trade, but appeared to mislead the listener. The MHRA claimed that there had only been one instance of counterfeit medicines coming into the UK via parallel trade, since 2004. The agency is able to say this because the MHRA makes a distinction between "parallel trade" and "parallel distribution". Apparently, parallel trade involves a licence issued by the MHRA, while with parallel distribution the licence is issued by the European Agency for the Evaluation of Medicinal Products (the European equivalent to the MHRA). Well, I might be incredibly naïve, but I fail to see the distinction. In both cases the medicines are shipped throughout the EU, passing though up to 25 sets of hands until, re-packaged, they are dispensed to UK patients. The risks are the same, the process is the same and, to my mind (and, I'd wager, that of any reasonable observer) these virtually identical methods of procuring NHS medicines are one and the same thing.

In May and June this year, the MHRA issued no less than four Class 1 Recalls of prescription medicines[2]. These potentially life saving medicines had been 'parallel distributed' – and were for the treatment of prostate cancer, schizophrenia and bipolar disorder, stroke and serious cardiac illness. Some of the medicines contained sub-optimal levels of the active pharmaceutical ingredient – the bit that benefits the patient. It is unlikely that any patient, who had received these fake medicines, would have cared about the distinction between parallel trade and parallel distribution. However, I am sure

that every patient cares that their medicines are safe and work as prescribed. Legally, it is the job of the MHRA to guarantee that the patients receive safe and effective medicines. However, disguising four life threatening instances of counterfeit medicines reaching patients in the UK through parallel trade behind arbitrary distinctions is not part of its remit – patient safety is not arbitrary, it is absolute.

As if the MHRA's attempts to mislead the public over parallel trade weren't bad enough, the BBC audience was then told of the tiny number of counterfeit incidents found relative to the vast number of prescriptions written annually in the UK – the theory here is that the MHRA is on top of this issue. Let's examine that theory.

In the ten years leading up to 2005 the MHRA, by its own admission, randomly-sampled between 2,000 and 2,500 packs of medicine per year, giving them the benefit of the doubt this is roughly 25,000 packs of medicine over ten years[3]. Taking the NHS information centre's figure for total NHS prescriptions between 1995 to 2005 (7 billion)[4], this would mean that the Agency sampled 0.000357% (or 1 pack out of every 280,000) of the supply. Were I responsible for guaranteeing the authenticity of footballs or umbrellas – let alone medicines – I think I would endeavour to inspect rather more than 0.000357% of the sample.

When the MHRA claims that the UK doesn't have a problem because there are over 700 million prescriptions written per annum[4] and only 9 instances of counterfeiting have come to light since 2004, it deliberately misleads the patients that it is paid to protect. If it is assumed that the 9 instances of counterfeit medicines were discovered from the 7,500 random samples tested (and therefore not by any other means – such as patient vigilance, industry investigations, etc.) then how many counterfeits would have been found if the MHRA had tested every one of the 2.1 billion prescriptions written since 2004. My guess is more than 9, about 2.5 million more based on the numbers above.

The reality is that the MHRA doesn't find fake medicines among those 700 million packs (per annum) because it doesn't look. How could it? The supply equates to around 2 million packs per day – it is an impossible task. Therefore, what the agency SHOULD do is support moves to shrink the distribution chain to the point that it can fulfil its statutory duty to protect patients. What it SHOULD be saying, is that parallel trade (or distribution) is unsafe – and call for an immediate end to it. Instead, we are assured (using a host of smoke and mirrors tactics) that we are safe.

Well here's a final, sobering, thought. The World Health Organization (WHO) recently downgraded its estimate for the presence of counterfeit medicines in the developed world – from ten per cent to one per cent, which sounds reassuring. However, if the WHO is to be believed (and it is not known for overstating the case) that would mean that, last year alone, over seven million UK prescriptions were filled with fake medicines – 4.5 million more than the estimate above. Based on the WHO's estimate one in eight UK patients has received a medicine that wasn't what it claimed to be. As a patient, I would be very interested to know why the MHRA feels that it is acceptable to defend a trade that presents an opportunity for one in eight UK patients – the same patients who pay its wages – to be put at risk. It is unacceptable, and it is a public disservice.

REFERENCES

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2 MHRA, How we are tackling counterfeit medicines and devices, Drug Alerts issued relating to counterfeit medicines. Available at: http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&useSecondary=true&ssDocName=CON019608 (Date accessed: 12/08/07)

3 MHRA, Medicines testing. Available at: http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=142 (Date accessed: 12/08/07)

4 The NHS information centre, Prescriptions Dispensed in the Community 1996-2006. Available at: http://www.ic.nhs.uk/statistics-and-data-collections/primary-care/prescriptions/prescriptions-dispensed-in-the-community-1996-2006-%5Bns%5D (Date accessed: 12/08/07)