EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL
Consumer goods
Pharmaceuticals

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

Aegate Response

Introduction

Aegate provides a unique patient safety network that opens a direct, IT enabled communications channel between pharmacies and pharmaceutical companies. The channel attacks counterfeits by allowing for the verification of the authenticity of the package at the time it is dispensed, and communicates other important real time information (expiry, recalls safety) at the same time.

Good real-time communication between the pharmaceutical company and the pharmacist is becoming essential to ensure patient safety. Aegate provides a patient safety communications service which verifies the identity and authenticity of each individual medicine whilst it is being dispensed by the pharmacist, and passes on any pertinent safety or regulatory information before the medicine is handed over to the patient.

This prevents substandard medicines from being delivered to patients, such as out-of-date, discontinued, recalled, counterfeit or stolen medicines. The rapid speed of information delivered by Aegate (significantly less than one second after scanning) improves existing product recall methods and ensures that professional pharmacists maintain their role at the centre of patient care.

The Aegate services are currently in operation in Belgium, Greece and Italy, with plans in place for further growth across Europe in 2008.

Aegate has been trading since 2003 and is backed by PA Consulting Group, A major worldwide Technology and Consulting firm.

We agree with the DG Enterprise and Industry analysis that the concerns around counterfeit medicines represent a clear and growing risk to public health. As Dr

Jonathan Harper recommended in the Council of Europe Counterfeit Medicines Survey Report [1] 'Now is the time to "get real" with counterfeit medicines in Europe'

Aegate supports the Commission in bringing forward legislation that will protect European patients now and into the future. Aegate believes that this presents an opportunity for the Commission to take a Global lead in implementing a pathway of standardised solutions that will improve patient safety extending beyond European boundaries.

Aegate has the following specific comments to make in response to the consultation document.

4.1 Tightening requirements for manufacture, placing on the market of medicinal products and inspections

4.1.1 The distribution chain does not remain constant. Mergers, acquisitions consolidation and opportunities for new players are part and parcel of the European free market. To protect patients in this changing environment supply chain, regulations need to be backed by enforceable legislation and must apply to all parties involved in the distribution chain.

4.1.2 A single European standard needs to be adopted for inspections (including reporting and supervision) of all parties involved in the distribution chain.

4.1.3 Patient safety can only be assured if the medicine reaches the patient in the condition intended by the manufacturer. Obligatory sealing of medicinal products and restricting the right to open the pack is the minimum standard that could achieve this.
We also strongly recommend that seals should be tamper evident, to ensure that the integrity of the contents has been maintained.
It is important that all products are treated in this same way and that regulations are not selectively applied or limited only to certain products, that are perceived as a higher risk. A risk-based approach would offer opportunity for confusion and an entry point for counterfeit goods. Aegate would refer the Commission to the Food Packaging Standards where tamper evidence is part of the packaging standards.

If authorised opening does occur and the original pack is discarded, regulations should provide for the immediate destruction of the pack to prevent any potential for misuse.

4.1.4 An obligatory approach to trace the movement and ownership (pedigree) of a medicinal product is an idealistic solution, not one that is practical in the near term. Evidence from Italy (Tracciabilita del Pharmaco using the Italian Bollini) and the USA (California e.pedigree legislation) shows that these countries have had great difficulty in gaining alignment, agreement and implementation of a full track and trace solution. Indeed in neither of these examples has track and trace been implemented, and California has further delayed their e.pedigree legislation from 2009 to 2011. Given the need to act now to protect patient safety an Authentication solution based upon the mass serialization or all medicines is a more efficient and effective way to both improve patient safety and provide a barrier to the entry of counterfeit medicines into the distribution chain.

We see other stakeholders being concerned at the role of the pharmacist in a track and trace environment and the difficulty of being able to clearly identify counterfeit product in a track and trace environment before reaching the patient.

4.1.5 The introduction of mass serialisation for pack-tracing and authenticity checking (usually known as “Authentication at the point of dispensing, APOD”), for all products will provide the patient safety and security benefits without the cost, complexity and time to implementation of the approach outlined in 4.1.4. Indeed the mass serialisation approach is also supported in a recent Frost & Sullivan report [2]. The obligatory use of ‘tamper evident techniques’ and ‘restricted right to opening’ are required to further benefit the solution.
The use of a simple barcode solution would be very cost effective and a significant environmental benefit against the RFID alternative, (which would require manufacture ,distribution and ultimate safe disposal of billions of metal intensive RFID tags, and of tens or hundreds of thousands of complex and expensive RFID readers).

Evidence and understanding from the Aegate experience following implementation of an Authentication solution in Belgium, Greece and Italy supports the mass serialisation approach.
Aegate have also been able to identify major additional patient safety benefits from this type of approach, such as recall and expiry control, compliance messaging and other patient safety messages.

4.1.6 The same standards should be applied to all parties operating within the pharmaceutical distribution chain.

4.2 Tightening requirements for the import/export/transit (transshipment) of medicinal products

To provide the patient safety protection required, all products destined for use by patients in the EU must be subject to the same regulations and standards, whatever the country of origin.
Tightening requirements for transit products will help ensure that the EU is not responsible for forwarding sub-standard or counterfeit products.
Aegate believes that these measures will improve patient safety in the legitimate and indirectly the illegitimate supply chains.
Countries outside the EU who import medicinal products from the EU should be able to set their own import requirements. Here we would see that adoption of the EU requirements by other countries would be the best way to demonstrate the benefit of this approach.
Adequate resources need to be available to supervise and enforce any new requirements

4.3 Tightening requirements for manufacture, placing on the market of active substances and inspections

This is very important in improving patient safety, since if counterfeit or sub-standard Active Pharmaceutical Ingredients (APIs) are used in the manufacture of the finished product then security measures applied later in the distribution chain are of course a waste of time.
Aegate believes that it is currently relatively easy for uncontrolled ingredients (APIs and excipients) to enter the legal manufacturing process.

The Commission should consider adopting the principles contained in the key ideas proposed in section 4.1 for finished products to APIs and excipients.

References

1. Dr Jonathan Harper, Counterfeit medicines, Survey report. Council of Europe Publishing January 2006
2. Frost & Sullivan, Working Together on Mass Serialisation: Whose Responsibility is Ensuring Patient Safety?, Published April 2008