European Alliance for Access to Safe Medicines

DG Enterprise and Industry public consultation response

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Introduction

The EAASM is a pan-European, multi-sectoral, patient safety organisation. It is a not-for-profit, Community Interest Company, with a membership encompassing patient groups, pharmaceutical companies, technology providers, healthcare providers, non-governmental and inter-governmental organisations, it represents these key stakeholders in promoting patient safety. As such, it was pleased to make a formal submission during the DG Enterprise and Industry consultation process, and even more pleased to note Vice Commissioner Verheugen's subsequent statements concerning the DG's intention to bring forward legislation to strengthen medicines distribution in Europe.[1] The EAASM formally notes its support for that position.

Counterfeit medicines are the single biggest global threat to patient safety. They are reaching Europe at a rate unprecedented in history and that rate is increasing incredibly fast – outstripping all other commodities in terms of customs 'finds'. It causes discomfort to those of us working in this field, to note that medicines are now the fastest growing counterfeit market.[2]

One specific issue we would raise is that the consultation is only concerned with securing the legitimate supply chain from counterfeits (as befits a document issued by DG Enterprise and Industry.) However, our view is that, as the counterfeiter does not recognise departmental, regulatory, legislative, national or regional boundaries, a holistic approach to fighting counterfeits is the appropriate response. For example, as counterfeiting medicines can lead to loss of life, the penalties for those engaging in this business should be appropriate, including the seizure and destruction of assets which (as is the case in parts of the USA, could then be used to fund anti-counterfeiting initiatives). More attention is needed to halt the proliferation of counterfeit medicines via the internet (the EAASM is at present engaged in a project to evaluate the size of this problem and to raise public awareness). Further resources should be made available to inform the public about the dangers of counterfeit medicines and what measures patients can take to protect themselves from risk – in effect to become the last barrier to harm. We also feel that governments should be encouraged to provide adequate funding to law enforcement and customs agencies and that measures should be put in place (some are already) to create protocols for cross-border co-operation. Another area of concern is the highly variable reporting methods and structures within the member states.

While DG Enterprise and Industry will rightly concentrate on the aspects of the debate most appropriate to its areas of operation, the EAASM calls on the DG to incorporate some comment or proposals to address these other concerns.

Current legislation was framed during times when counterfeit medicines were unrecognised as a problem, certainly in Europe. Those times are in the distant past, both chronologically and in terms of the level of criminal counterfeiting activity. Europe requires legislation that will not only address the issue of supply chain security in the conditions prevailing today, but that will be fit for purpose in the years to come, when counterfeit medicines are widely predicted to become even more of a risk to the safety of Europeans.

The EAASM reiterates its support for the Commission's determination to act swiftly to protect patients from this invisible parasite preying on patients and has the following specific comments to make in response to the consultation document.

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

The EAASM strongly supports the need to tightly regulate both the manufacture and distribution of medicines. In order to achieve this, the EAASM believes that medicines should be supplied as directly as possible from the point of manufacture to the point of consumption by the patient. Many of the recommendations in the consultation document appear to be attempts to better regulate the current system, in which medicines pass from one trader to another, bringing no benefit to patients and often increasing patient safety risks. The EAASM would therefore make the following recommendations in response to the key ideas put forward by the Commission:

4.1.1 Rather than subjecting all parties involved in the distribution chain to pharmaceutical legislation, the Commission should look to limit the parties involved to only those essential in bringing benefit to patients.

4.1.2 Inspection should be from a patient safety perspective, and look for specific examples of benefits to the patient being added. These inspections should be carried out by government agencies with the power to seize and destroy products.

4.1.3 A ban on repackaging of all pharmaceutical products is essential to ensure that the medicine consumed by the patient is the same quality as at the point of manufacture.

4.1.4 Previous issues with medicines traceability have been a direct result of the elongated supply chain. As per 4.1.1, the supply chain should only include parties bringing genuine value to patients (who are, through taxation, ultimately the 'payers' in any event) – by simplifying the supply chain traceability would be dramatically improved. Any central database or additional tracking added to packages would be negated by repackaging. Therefore, any traceability measures introduced must be launched in conjunction with a ban on repackaging.

4.1.5 In a supply chain focusing on value to the patient, pack identification would be relevant to enable manufacturing errors to be traced. Again, this must be introduced in conjunction with a ban on repackaging, to be of value.

4.1.6 Authorisation of wholesalers should include a rating of patient value to avoid trading of medicines purely for profit by intermediaries.

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

The EAASM strongly supports this provision and sees this as being a key proposal to reduce counterfeit penetration of the legitimate supply chain. We believe that these measures should provide customs and other officials with the explicit authority to stop the importation, exportation and transshipment of counterfeited medicinal products. In addition, this proposal may also have the effect of increasing public health protection by facilitating the seizure of counterfeit medicines destined for illegal supply chain routes. Such as, counterfeits being ordered and dispatched from unauthorised internet outlets.

We urge the Commission to work in conjunction with customs, law enforcement and postal authorities to ensure not only that high volume seizures of counterfeit medicines are targeted/intercepted at borders and ports, but also sufficient resources and legislative changes are prioritised to allow detection of smaller volumes of counterfeit medicines in postal packages. This is of key importance to the EAASM as delivery of small postal packages is the most common route by which European patients receive counterfeit medicines once they have been duped into purchasing them from internet sites.

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

Ensuring the quality and safety of Active Pharmaceutical Ingredients (API) is an extremely important measure in protecting patients from harm. If legitimate medicines manufacturers are unwittingly marketing counterfeit medicines because the APIs used are fake, then any security measures or legislation further down the supply chain will be rendered useless.

The EAASM is pleased to see that the Commission has recognised that API manufacture and distribution is not as well regulated as final medical products are. The controls, where they exist, are highly variable and inconsistent between European states and often there is little or no satisfactory regulatory controls of APIs (for example, manufacturing and broker/trader licensing and inspection, documentation validation, batch traceability and import/export/transit control). Thus it becomes all too easy for uncontrolled APIs to enter the legal manufacturing process.

4.3.1 Recording of API importers and manufacturers is vital to patient safety. A central database recording information about importers and manufacturers of API would facilitate identification of possible fake API. It would also provide a mechanism for carrying out inspections and tracing suspect API.

4.3.2 API manufacturers should be inspected on a regular basis by an independent body with the power to carry out random inspections of API manufacturers. Furthermore, it is essential that a European standard for Good Manufacturing Practice (GMP) is established and enforced. Any technologies or techniques that can improve auditing or manufacturing processes should be used by all stakeholders and be included in the standard for GMP where appropriate.

4.3.3 A central authority must be given the resource and legislative backing to be able to carry out announced and unannounced inspections of API manufacturers. Inspections should be carried out at random on all manufacturers supplying API as well as on any manufacturer suspected of non-compliance with GMP.

REFERENCES

1. Günter Verheugen, Vice President of the Commission. Statement made during question time in the European Parliament. Strasbourg, 15 January 2008.

2. European Commission, Taxation and Customs Union. (2007) *Summary of community customs activities on counterfeit and piracy.* Available at: http://ec.europa.eu/taxation_customs/resources/documents/customs/customs_controls/counterfeit_piracy/statistics/counterf_comm_2006_en.pdf (Date accessed: 11/04/08).