



EuropaBio

Contributions to the Consultation of the

DG Enterprise and Industry Project on Distribution Channels

March 2007

Counterfeiting of Medicines and Safe Medicines in Parallel Trade

Executive Summary

EuropaBio welcomes the opportunity to comment on DG Enterprise and Industry's forthcoming review of the current situation surrounding counterfeit medicines and safe medicines in parallel trade (or importation) in the EU. The counterfeiting of medicines and the supply of safe medicines in parallel trade are issues which are of great concern to us, as we believe that ensuring the integrity of the medicines supply chain is essential to protect patient safety.

The EuropaBio Position

EuropaBio believes that changes must be made to the way in which medicines are distributed and sold in Europe. There are now effectively 27 separate markets in the European Union, and there has been an overwhelming growth in the number of wholesaler intermediaries and traders involved in the European flow of medicines.

EuropaBio has six main concerns regarding the issue of the supply of safe medicines:

- Counterfeiting
- Human Error
- Batch Recall
- Pharmacy Stock-Outs
- Biological Instability due to Incorrect Storage of Medicines
- The Illegal Approval of Biotech Products

Given the fractured and fragmented nature of the system of parallel trade in medicines, and the risk this poses to patient safety, EuropaBio believes that until the integrity of the European supply chain is markedly improved, the parallel trading of medicines should be monitored and controlled by regulators to enable necessary measures to set the right framework for direct distribution of medicines to pharmacies and patients in Europe. For example, governments, industry and other partners could work together to develop a

standardised process across all EU member states to track and trace product pedigrees, starting with products most at risk from counterfeiting.



I. About EuropaBio

EuropaBio, the European Association for Bioindustries was created in 1996 and represents 78 corporate members operating worldwide, 12 associate organisations, 6 bioregions and 25 national biotechnology associations. Through its associations EuropaBio is also the voice of over 1800 small and medium-sized enterprises involved in research, development, testing, manufacturing and commercialisation of biotechnology applications.

EuropaBio's mission is to promote an innovative and dynamic biotechnology-based industry in Europe. We advocate free and open markets and the removal of barriers to competitiveness with other areas of the world. We are committed to an open, informed dialogue with all stakeholders about the ethical, social and economic aspects of biotechnology and its applications. We champion the responsible use of biotechnology to ensure that its potential is fully used to the benefit of people and their environment.

II. Introduction

EuropaBio welcomes the opportunity to comment on DG Enterprise and Industry's forthcoming review of the current situation surrounding counterfeit medicines and safe medicines in parallel trade in the EU. The counterfeiting of medicines and the supply of safe medicines in parallel trade are issues which are of great concern to the biotech industry, as we believe that ensuring the integrity of the medicines supply chain is essential to protect patient safety.

The pharmaceutical supply chain in Europe is extremely complex, with hundreds of millions of pharmaceutical products moving throughout the EU each year. Through legal European flows, each of these medicines can in fact travel through as many as 20-30 pairs of hands before finally reaching the patient¹. Over the last five years the complexities of the pharmaceutical supply chain have become more apparent, whereas in other industries a more streamlined and transparent chain has evolved. The pharmaceutical supply chain has now become more fragmented and porous with effectively 27 separate markets in Europe, and there has been an overwhelming growth in the number of wholesaler intermediaries and traders involved in the European flow of medicines. As a result of this, and due to both the rapid growth in the repackaging of original manufacturers medicines and the lack of exchange of information, transparency in the supply chain is decreasing.

EuropaBio believes that parallel and grey trade in medicines cause significant risks to patient safety. They can act as vehicles for counterfeits to enter the legitimate supply chain, cause human error in repackaging, batch recall problems, pharmacy stock outs, stifle innovation and can cause medicines to be stored and transported incorrectly - a risk which is particularly dangerous concerning biopharmaceuticals, due to the fact that they often must be directly injected into patients. We believe that until the integrity of the European supply chain is markedly improved, the parallel trade of medicines must be monitored and controlled by regulators, to enable necessary measures to set the right framework for direct distribution of medicines to pharmacies and patients in Europe.

¹ Haigh, J., IMS Global Consulting, quoted in 'Parallel Trade in Medicines', Social Market Foundation, June 2004.

EuropaBio is greatly encouraged by DG Enterprise and Industry's decision to undertake a simultaneous review of both counterfeiting and parallel trade. These issues cannot and should not be separated and indeed solutions to one problem will therefore bring benefits to deal with the other.

It is becoming ever clearer that changes are needed to ensure that patients' confidence in medicines is maintained and that they are protected from any potential and unnecessary risk. EuropaBio is wholeheartedly committed to developing systems/legislation which will ensure the integrity of the modern supply chain and enhance patient safety throughout Europe.

The data provided in this document has been prepared as to align as much as possible with many of the parameters set down by DG Enterprise and Industry at the Stakeholder meeting on 29th November 2006. This document will address the extent of the problem of counterfeit medicines and makes key recommendations on how to go forward and provides suggestions on actions which should be taken by both the EU institutions and industry to safeguard European patients from counterfeit medicines.

III. The Extent of the Problem

1. Counterfeiting

Advances in technology and a growth in medicines trading have contributed enormously to an increasing rise in counterfeit medicines over the past five years worldwide. Indeed, Alexander Vladchenko, Director General for Social Cohesion in the Council has stated that "Counterfeit drugs are on the verge of becoming a silent pandemic".² Counterfeit medicines can now be easily produced and traded throughout the world. The counterfeiting of medicines is a global phenomenon which is becoming increasingly problematic – including in Europe. In Europe alone, more than half a million counterfeit medicines were seized during 2005.³

At the WHO International Conference on Combating Counterfeit Medicines in February 2006, Dr. Nils Behrndt, Deputy Head of Pharmaceutical Unit of DG Enterprise and Industry stated that in the four years between 2001 and 2005, there have been at least 27 incidents involving counterfeits in the legitimate supply chain. This serves as a clear indication of the increasing sophistication of those involved in counterfeiting and the serious risk to public health it creates, as counterfeits are now becoming increasingly difficult to detect.

The WHO defines a counterfeit medicine as "A drug which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit medicines may include products with the correct ingredients but fake packaging, with the wrong ingredients (some of which may be toxic), without active ingredients or with insufficient active ingredients".⁴

EuropaBio accepts this definition as providing necessary parameters to enable aligned discussions amongst all stakeholders on the subject of counterfeiting. The definition adequately illustrates our viewpoint that any product which either deliberately or falsely claims to be a medicine produced by a licensed manufacturer, irrespective of whether or not it contains an active biopharmaceutical ingredient is a counterfeit. This is an important point to reinforce, due to the fact that some stakeholders have tended to differentiate between counterfeits which contain some active ingredient and others which do not, believing that the former will still provide medicinal benefits to the patient and therefore are of a lesser risk.

² WHO Conference, Rome 16-18 February 2006

³ European Commission, Countrywide Statistics 2005.

⁴ WHO Fact sheet N°293, The Safety of Medicines, September 2005

This is untrue, as counterfeit medicines with biopharmaceutical ingredients tend to contain the wrong active ingredient, less or more active ingredient or are manufactured in conditions contrary to good manufacturing practice (GMP), leading to a sub-therapeutic treatment for the patient.

Biopharmaceutical medicines evidently undergo many years of development before being licensed for use and ongoing pharmacovigilance closely follows their impact on patient health. The biotech industry takes its responsibility to the patient extremely seriously and prescribers refer to strict guidelines on medicine use and the suitability of the patient before deciding on a course of medication. EuropaBio therefore believes that any differentiation on how counterfeits are viewed is not acceptable under a regulatory regime that demands the highest possible standards.

Illegal Internet pharmacy websites

One of the biggest challenges regulators face is the internet supply of illegal and legal drugs, due to the fact that there is no qualified personnel who can act to ensure patients health and safety. Counterfeiters are increasingly taking advantage of new technologies such as the internet to conduct their criminal business without any regard for patient's health. Indeed, the report by the Directorate-General for Taxation and Customs Union in September 2006 clearly pointed out the increasing use of internet to sell mainly counterfeit medicines.⁵

In order for this worrying and dangerous side of internet medicines practice to be eradicated, there needs to be a public private partnership with all key stakeholders at local, national and international level to encourage patients to purchase prescription medicines through authorised distribution channels only. There should also be systems in place in order to ensure that the drugs offered via the internet do not represent a risk to the patient. A pan European license system with authorized internet pages for internet pharmacies could therefore perhaps be established.

2. Parallel Trade

The primary concern for EuropaBio with regard to parallel trade is the risk which it poses to patient safety, due to the fact that parallel imports can:

- a) Act as a potential vehicle for counterfeit medicines to enter the legitimate supply chain
- b) Cause human error in repackaging
- c) Cause batch recall problems in repackaging
- d) Cause pharmacy stock-outs
- e) Cause biological instability due to incorrect storage and transportation of medicines

Parallel trade also indirectly causes risk to patient safety due to the fact that it stifles the development of innovative biopharmaceutical products for patients.

a) Parallel trade can act as a potential vehicle for counterfeit medicines to enter the legitimate supply chain and

Parallel trade involves the diversion of medicines originally intended for use in one country to another. As a result, 140 million medicine packs cross borders every year within the EEA.⁶ This has caused the medicines supply chain in Europe to become increasingly fragmented

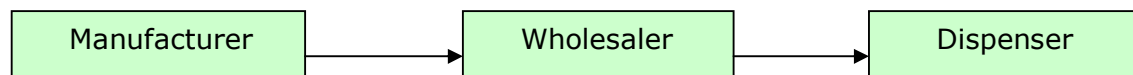
⁵ DG TAXUD, 2005 Customs seizures of counterfeit goods

⁶ MacArthur, D., European Association of Euro-Pharmaceutical Companies, quoted in "Parallel Trade in Medicines", Social Market foundation, June 2004.

and porous, with effectively 27 separate markets, and there has been an overwhelming growth in the number of wholesaler intermediaries and traders involved in the European flow of medicines. As a result of this, and the lack of exchange of information, transparency in the European supply chain is decreasing. This poses a serious threat to patient safety throughout Europe. Europabio believes that changes must therefore be made to the way in which medicines are distributed and sold in Europe.

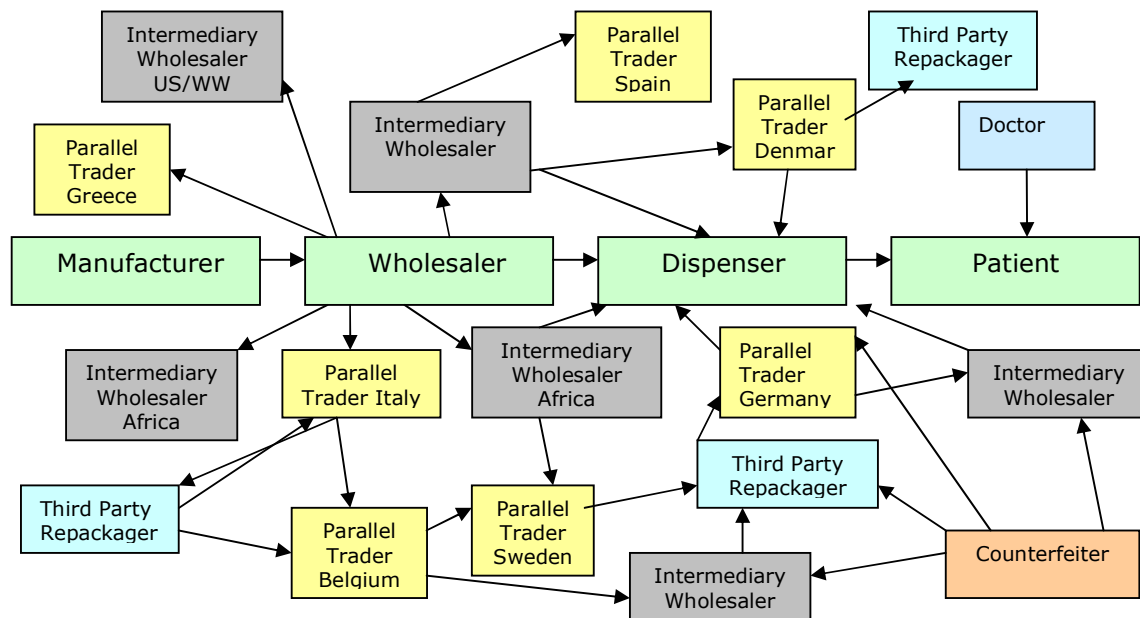
Medicines' wholesaling provides a vehicle for counterfeits to enter the European legitimate supply chain. The major problem is not that the wholesaler acts as a medicines supplier or distributor to pharmacies, but their additional and optional role as a medicines trader within and across member states. Diagram one is the often assumed but misinformed understanding of how the medicines supply chain works in Europe. It reflects a straightforward relationship between the manufacturer and the wholesaler, and between the wholesaler and the dispenser. However, parallel trade causes pharmaceuticals to rarely move directly from the manufacturer to the retailer, instead they pass through a network of wholesalers and repackagers en route to pharmacies.

Diagram One



Should this model be implemented effectively, it would provide an effective safeguard against counterfeit biopharmaceuticals entering the medicines supply chain as it is both transparent and secure. However in reality, modern medicines distribution works very differently. Some medicines are indeed supplied through this straightforward supply chain, but it fails to address the subsequent levels of trading and business which occur legally, but weaken supply chain integrity and endanger patient safety. Diagram Two illustrates the real complexity of the situation and the problems faced by the biotech industry in attempting to ensure the integrity of medicines once they reach the patient.

Diagram Two



As illustrated, not all medicines bought from manufacturers will be sold directly to a pharmacy in the intended market. Some medicines may be parallel traded, whilst more may be forwarded to numerous intermediaries who also operate in the grey or spot market. It is this complex and unclear trade that makes medicines trading difficult to regulate and monitor, which provides convenient cover to counterfeiters intending to penetrate the European market. Though more responsible traders may refrain from securing medicines from the grey or spot market, many continue to do so despite the inherent risks of purchasing counterfeit or substandard products. The internet, as well as telephone sales and cold calling, is a chosen method to buy and sell medicines in the grey market. Trader boards exist where requests can be tabled and orders fulfilled. The ever present lack of transparency and inability to regulate makes the internet a likely source for many counterfeit transactions and therefore an area where controls are needed.

Each step of this provides another opportunity for counterfeits to be introduced into the legitimate distribution system. If medicines are repackaged by parallel traders - which is often the case -, any tamper-evident packaging and possibly other security features are removed in this process, and there can be no assurance as to the integrity of the medicine once it reaches patients. Many packs carry instructions printed in a foreign language, which can lead to patient confusion and poor compliance.

European Commission Director General, Catherine Day, recently confirmed that one of the Commission's main objectives this year is to continue to regulate better.⁷ EuropaBio believes that this priority is especially poignant for the review of the situation surrounding safe medicines in parallel trade. As the Secretary General pointed out with regard to better regulation, policies should be seen as a cycle, not as an endpoint. What may have been suitable when policy was formed 20 years ago may not be suitable today. The Commission's ongoing Better Regulation agenda aims to address this. In the case of parallel trade, this may have been a suitable practice originally, but changes must now be made to the way in which medicines are distributed and sold in Europe. EuropaBio believes that the increasing number of parallel traders have caused the medicines supply chain to become fragmented and herein lies the problem. This fragmented supply chain can act as a potential vehicle for counterfeit medicines to enter the legitimate supply chain.

A more effective way to secure the medicines supply chain would be for wholesalers to stop buying medicines from the grey and spot markets. In the current environment EuropaBio believes this is unlikely to happen voluntarily. The growth in licensed wholesalers and parallel trade licenses is a consequence of a highly lucrative business. It makes medicines wholesaling an increasingly competitive sector where financial return is governed largely by securing product volume at a competitive price and selling to dispensers (or to the spot market) at an optimum time to maximise return. This 'commodity' trading of medicines is largely unregulated and un-recorded and provides an ideal environment for counterfeits to enter the legitimate supply chain.

The rising tide of counterfeiting as a result of parallel trade threatens to undermine the secure supply chain which we endeavour to preserve - costing people their health, and potentially their lives.

b) Human Error

As part of the repackaging process, parallel traders open medicine packs and then repack them with a new information leaflet (PIL). Medicines can pass through as many as 20-30 pairs of hands between leaving the manufacturer and reaching the patient, a process

⁷ EPC Breakfast Policy Meeting with Catherine Day, Secretary General of the European Commission, 27 February 2007

that at each step will increase the likelihood of human error occurring, further undermining the efficacy of the medicine.

c) Batch Recall

The process of parallel trade hinders effective batch recall. Currently there is no requirement for a trader to lodge the batch numbers of imported or exported medicines with regulatory authorities across the EU. There is no unified system of track and traceability of medicines which leads to a concern about how effective a cross-border recall, could be. This holds serious implications for patient safety and actions must be taken to address this fundamental weakness.

d) Pharmacy Stock-Outs

Medicine shortages have become increasingly common over the last few years. Parallel trading currently enables wholesalers to export a product and thereby deny it to domestic pharmacies in favour of external markets where the prices may be higher. In a recent report, "Pharmaceutical Parallel Trade in the UK", Dr, David Taylor, NHS Trust Chairman & Professor at School of Pharmacy, University of London, highlighted this trend: "Supply problems can occur when medicines are diverted away from domestic to external markets"⁸. Parallel trade makes it difficult for manufacturers to forecast the quantity of products which need to be produced and put on the market at any time. Irregular and unpredictable flows of parallel traded products mean that manufacturers have no way of knowing with any degree of certainty how much parallel trade will flow into their market at any given time.

e) Biological Instability due to Incorrect Storage and Transportation

Most biotechnology products are complex, protein-based biologics which are produced by living systems and are particularly vulnerable to changes in their environment. These protein molecules are sensitive to heat, light, and chemical contaminants. Their correct storage and transportation is therefore of utmost importance. Most biopharmaceuticals must be refrigerated at all times before being administered; this is in order to prevent fundamental changes that can render the drug ineffective or unsafe. Some products also must be kept at a certain pH level; others must be kept out of direct sunlight. In addition, minute concentrations of metals, plasticizers, and other packaging materials can deactivate or denature therapeutic proteins/peptides. The seriousness of chemical contamination of biopharmaceuticals is compounded by the extremely low concentrations typical of such drugs.

Whether in liquid or lyophilized form, biopharmaceuticals possess properties which make them sensitive to their packaging or delivery system. They have a tendency to adsorb onto the surface of containers and closures, which because of the small amount of drug present, can essentially remove all active material from a drug formulation. In situations where the drug desorbs back into solution, it could lose potency due to that interaction. Freeze-dried proteins are no less immune from the effects of packaging. This is because most lyophilized cakes are sensitive to moisture, and an inadequate seal can allow water and other contaminants to enter a package and deactivate the drug inside.

As an example, many biopharmaceuticals are sensitive to silicone oil, a material commonly used to lubricate elastomeric stoppers during fill and finish to facilitate insertion of stoppers into vials. Silicone oil has been associated with inactivation through nucleation of proteins around oil droplets. Recently introduced fluoroelastomer coatings on stoppers provide needed lubricity in addition to an added level of chemical inertness, barrier protection, and

⁸ Quotes in Kanavos, P. & Holmes, P. "Pharmaceutical Parallel Trade in the UK", Civitas, April 2005.

safety. Fluoroelastomers thus serve as both a lubricant and a barrier to improve compatibility between drugs and their rubber closures.

Europabio believes that primary packaging and correct storage and transportation should be a top priority for all biopharmaceutical drug products. The risks associated with the current parallel trading of biopharmaceuticals are evident; repackaging adds an extra unnecessary layer of trading and may result in serious threats to patient safety. Moreover, the concerns about repackaging, storage and transportation are amplified several-fold with injectable biotech products, not only because of the chemical and physical unpredictability of proteins/peptides, but also because the risks to patient safety with such products can in fact be even greater with counterfeit or adulterated biologic drugs than ordinary counterfeited pharmaceuticals, due to the fact that they must be injected or infused directly into a patient's bloodstream.

EuropaBio believes that in order for patient safety to be protected, the parallel trade of medicines must be monitored and controlled by regulators, to enable necessary measures to set the right framework for direct distribution of medicines to pharmacies and patients in Europe.

Parallel trade stifles the development of innovative biotech products

EU national governments authorise parallel trade in attempts to contain health care costs, particularly in countries where medicines prices are high. Many claim that parallel trade brings high benefits to both governments and the consumer, however it can be seen that it in fact brings no price or welfare benefits to either national payer systems or consumers. The parallel trading of medicines which has resulted from the Members' States' prerogative to price and reimburse has caused medicines to be traded across European borders for profit. The result of this is a decrease in profits for the biotech industry and an obligation to invest less towards the innovation and creation of new medicines. This in turn causes patient safety to suffer.

It is not proven that parallel trade brings savings to either the payers or the patients. As demonstrated by a recent study conducted by Dr Panos Kanavos of the London School of Economics and Political Science, the vast majority of the benefits from cross-border trade in branded medicines go directly into the pockets of the third-party companies who buy and resell these medicines, with modest savings for payers and zero or marginal benefits for patients. Lucrative profits accrue mostly to the traders themselves, depriving the research-based pharmaceutical industry from valuable resources to fund the research and development of new products.⁹

Not only does the lack of opportunity to innovate cause patient safety to suffer, it harms a young and growing biotech sector which sees innovation as an essential part of its future growth. It is important that the healthcare biotechnology industry be allowed to thrive as it is increasingly playing a role in conventional drug discovery as well as opening up new possibilities to prevent, treat and cure hitherto incurable diseases using novel methods of treatment and diagnosis. Biotech medicines such as proteins, antibodies and enzymes now account for 20% of all marketed medicines and 50% of those in clinical trials.

This is all thanks to new discoveries brought about by the sequencing of the human genome, improved knowledge of the way living organisms work and investment in enabling technologies to turn these discoveries into individual benefits. Through genetic engineering, biotechnology also uses other living organisms – plant and animal cells, viruses and yeasts - to assist in the large scale production of medicines for human use (bio manufacturing). The

⁹ The Economic Impact of Pharmaceutical Parallel Trade in European Union Member States: A Stakeholder Analysis (2004)

health care areas in which biotechnology is currently being used include medicines, vaccines, diagnostics and emerging cell and gene therapies.

By using the human body's own resources to fight disease biotechnology offers the potential to meet unmet medical needs and to make medical treatment not just more comprehensive and highly individualised, but also enables doctors to move from treatment towards disease prevention and cure.

Healthcare biotech is providing patients with innovative treatments to fight disease as well as innovative diagnostics. Biotechnology is providing doctors with more tools which are helping to move from the treatment of diseases towards prevention and cure. A whole new range of tools are being developed to support the human body to utilise its own capacities to fight infectious or cancerous diseases as well as injuries.

Thanks to the unravelling of the human genome, biotechnology is also increasing the number of disease targets for conventional drug therapy. Today conventional drugs target fewer than 500 disease targets, but in the future this is likely to rise to between 5-10 000 targets. The pharmaceutical industry will be powered more and more by biotechnology. The increased understanding of complex biological processes is opening up vast new areas of possibilities to fight and cure disease.

However, the enormous potential of this revolutionary healthcare sector is being stifled - Europe's biotechnology sector is growing fast, but not as fast as its US counterpart.¹⁰ In this context, competitive research is the key and should medicines continue to be traded for profit, this will not be allowed to happen. Europabio believes that direct distribution of medicines to pharmacies and patients in Europe would be a first step to ensuring that this important industry continues to compete.

The Illegal Approval of Biotech Products

Another issue of major concern for the safety of patients in Europe relates to the fact that a number of biotech products have been approved illegally by the health authorities in Europe. According to information available to members of EuropaBio, authorities in EU Member States such as Bulgaria, Latvia, Lithuania, Poland and Romania have approved biotech products at national level in the following product classes: recombinant human erythropoietin, recombinant human growth hormone, recombinant granulocyte-colony stimulating factor and interferons (alpha and gamma). These nationally approved biotech products are currently being administered to patients and exported to EU or non-EU countries. A similar situation arises in a number of accession countries or potential accession countries to the European Union.

This raises several concerns. First, these products have generally not been approved in accordance with EU standards, which require conducting clinical trials, and thus their safety and efficacy has often not been properly demonstrated by the applicants. Second, the national authorities lack power to assess compliance with EU standards in relation to DNA recombinant biological products. Medicinal products developed by means recombinant DNA technology can only be approved centrally by the European Commission, upon recommendation by the EMEA/CHMP (refer to Regulation 726/2004). This "double standard" approach is extremely worrisome for the safety of patients in Europe

¹⁰ The Pharmaceutical Industry in Figure, 2006 Edition, European Federation of Pharmaceutical Industries Association

VI. Recommendations

Supervision/ Enforcement

EuropaBio has many concerns about the supervision of the European medicines supply chain and the enforcement of regulations overseeing it. The European Commission's statement that more than 500,000 counterfeit medicines were seized at the external borders of the EU in 2005 certainly reinforces the need to tightly secure the entire pharmaceutical supply chain in Europe as international traders increasingly take advantage of more open borders.

It can be seen that there is therefore an urgent need for improvement if Europe's patients are to be sufficiently protected. Customs must be able to quickly identify, act and deal with new routes of fraud and constantly changing counterfeit patterns in order for patient safety to be protected. European customs authorities must be provided with the resources to carry this out effectively.

Awareness Raising and Methods of Cooperation

EuropaBio welcomes recent steps taken at European and global level to thwart the scourge of counterfeiting in the EU, such as the Council of Europe's investigations into counterfeiting, which resulted in the Harper Report,¹¹ and the newly developed WHO group IMPACT (International Medical Products Anti-counterfeiting Taskforce). EuropaBio also welcomes recent legislative steps taken at EU level, such as the Directive on Criminal Measures aimed at ensuring the enforcement of intellectual property rights.

However, EuropaBio believes that awareness raising amongst industry players, governments and patients is an essential tool in the fight against counterfeiting. We believe that all stakeholders should be better informed about the risks of counterfeit and sub-standard medicines and actively engaged in addressing the problem. We strongly believe that additional measures are needed in order to secure the integrity of the supply chain and safeguard patient safety. Patients may be aware of the dangers, but this is mitigated by the reality that counterfeited medicines can be found in the legitimate supply chain.

Clear and consistent communications should therefore be a priority to a) deter criminals from counterfeiting medicines b) to highlight risks and responsibilities to all stakeholders supplying, prescribing and dispensing medicines c) to educate the general public on i) the risks and consequences of buying medicines from un-licensed websites, ii) the need to be vigilant when buying medicines from trusted sources in the legitimate supply chain and iii) to report any suspicious or substandard medicines.

EuropaBio believes that the Commission should create a European taskforce to coordinate actions between all stakeholders involved in or responsible for awareness raising and communications on this issue. In this way, all European citizens will be exposed to an agreed level of consistent messages.

Tracking and tracing medicines

The standardised and unique coding of medicines can introduce pedigree, lead to improvement to patient safety and enhance the security and efficiency of the medicines supply chain through greater transparency and reliable data. Coding initiatives already exist in Italy, Belgium, France, Portugal and the Netherlands. In Spain, the draft 'Royal Decree

¹¹ Harper, J. Counterfeit medicines - Survey report 2006

Regulating the Traceability of Drugs for Human Use' is expected to come into force on the 1st March 2007; and discussions in Greece and Germany on similar legislation are ongoing. It is our interpretation that many of these schemes are primarily intended to support the authorities in securing reimbursement on discounts provided to pharmacies and not as a measure to tackle the growing incidents of counterfeiting.

As well as measures recommended in the previous section, EuropaBio believes that for any traceability system to work effectively as a measure against counterfeit medicines entering the legitimate supply chain it has to possess several key characteristics.

1. Fully compatible with technologies used in other EU markets thereby creating a secure supply chain network. To these ends EuropaBio supports a common European technology solution and standards for tracking and tracing medicines
2. Technology adopted needs to be highly secure and itself free from the risk of being counterfeited. To these ends the adopted system must be based on authentication of coded data and not certification, which is easier to reproduce
3. Tracking and/or tracing mechanism must be fully integrated into the original medicine packaging and remain tamper free. This is the only secure way of successfully accumulating and conveying data on the origin and pedigree of the medicine on its journey through the supply chain.
4. Secure encryption of any data contained on the medicine with access highly restricted to the manufacturer (at the beginning of the distribution process), the dispenser (at the end of the distribution process) and relevant Government and regulatory authorities

EuropaBio shares a common position with other manufacturers on track and traceability of medicines and this is reflected through EFPIA. As such EuropaBio supports the EFPIA position on 2D Data matrix bar coding being the preferred choice of technology. It has been found to be more effective than other technologies available and is easier to integrate on medicines packaging. EFPIA will be submitting its own evidence on track and trace and 2D Data Matrix Bar Coding to this study.

Key Recommendations

EuropaBio believes that changes need to be made to the way in which medicines are distributed and sold in Europe. This will go a considerable way to ensuring that patients' confidence in medicines is maintained and that they are protected from any potential and unnecessary risk. EuropaBio would therefore recommend that in order to achieve this, EU Institutions and EU Member States must take action on at least six specific areas, in addition to the work being done by the biotech industry.

1) Action to be taken by EU Institutions/Member States- Direct to Pharmacy Distribution

EuropaBio recommends simplifying the European regulatory framework which determines the distribution of medicines in Europe in order stop counterfeits entering the legitimate supply chain and diminish the risk of biological instability caused by incorrect transportation of biotech medicines. This can be executed by delivering directly to pharmacies. EuropaBio believes this system will ensure pharmacies can buy directly from pharmaceutical companies with complete confidence. Direct to pharmacy distribution excludes the risk of pharmacists inadvertently buying counterfeit medicines, human error and enables fast and efficient batch-recall from pharmacy.

2) Action to be taken by the EU Institutions/Member States - Prohibition of Repackaging as Done Currently

EuropaBio members believe that new packaging and security measures can become a key component of anti-counterfeiting efforts and will help to ensure patient safety. Many of the risks associated with the integrity of the supply chain lie in the repackaging of medicines. EuropaBio recommends that the EU adopt a regulation to prevent the opening of, and interference with, original manufacturers' medicine packaging. This would mitigate some of the problems posed by counterfeiting.

3) Action to be taken by the EU Institutions/Member States - Product Pedigree

In order to improve the security of the supply chain and to maintain public confidence in medicines, it is necessary to be able to validate the authenticity of medicines at any point along the supply chain, from the manufacturer to the patient. This "pedigree" in addition to helping the detection of counterfeits will greatly enhance the ability to "track and trace" medicines. Since current technological track and trace solutions are not yet fully tested and standardised, we believe implementing any solution at this stage on a country or European wide basis is premature. We encourage the Commission to learn from ongoing initiatives that test various track and trace solutions with the goal of developing a harmonised solution across all EU member states. Once a harmonised solution is available EuropaBio supports a step-wise implementation based on counterfeiting risk per product.

4) Action to be taken by the EU Institutions/Member States – Withdraw the Marketing Authorizations for Biotech Products Approved Illegally at National Level

In order to ensure the safety of patients in the European Union, we urge the European Commission to take the necessary measures to ensure that the marketing authorizations for those biotech products which have been approved illegally at national level are revoked and that these products are withdrawn from the national markets. We also urge the competent authorities of the Member States to take all necessary measures to prevent the marketing, sale, distribution and export of illegally approved biotech products.

5) Creation of a European Taskforce to coordinate communication activities (Action to be taken by the European Commission)

EuropaBio believes a European taskforce should be created to coordinate actions between all stakeholders involved in or responsible for awareness raising and communicating on medicines safety and anti-counterfeiting. In this way, all European citizens will be exposed to an agreed level of consistent messages.

Conclusion

EuropaBio believes that safeguarding the security and integrity of the supply chain is crucial to the protection of patient safety. We believe that it is essential all stakeholders are committed to working in partnership to ensure a secure supply chain. This includes patient advocacy groups, healthcare providers, regulatory authorities, legislators as well as customs and law enforcement authorities.