ΘΕΣΕΙΣ

The New Data on Pharmaceutical and Health Care Expenditure in Greece

ΣΥΝΔΕΣΜΟΣ ΦΑΡΜΑΚΕΥΤΙΚΩΝ ΕΠΙΧΕΙΡΗΣΕΩΝ ΕΛΛΑΔΟΣ

ΣfEE

HELLENIC ASSOCIATION OF PHARMACEUTICAL COMPANIES

ΣfEE 's Offices
Non smoking area

#68

APRIL 2008

Hellenic Association of Pharmaceutical Companies
280, Kifissias Ave. & 3, Agriniou Str.,
15233 Halandri, Athens-Greece
Tel.: +30210 68 91 101, Fax: +30210 68 91 060
Internet: www.sfee.gr, e-mail: sfee@sfee.gr

www.sfee.gr

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The **Present**, the **Future** and the **Role** of ΣfEE

Dionysios S. Filiotis
PRESIDENT OF ΣfEE
President & Managing Director of
PHARMASERVE LILLY S.A.C.I.

There is a series of milestones that designate the maturing and progress of Greece in relation to the pharmaceutical market and to the contribution of the pharmaceutical industry toward this progress. It is a development that concerns society as a whole-that concerns all Greek citizens.

One of these milestones, the most important, is the securing of direct access to all treatments and all branded medicines to all citizens. It is a fact that following years of drawing up and adopting policies for medicines, we have reached a system that does indeed guarantee direct access of all those insured to all branded medicines, the only medicines to guarantee quality, effectiveness, and safety.

Ensuring the thorough quality of medicines by having them prescribed under their brand name through the responsibility of a treating physician is another landmark, which, today constitutes the most powerful safety valve in our country against the ever-expanding trade of counterfeit medicines, a danger to public health.

Two other milestones, achieved through years of systematic work, are the emphasis on abiding by the Code of Practice in all phases, from production to distribution, and the shaping of a high quality and efficient distribution chain. It is clear that these landmarks create a new landscape for Greece and at the same time demonstrate a high cultural level, a level equal to that of other European countries.

However, although we have achieved remarkable progress during the past decades, there are areas in which we witness problems that have accumulated.

A basic area where necessary steps have not been taken is in the financial sector. We have not yet established mechanisms to control expenditure. IT and technological streamlining of the system is still needed and sought. We know that a thorough and effective program to deal with inefficiencies, misspending, and overspending is the main prerequisite for the sustainability of the system and for ensuring direct and timely access to all insured. Another sector where we have to move more quickly is ensuring a sufficiency of medicines in the market, which should not be threatened by the trend to re-export. There have been steps

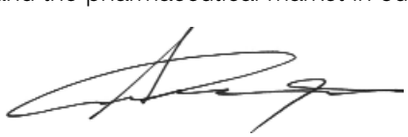
taken in this area but the progress achieved to date will attain permanence if, and when, there is full (and not occasional) compliance with the rules and decrees in the pricing of medicines.

In conclusion, we have achieved a lot, but we have important challenges ahead, not just as a sector but also as a country. We believe that more progress can be made in the framework of a continuous public dialogue on health and medicine, a dialogue in which SFEE in recent years has played, and continues to play, a leading role.

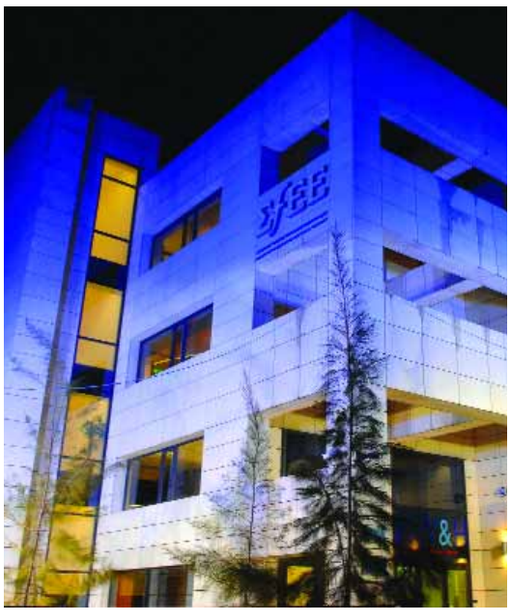
Public dialogue, however, must be based on actual data and not on irresponsible and exaggerated simplifications. A recent example of irresponsibility and exaggerated simplification was the “distorted publication” in several mass media of the size of total pharmaceutical sales as public pharmaceutical expenditure. The total pharmaceutical sales of approximately 7 billion Euros was “baptized” as expenditure that burdens the State, while the truth is that less than half of consumption constitutes pharmaceutical expenditure. We immediately took a stand on this and with a direct information campaign to the mass media, to ministers and legislators, demonstrated to all the indisputable truth.

And indeed, our position was confirmed by the revised data, which have recently been published by the National Statistical Service of Greece. According to this data, public pharmaceutical expenditure is _3.2 billion, while total pharmaceutical expenditure is only 1.6% of GDP and 17.6% of total health care expenditure, remaining close to the EU-average.

This is the manner in which we will proceed in all issues. Because we believe that SFEE has a role and a voice that is central and integral in a healthy and constructive public dialogue that will lead to the achievement of solid and stable progress in all issues regarding medicine and the pharmaceutical market in our country.



Dionysios S. Filiotis
President of ΣfEE



Inauguration of New Offices

Hellenic Association of Pharmaceutical Companies (ΣfEE)

In an official ceremony the Hellenic Association of Pharmaceutical Companies (ΣfEE) inaugurated its new offices on February 19, 2008, in the presence of the Minister of Health and Social Solidarity, Mr. Dimitris Avramopoulos. Distinguished personalities from the country's political, business, scientific, and academic communities had the opportunity to visit ΣfEE's new offices and meet with ΣfEE members.

Mr. Dionysios S. Filiotis, President of ΣfEE, cut the traditional New Year's Pita and wished the many guests a happy and prosperous new year.

"We are very pleased with our new offices because they represent our effort to upgrade our stature and streamline the operation of our Association. From our new premises we will be able to more effectively fulfill our vision to safeguard public health and to ensure that this sector has the place it deserves in the Greek business community. Our goal is, through our position on issues and our proactive role, to contribute to the progress of our society, and to the progress of our country."

The inauguration took place with the Minister of Heath and Social Solidarity, Mr. Dimitris Avramopoulos, cutting the ribbon. In his address the Minister wished the best for ΣfEE in its new offices and stated, "These modern offices of ΣfEE reflect the general spirit which characterizes the pharmaceutical sector in its efforts to upgrade its role and contribution to health care." Mr. Avramopoulos continued by congratulating ΣfEE for its dynamic activities and the proactive initiatives it is undertaking, citing as an example the recent publicizing of the Code of Practice. The Minister further requested "A greater effort from all bodies in the health sector to put behind whatever has cast a shadow on the good climate between the public and private sector, to the benefit of public health."

ΣfEE's new offices are located at 280 Kifisias Ave. & 3 Agriniou Str., in Halandri. The architect was inspired by the letter f in the ΣfEE logo, and shaped the central corridor of the offices in the shape of this letter, a subtle reminder to every visitor of ΣfEE's vision of ensuring all citizens direct access to all quality branded medicines, within the framework of an upgraded health system and in full compliance with the Code of Practice.

Dionysios S. Filiotis
PRESIDENT OF ΣfEE
President & Managing Director of
PHARMASERVE LILLY S.A.C.I.

Address of Dionysios Filiotis, Sfee President, at the Inauguration of Sfee's New Offices

It is a great honor for us to welcome you this evening. It is a great honor that you are here for the inauguration of the new offices of ΣfEE and it is indeed a special privilege to have the Minister present at this ceremony.

We have initiated a major endeavour to upgrade ΣfEE's stature: to establish ΣfEE not merely as an association of the pharmaceutical sector but also as a partner that plays a central role in safeguarding public health, both as an advisor and a supporter of the State.

ΣfEE has upgraded its stature in the social and business environment, and participates in a creative and constructive way in the public dialogue; at the same time ΣfEE is a reliable advisor to the State on issues regarding public health, especially in the area of medicine.

We have a vision for the pharmaceutical sector which, at the same time, is a vision for our society. Our vision is to ensure direct access to all quality branded medicines, in the framework of an upgraded health system, always abiding by the rules and principles of deontology. It is clear that such a vision reflects the common interest of all citizens, the nation, and the pharmaceutical companies.

Our goal is not simply to promote the interests and issues of our sector. Our goal is, through our position on relevant issues and our proactive role, to contribute to the progress of our society, to the progress of our country.

We believe that the goal of ΣfEE is active and comprehensive participation so that Greece may remain among the progressive countries that implement the most successful and effective policies in the sector of medicine and public health in general.

One current example of the effort to upgrade our stature and streamline the operation of ΣfEE is our Association's new offices.

From our new premises we will be able to more effectively fulfill our vision to safeguard public health and to ensure that this sector has the place it deserves in the Greek business community.

"**Our goal** is not simply to promote the interests and issues of our sector. **Our goal is,** through our position on relevant issues and our proactive role, to contribute to the progress of our society, to the progress of our country"

The President of ΣfEE Mr Dionysios S. Filiotis greets the President of the National Organization of Medicines (EOF)

Address of the Minister of Health and Social Welfare Mr Dimitris Avramopoulos, at the Inauguration of the New Offices of ΣfEE

Dimitris Avramopoulos
Minister of Health & Social Solidarity

It is a great pleasure to be present here today at the inauguration of the new offices, the new premises of the Hellenic Association of Pharmaceutical Companies.

Renewal and continuous modernization are concepts characterizing the pharmaceutical industry, from whose research, technology, and new medicines the public expects improved and more effective methods in the treatment of disease and protection of public health.

We expect and believe that the contribution of pharmaceutical industry in the National Plan on Health, with ΣfEE as main representative, will be decisive and very constructive.

The contribution of your Association for years in the economic environment of this country and your initiatives in the Health sector have proven your sensitivity and your continuous interest in adopting and implementing solutions that upgrade the level of health services provided and patient treatment.

A recent great initiative in this direction is publicizing your Code of Practice.

Your initiative in accordance with the principles of the Code proves and confirms that the medicinal product, besides being a consumer product, is mainly a social commodity. The State and Insurance Funds safeguard this particular characteristic of medicines.

The pharmaceutical policy we are designing and implementing has, as its main target, the safeguarding of public interest and public health, as well as the securing your rights.

For this purpose we have established a procurement system, exclusively for the health sector and have, for the first time in the history of the provision health services an integrated primary healthcare system.

With our initiatives we abolish the factors of opacity and the uncontrolled process of procurement and consumption of medicinal products, and we establish transparency in the management of public funds.

The pharmaceutical industry plays a leading role in the development prospects of the country and the exercising of economic diplomacy.

With the expertise and responsible position of its executives and the effective supervision and assistance of the State, these prospects will soon become a reality to the benefit of all.

I wish that your settlement in these new premises marks the beginning of an even more creative course for the future of Healthcare sector and the population of our country.

I congratulate the President and the members of ΣfEE's Board of Directors and all the member companies of your Association for this initiative and for continuously striving to advance and improve your working infrastructure.

Mr Dionysios Filiotis welcomes the Minister of Health Mr Dimitris Avramopoulos

The New Data on Pharmaceutical and Health Care Expenditure in Greece

K. Souliotis
Lecturer, University of Peloponnese

H. Kousoulakou
Health Economics Research Officer
IOBE

The new data on pharmaceutical and health care expenditure in Greece appear to be more "reasonable" and closer to the real picture of the health care market. These data are the result of the second National Accounts revision of December 2007, which was undertaken by the National Statistical Service of Greece (ESYE).

The new estimates have been calculated by incorporating some methodological issues discussed in cooperation with the academic and research community of the Greek health economics sector -after the publication of the initially revised data-, especially regarding private health care expenditure and pharmaceutical expenditure. It must further be noted that the procedure of re-estimating health care expenditure is very complicated. Nevertheless, systematic work being carried out by (ESYE) in recent years has lead to a more precise description of the health care market.

According to the ESYE data, total health care expenditure was 7.8% of GDP in 2000 and reached 9.1% in 2006, while the first revision estimates (September 2006), showed a share of 9.3% in 2000 and 10.1% in 2005. Therefore, the first strong conclusion that arises from the new data, is that health expenditure does not exceed 10% of GDP, as regularly quoted in public dialogue.

Another impressive and favorable finding is that public coverage of the health care cost is almost 15 percentage units higher than the estimate of the first revision. It should also be underlined that the final revision has produced data that are in accordance with data from other studies conducted by ESYE, such as the Household Budget Surveys.

However, it should not be disregarded that private health care expenditure in Greece is still higher than the European average, which is about 25% of total health expenditure.

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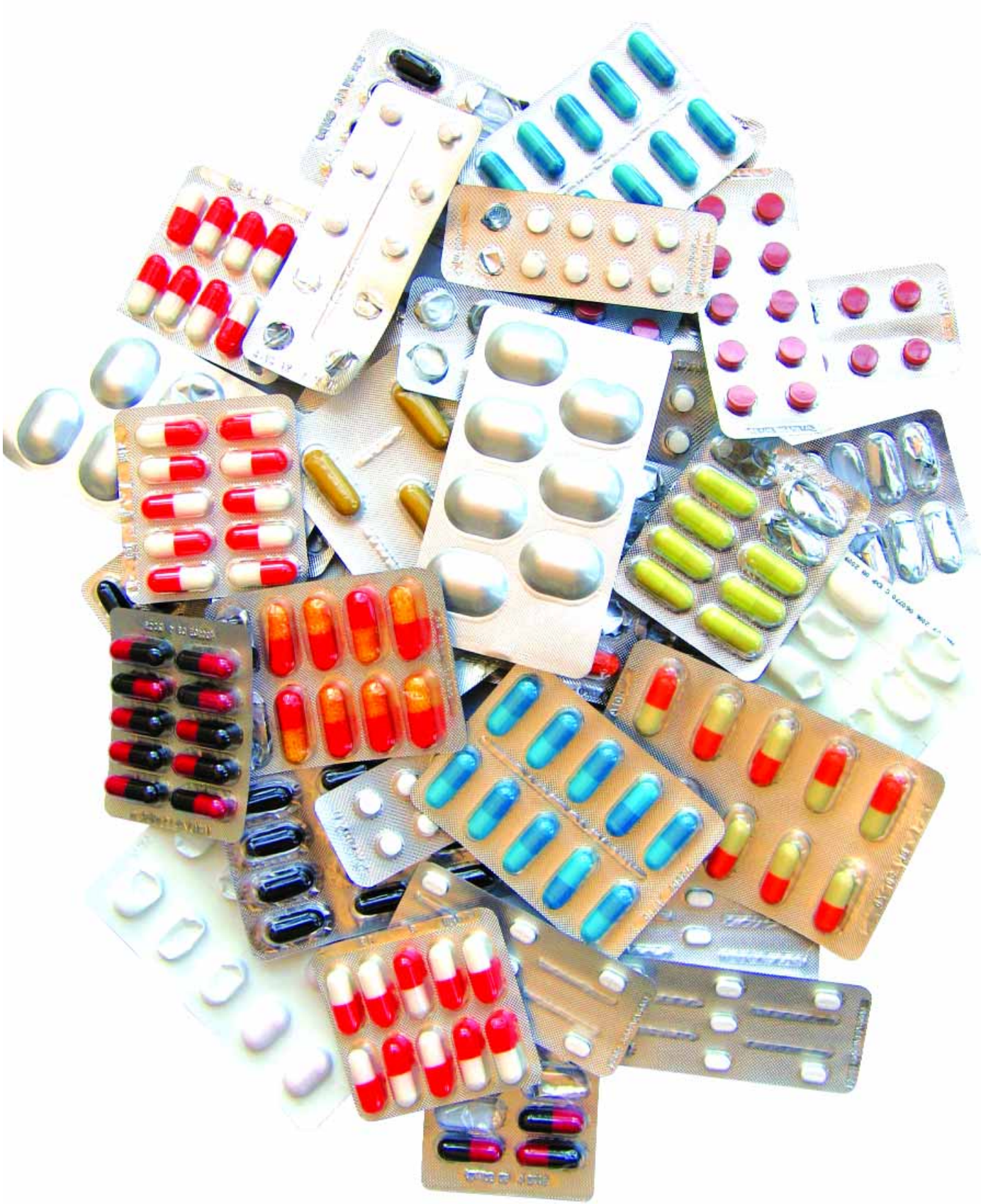

Health Care Expenditure in Greece before and after the Revisions

	2000	2001*	2002*	2003*	2004*	2005*	2006*
Revision of December 2007							
Total Health Care Expenditure	10,589	12,256	12,996	14,626	15,294	17,803	19,508
Health Care Expenditure as % of GDP	7.8%	8.4%	8.2%	8.5%	8.3%	9.0%	9.1%
Public Health Care Expenditure	6,444	7,814	8,254	9,182	9,449	11,178	12,018
Public as % of Total Health Care Expenditure	60.9%	63.8%	63.5%	62.8%	61.8%	62.8%	61.6%
Revision of September 2006							
Total Health Care Expenditure	14,572	16,519	17,601	19,714	20,504	22,991	
Health Care Expenditure as % of GDP	9.3%	9.8%	9.7%	10.0%	9.6%	10.1%	
Public Health Care Expenditure	6,444	7,832	8,274	9,146	9,143	9,851	
Public as % of Total Health Care Expenditure	44.2%	47.4%	47.0%	46.4%	44.6%	42.8%	
Prior to the Revision							
Total Health Care Expenditure	11,780	13,429	14,345	15,776	16,399		
Health Care Expenditure as % of GDP	9.7%	10.2%	10.1%	10.2%	9.8%		
Public Health Care Expenditure	6,353	7,614	7,942	8,641	8,833		
Public as % of Total Health Care Expenditure	53.9%	56.7%	55.4%	54.8%	53.9%		

Source: General Secretariat of National Statistical Service of Greece (ESYE).
** Provisional data*

Regarding pharmaceutical expenditure-a category which includes, as is widely known, pharmaceuticals dispensed only to outpatients- the revision shows that in 2006, pharmaceutical expenditure in Greece was _3.4 billion, representing 17.6% of Health Expenditure and 1.6% of GDP.

In addition, during the period 2000-2006, pharmaceutical expenditure increased at a mean annual rate of 10.5%, which is almost the same as the rate of change of total health care expenditure (the mean annual growth rate for health over the same period was 10.7%).

It is also important to note that, although the health care data show a relatively high private expenditure (about 40%), in the pharmaceutical sector, as indicated by the new data, the system of social insurance performs efficiently, covering about 80% of people's needs in medication (average public pharmaceutical expenditure for the period 2000-2006).

Pharmaceutical Expenditure in Greece

	2000	2001*	2002*	2003*	2004*	2005*	2006*
Total Pharmaceutical Expenditure	1,884	1,996	2,183	2,607	3,017	3,300	3,438
Pharm Exp as % of Health Care	17.8%	16.3%	16.8%	17.8%	19.7%	18.5%	17.6%
Pharm Exp as % of GDP	1.4%	1.4%	1.4%	1.5%	1.6%	1.7%	1.6%
Public Pharmaceutical Expenditure	1,278	1,502	1,793	2,132	2,476	2,875	3,193
Public as % of Total Pharm Exp	67.8%	75.3%	82.1%	81.8%	82.1%	87.1%	92.9%
Private Pharmaceutical Expenditure	606	494	390	475	541	425	245
Private as % of Total Pharm Exp	32.2%	24.7%	17.9%	18.2%	17.9%	12.9%	7.1%

Source: General Secretariat of National Statistical Service of Greece (ESYE).
** Provisional data*

We can conclude, therefore, that, total pharmaceutical expenditure is lower than 1/5 of health care expenditure over time, and that it increases at the same rate as that in the health care sector. Additionally, it is clear that in Greece pharmaceuticals are considered to be public goods and covered by social insurance.

The availability of reliable statistical data is of high importance for the field of health economics, since it enables researchers to conduct scientific analyses over time, as well as make international comparisons of the health care and pharmaceutical sectors. At the same time, restoring the accurate picture of the pharmaceutical and health care markets is extremely important for all stakeholders, as it contributes to rational decision making in both the private sector (for strategic planning), and in the public sector (for pharmaceutical and health policy making).

In order to achieve the availability of reliable statistical data, and given the complexity of this market, the estimation procedure carried out by the official sources should be assisted by the academic and research field of health economics. The organized and systematic implementation of a uniform method to collect and process data is indeed an investment in health care policy, as it provides the documentation on which decision making is and should be based.

efpia
European Federation of Pharmaceutical Industries and Associations

Protecting EU patients against counterfeit medicines

EFPIA welcomes the Commission's commitment to take action

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Brussels, 14 March 2008 - EFPIA, the European Pharmaceutical Industry Association, welcomes the European Commission's initiative to launch a public consultation in preparation of a legal proposal to combat counterfeit medicines for human use.

Counterfeiting of medicinal products has become an increasing threat for patients in Europe. EFPIA has called for a range of measures to ensure that the highest quality products reach the patient; a ban on repackaging of pharmaceutical products; clearly defined liabilities for all involved in the distribution chain (including brokers, traders and agents); stricter auditing rules and controls of the supply chain and applying penalties for trafficking in counterfeits.

In addition, investments in anti-counterfeiting technologies are being made by the pharmaceutical industry to enhance product security. EFPIA is also making plans to launch a pilot project in the area of mass serialization (2D barcoding system) towards the end of 2008.

The data and analysis outlined by the Commission corroborates the evidence collected by EFPIA on prevalence of counterfeits, including the increasing penetration in the EU legitimate supply chain. As long as repackaging and breaking of seals in the distribution chain is allowed, patient safety will be highly at risk.

While Europe is part of a global network of routes for counterfeit medicines in transit, the complexity and fractured nature of the distribution system in the EU and regulatory loopholes and shortcomings in the enforcement of Community legislation offer an opportunistic means for illegal operators to access Europe's legitimate supply chain.

EFPIA insists that there should be 'zero tolerance' for counterfeit medicines and calls for the application of the precautionary principle to protect patient safety (1). Counterfeits pose a number of serious public health risks (2): the counterfeit may not contain the correct active ingredient or the right amount of active ingredient; quality standards may not have been

respected; the medicine may have an incorrect dose; foreign or toxic bodies may be present in the medicines, etc.

In addition to the direct risk of harm to patients, consideration should be given to the harm and costs that counterfeit drugs involve caregivers, health system resources and the health delivery system at large.

EFPIA believes that decisive and urgent action is required to enhance product security in order to protect European patients and will submit a detailed response to the Commission's public consultation by the 9 May deadline.

(1) EFPIA documented seven cases of counterfeit medicines entering the EU legitimate supply chain, all having been detected in the UK. Each case involves thousands of boxes, i.e. thousands of potentially injured patients.

(2) For a full overview of counterfeit risks EFPIA suggests a reference to the WHO's guidance.

EC proposes "firm action" to tackle counterfeits

The European Commission has come up with a set of proposals for tackling counterfeit medicines. As well as stricter enforcement and inspection regimes, they include measures such as a unique seal on product packs and a ban on the repackaging of medicines.

The proposals are contained in a paper just released by the enterprise and industry directorate for a two-month public consultation. In it the commission says it has observed a number of worrying trends in counterfeiting, including a 384% increase in the number of fake drugs seized in 2006 compared with the previous year, and a tendency for counterfeiters to target life-saving medicines.

Criminals used to focus mainly on lifestyle products such as medicines for erectile dysfunction and weight loss, but now they are increasingly dealing in products such as anti-cancers and drugs for heart disease.

Moreover, counterfeiters increasingly have the licensed distribution chain in their sights, rather than just the internet. Using authorised wholesalers, parallel traders and pharmacies allows the distribution of high volumes of medicines, the commission observes.

It has identified a number of factors that contribute to the rise in counterfeiting. They include:

* deficiencies in the supply chain: it is not clear whether certain players, such as brokers and business-to-business platforms are subject to the pharmaceutical legislation;
* shortcomings in product integrity, "especially when packs are opened for repackaging and changed for relabelling purposes";
* legal uncertainties and differing practices among member states in terms of applying pharmaceutical legislation to imports that are to be re-exported; and
* failure of active pharmaceutical ingredient (API) manufacturers to meet GMP standards.

risks rising

"In addition, there is evidence that member states are starting to consider taking unilateral action to address the problem of counterfeit medicines," the commission notes While these measures may be motivated by justifiable concerns, they may lead to different levels of public health protection, which could indirectly encourage counterfeiters to target specific member states with lower levels of protection for the distribution chain.

"There is clear evidence that the risks to public health in the EU are set to increase still further if the Community does not act firmly," it declares. It has therefore outlined proposals to amend the EU legislation to introduce new measures to tackle the entry of fake medicines into the Community. The three main areas it is targeting are traceability and the distribution chain, import/export and transit issues, and the supply of APIs.

repackaging ban?

One proposal is to ensure that products can get from the manufacturer to the patient without being tampered with on the way. The commission says counterfeiters tend to target traders who alter product packaging for the market of destination (ie, parallel traders).

When products are repackaged, it says, safety features on the outer packaging (eg mass serialisation) can disappear; moreover, discarded original packs can be used to package fakes. So maintaining the integrity of the outer packaging is crucial.

This should be done by obligatory product sealing. The right to open the seal would be restricted to the market authorisation holder and the end user, and this would be supported by a ban on repackaging.

Such a ban was proposed last year by the European industry federation EFPIA, which complained that the commission appeared to be prioritising the free movement of goods over patient safety considerations (Scrip No 3304, p 3).

A ban could have a detrimental effect on parallel traders, which often repackage medicines to allow or facilitate their sale in the destination market. Heinz Kobelt of the EAEPC, which represents European parallel traders, said a ban would mean the end of parallel trade.

However, the effects of a ban might not be that drastic. For one thing, the commission says the seal requirement could be limited to certain categories of product where counterfeits posed the most risk to patients. And Mr Kobelt suggested that the term market authorisation holder might actually include authorised parallel traders: "The commission needs to be clearer," he said.

Moreover, Nick Beckett of law firm CMS Cameron McKenna said he had detected a shift on the part of parallel traders from repackaging to overstickering, which did not involve opening the pack. "There seems to be greater acceptance of overstickering, by both patients and parallel traders," he commented. He therefore did not think a ban on repackaging would conflict with the rules on the free movement of goods.

traceability and inspections

Other measures the commission is proposing include the following:

* a centrally accessible record to allow specific batches to be traced throughout the distribution chain;
* mass serialisation for pack tracing and authenticity checks for individual products _ at present only batch numbers can be traced;
* requiring a good distribution practice (GDP) certificate to be issued after a wholesaler has been inspected;
* setting up an EU database of wholesalers documenting GDP compliance; and
* tightening the requirements for the import, export and transit of medicines. Divergent enforcement practices at member state level have led to "blind spots" in the supervision of product entering the EU, according to the commission.

APIs

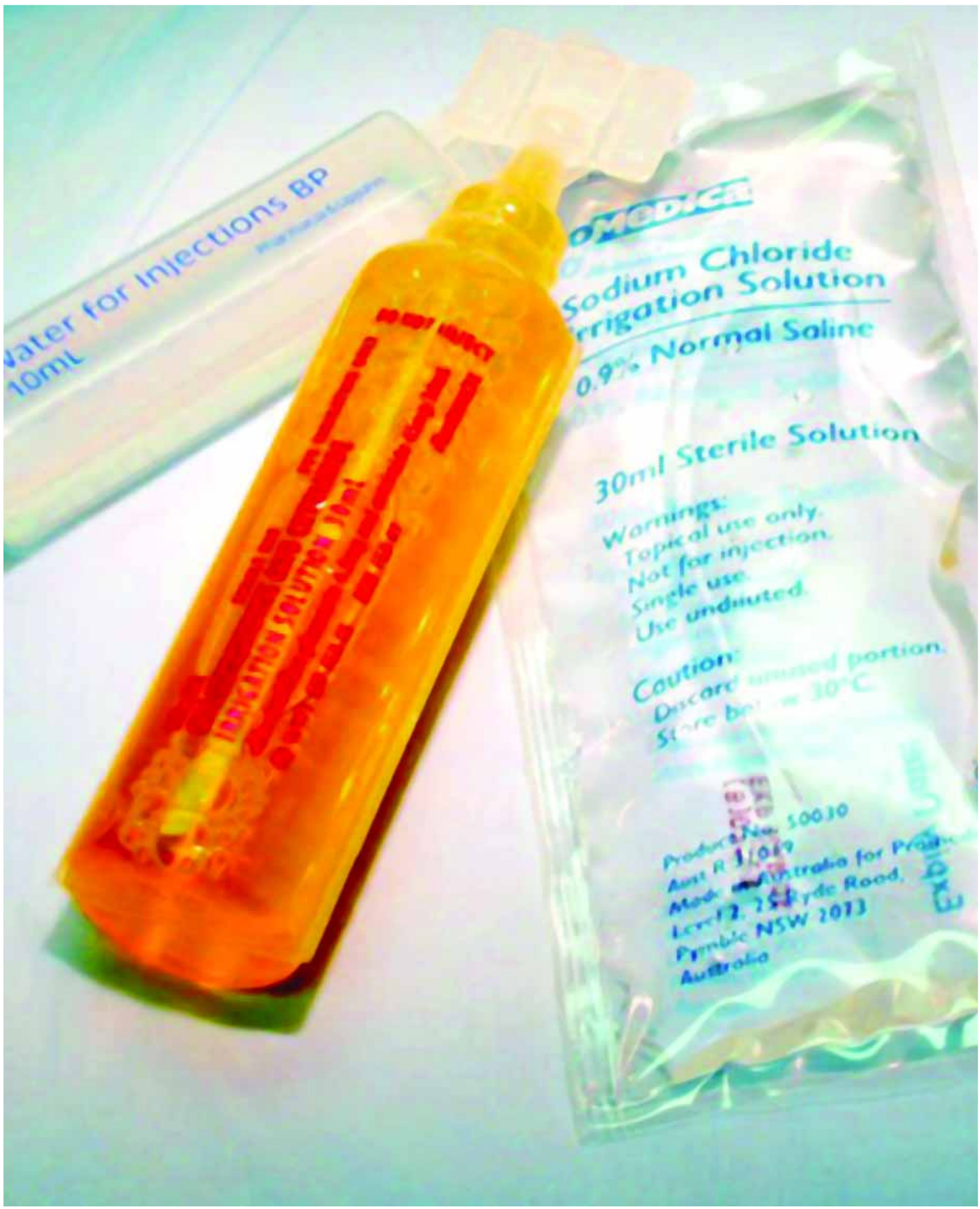
Changes are also proposed in the area of APIs. The traditional focus in pharmaceutical legislation has been on the manufacturing, import and marketing of finished products, rather than APIs, the commission notes. However, it is possible risks may also occur at the early stages of the production chain.

The commission therefore proposes a mandatory notification procedure for the manufacture and import of active substances, and mandatory regular audits of API suppliers regarding GMP compliance. Authorities should be able to carry out inspections of API manufacturers to verify compliance with good manufacturing practice (GMP) at any time, rather than just when non-compliance is suspected, as is the rule at present, it says.

next steps

The public consultation on the proposals is open until May 9th. The commission says it would like all stakeholders to comment, including citizens. These responses will be taken into account when the commission proposes changes to the legislation, as will the results of the earlier commission study on counterfeiting.

ian.schofield@informa.com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Not for injection.
Single use.
Use undiluted.
Caution:
Discard unused portion.