JIM THOMSON

Defending the patient

The EAASM has courted controversy with proposals to protect consumers from counterfeits

It was back in 2007 that a group of concerned stakeholders first discussed the notion of establishing an intersectoral voice to promote patient safety against the seemingly relentless advances of medicine counterfeiting.

The pharma industry, law enforcement and regulatory bodies had achieved some success, but patient groups had been woefully under-represented. We didn't really know what we needed to do, but we did know that we were sick and tired of talking about the problem and were ready to tackle it head on.

From those initial discussions grew first an idea and then an organisation. The idea was that only an intersectoral approach could match medicine counterfeiters blow for blow. It seemed a straightforward objective but, within a year of its launch, the European Alliance for Access to Safe Medicines (EAASM) had disturbed a hornet's nest and we found ourselves involved in a spat with the group representing parallel trade in Europe.

The EAASM's initial 24 months were very active and demanding. It seems a long time ago that we commissioned Dr Jonathan Harper – a former NHS doctor, European policy adviser and senior fellow of the Center for Medicines in the Public Interest – to evaluate the European supply chain and look at security breaches by counterfeit medicines. Some months later, a 104-page report entitled *European Patient Safety and Parallel Pharmaceutical Trade – a potential public health disaster?* (better known in some quarters as "that bloody Harper Report") dropped like a cartoon bomb, fuse-burning, onto the desks of European legislators.

When Mairead McGuinness MEP asked the then EC vice-president Günter Verheugen what action he proposed, and he revealed intentions to introduce legislation to control parallel trade, the bomb exploded.

The European elections came at a good time for those who would like to see the anti-counterfeiting element of the European pharmaceutical package diluted. However, those who advocate new legislation to protect Europe's patients also used this time to good effect.

Illustration by David Jukes

The EAASM has been particularly active this summer: we held talks with stakeholders to help us develop a set of recommendations for the new European Parliament. The aim is to assist legislators towards a package that protects patients, first and foremost.

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PHARMA RE-PACKAGED

The strongest measure in the original European pharmaceutical proposals was a proposed ban on repackaging. The EAASM had identified this previously as critical to patient safety in the Harper Report and in subsequent submissions to DG Enterprise & Industry. Eventually, the proposed ban was axed from the package to ease its progress through the European Parliament, but we still believe that a ban on medicines repackaging is the only wholly secure means of eliminating opportunities for counterfeit medicines to enter Europe's regulated supply chain.

In the absence of such a ban, however, the EAASM asserts that alternative measures are vital for patient safety:

1. **Tamper-evident packaging**
   Only by having this in place will all parties know whether a product has been opened and/or repackaged prior to their receiving it. Currently, patients are uninformed about the journey of any particular medicine. A key element in the much-used term 'patient empowerment' should be the right to know whether a medicine has been repackaged and to choose whether or not to accept it.

2. **True equivalence.** Where a security feature is removed or compromised by a repackager, it must be incumbent upon that same actor to replace it with a truly equivalent feature. The EAASM's recommendations to European Parliament will include a comprehensive definition of security and safety 'equivalence'.

3. **Risk assessment**
   It is not feasible to rank medicines according to their risk from counterfeiting. Criminals will fake medicine even if the profit margin is slight. If legislators introduce risk assessment, counterfeiters will simply leave high-risk targets and focus on less obvious medicines, including generics. It is essential that all medicines be considered at risk and that a minimum level of anti-counterfeiting measures be introduced across the board.

4. **The internet**
   Before the European Parliament reformed in September, the previous Pharmaceutical Rapporteur, Adamos Adamou, introduced specific measures in his proposed amendments to counter online drug sellers. The EAASM has highlighted the significant risk to patient safety of unregulated internet pharmacies in our report *Counterfeiting Superhighway*. However, to include the internet in the pharmaceutical package could slow, or even stall, its progress. Therefore specific legislation must be developed to deal with the online environment.

5. **Time**
   Patients are receiving fake medicines that cause harm or even death. The European legislative process is famously slow. Once we know the proposed time-frame for implementing the package, we will, where necessary, press hard for interim measures to protect patients.

> "Specific legislation must be developed to deal with the online environment"

These recommendations arose through a consultative process among the EAASM board. The alliance continues to expand – at present comprising 14 European patient associations, nine pharmaceutical companies and two technology/security members.

PROMOTING AWARENESS

Through targeted communications and persistence, the EAASM has become instrumental in the emergence of counterfeit medicines legislation from Europe and is committed to publicising the dangers of substandard medicines. We have been working closely with producers for the BBC on two programmes about fake medicines. The first will be screened by the BBC's daytime arm as part of an upcoming 'Fake Britain' series, while the second will be shown globally in early 2010 on BBC World's 'Kill or Cure'.

To learn more about the parliamentary recommendations or media activities, please see our website – which is now available in five European languages. If your organisation is not a member, then please consider joining our expanding group and consider signing our 'Pledge for patient safety'.

The Author

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