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PGEU Response

Public Consultation in Preparation of a Legal Proposal to Combat Counterfeit Medicines for Human Use

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1. Introduction

The Pharmaceutical Group of the European Union (PGEU) is the European association representing community pharmacists in 30 European countries including EU Member States, EEA countries and EU applicant countries. Within the enlarged EU, over 400.000 community pharmacists provide services throughout a network of more than 140.000 pharmacies, to an estimated 46 million European citizens daily.

PGEU welcomes the opportunity to respond to the Commission's Public Consultation in preparation for a legal proposal to combat counterfeit of medicines for human use. Please note that our response has also received input from the *Fédération Internationale Pharmaceutique* (FIP), the international body representing pharmacists.

2. General Comments

PGEU accepts the fundamentals of the Commission's analysis with regard to the growing threat of counterfeit penetration into the European supply chain.

While all international trade in counterfeit goods is to be deplored, the counterfeiting of medicines is particularly threatening, not simply because of the potential to cause death, injury or suffering, or the failure to provide therapy, but also because of the adverse consequences that would follow from a loss of confidence in the medicines distribution system (perhaps leading to, for example, under or over use of medicines).

Our view has always been that the correct approach should be one of precaution. While some parties argue that the situation in Europe is not yet sufficiently serious to warrant legislative change, in the view of PGEU we cannot and should not wait to act until the loss of confidence referred to above occurs. That would be too late.

While action is needed and justified, the Commission will be aware that new regulatory approaches to an already highly regulated sector are not without risks. Of course, in no sector would the degree of regulation proposed by the Commission be cost free. In the health sector, two factors make the situation particularly complex. First, there is the need to control costs in a sector that is extremely sensitive to cost pressure. To the extent that costs are absorbed by governments, there may be knock on effects for other areas of health and medicine expenditure. Where costs are borne by sector actors themselves, there is a need to ensure that the viability of actors in the sector is not undermined.

Second, the essence of the medicines distribution system is availability of,and access to, medicines. Measures which have the overall effect of reducing availability or making accessibility more difficult need to be resisted.

So ideally, measures adopted by the Commission must, to the greatest extent possible, effectively target the counterfeit threat while minimising costs and disruption to a system which by most standards serves the European patient very well.

PGEU welcomes therefore the indication from the Commission that all the proposed measures will be subject to a full impact assessment. Such an impact must take into account not simply immediate cost to market actors, but the wide range of additional costs potentially generated through the health system as a whole.

It is also worth pointing out in this regard that in PGEU's experience, the thoroughness of such impact assessments varies in quality. In respect of the initial impact assessment undertaken for the Commission's initiative, the timeframe for the response to an extensive and detailed list of questions was two weeks, coinciding with the Easter holiday period. That should not be acceptable to the Commission. The potential impact of the proposals is profound, and impact assessments need to be taken seriously.

It is also worth noting two further key points. The first point is timing. Some of the proposed measures are relatively straightforward legal changes that can be implemented quickly. Others would require both legal changes and a high degree of technological investment. The latter cannot be achieved quickly. The Commission needs therefore to consider carefully its strategy for legislative implantation, to ensure that necessary, appropriate and achievable actions are not subject to delay on the basis that they are linked to more ambitious and longer term projects.

The second point is about equity. Any European initiative should aim to ensure that is equally effective across all Member States. But the costs of some initiatives may fall disproportionately on less rich Member States, many of whom are already struggling with rising pharmaceutical costs (a medicine pedigree would be an example). But if some countries are left out of an initiative, even initially, they will inevitably become targets for counterfeiters driven out of other markets. The Commission should bear in mind that a two tier approach to the problem will not be acceptable.

Comments on Specific Proposals

Subject to the proviso that there should be a thorough impact assessment of all measures, PGEU finds much to welcome in the consultation. The proposals in relation to auditing and wholesaler obligations (4.1.1), inspections (4.1.2 and 4.3.3), GDP certification (4.1.6), products imported for export (4.2), active ingredients (4.3.1), are positive and constructive proposals. We will restrict our comments therefore to areas of particular concern, save for four general observations.

First, the provisions of Article 48 and 49 of the Directive 2001/83 should specify that the 'qualified person' should be a pharmacist (some Member States have in fact specifically provided for a pharmacist to assume this role). It is logical that the individual who undertakes this role, of increasing importance in the detection of counterfeit penetration, should be a specialist in medicines rather than holding the peripheral qualifications referred to in Article 49.

Second, although criminal sanctions for counterfeiting are outside the EU's competence, the EU could take the lead in encouraging and co-ordinating the approach of Member States to pharmaceutical crime. It is widely recognized that current penal approaches are insufficient to deter counterfeiters.

Third, the proposed database of wholesalers should contain details on specific licensed activities (recent counterfeit cases involved wholesalers licensed for clinical trial products supplying to community pharmacies).

Fourth, pharmacists are involved in compounding medicines, that is to say the preparation of medicines out of raw materials and active pharmaceutical ingredients (API). The requirements in respect of mandatory notification should also include mandatory compliance

of product with pharmacopoeia in order to increase the protection afforded to compounding pharmacists. The issue of the quality of API has been recently highlighted through the tainted heparin case detected in the USA or through the death of hundreds of Panama patients in 2007 due to glycerin containing di-ethylen glycol which has transited in Barcelona (where an European company issued a fake analysis statement on the product).

1 Selective Authentication

The Authentication of individual medicine packs is, without much doubt, an effective way to catch counterfeited products that are already in the system (although of course, it would be preferable that the products did not enter the system in the first place.). Such an authentication system is already being piloted in Greece and Belgium and is the subject of an initiative by EFPIA (the two initiatives are not linked, and the EFPIA initiative is still in the conceptual phase). The advantages are clear: pharmacy level authentication provides a very high degree of assurance that the final act of distribution, dispensation, is free from counterfeit penetration. In addition, such authentication systems can facilitate recalls, and have notable ancillary advantages in terms of, for example, reimbursement fraud.

There are however some drawbacks.

First, authentication depends on mass serialization of individual products. This is happening in a patchy and uncoordinated way in different EU states (ranging from 1 dimensional bar codes in Belgium to consideration of Radio Frequency Identification in Spain). There are costs involved of course, and these maybe more difficult to absorb by manufacturers of lower value products. Additionally, the absence of a single European system of serialization will prevent the downward pressure on costs generated by economies of scale.

Second, there is cost involved in providing the equipment and the broad band connections necessary for the system to work efficiently. These costs can be relatively modest depending on the technology employed, although there must be a risk that sophisticated technology would have an excessive impact on the cost structure of community pharmacy.[1]

Third, authentication systems, since they are based on individual transactions, generate product and location specific sales data. The ownership and use of such data (which has very significant commercial value) would need to be thoroughly considered, as well as the data protection and privacy issues involved.

Fourth, the practicalities of such systems would need to be carefully considered, including for example, the potential of the authentication process to interrupt the work flow of the pharmacy.

PGEU does not believe there is any insuperable obstacle to a Europe wide system of pharmacy level authentication, provided the issues above can be addressed.

It must be said that the way this issue is dealt with in the consultation seems unsatisfactory. First, it is very unclear which products will be selected for authentication, for what period, and selected and authenticated by whom. Second, in previous discussions with PGEU the Commission has suggested that authentication systems would be disproportionately

[1] There is also a significant issue as regards integration of such a system with existing pharmacy software

expensive. If so, and bearing mind that proposals such as those of EFPIA are intended for all prescription only products, then selective use of authentication must be more disproportionate still. There would be a similar degree of fixed costs involved (serialization, databank, software and scanners and so on) but for a smaller range of products. That doesn't seem to make economic sense.

It is possible that more European governments will pursue some form of serialization strategy in the future. Given the possibility for fragmentation that would represent, there may be a case for a more thorough treatment of the issue than is presented in the consultation.

2 Medicines Pedigree

As the Consultation correctly notes, a pedigree system is currently being considered at WHO level, and has been implanted or is in process of being implemented in some US states. Another way of describing such a pedigree is a track and trace system, with the medicine tracked until the pharmacy door. Used in combination with authentication, the medicine would be traceable into the patient's hands.

The implantation of a medicines pedigree (presumably an electronic pedigree) on a Europe wide basis would be a very significant undertaking. Its costs would unquestionably exceed the cost of a point of dispensing authentication system, although admittedly with the additional advantage of helping to prevent counterfeit penetration further back in the supply chain (for example, the system would require complex interoperable technology for every supplier in the chain, as well as reconfiguration and coding or tagging of all packs). It is perhaps notable that the Californian pedigree system, perhaps the most ambitious system, has recently been delayed, at least partly because of cost concerns. The Commission should note also in this regard the comments about equity made in the general comments section.

The medicines pedigree may be an example of an approach to counterfeiting that is desirable in theory, but on a Europe wide scale simply unrealizable in the near future given the very substantial costs involved.

3 Repackaging

The proposals on repackaging are perhaps the most controversial on the Consultation. Repackaging is of course intimately linked with the parallel trade in medicine, although the consultation doesn't mention this explicitly.[2] The pharmaceutical industry is of course passionately opposed to parallel trade, although it is sometimes unclear whether this opposition is based on claims that repacking is inherently unsafe, or on claims about the risk of counterfeiting. In any event the Commission seems to accept the latter claim.

Clearly, the proposals would have an effect of discouraging parallel trade in medicines. Parallel traders would not be permitted to repackage and would need to find other ways to comply with requirements. But medicine packs which are delivered with, for example, the patient information leaflet attached to the outside, will not be acceptable to many patients. Such medicines may give the impression of being of inferior quality, which is of course not the case for an authentic parallel import. There must also be some concern that possibly

[2] A footnote acknowledges the effect of repacking restrictions 'by actors in the distribution chain'.

dangerous confusion will be caused due to patients dealing with multilevel packaging and more than one leaflet.

A further consideration is the selection of products to be sealed, since, as with the authentication proposal, the Commission does not apparently intend to cover all medicines. It is not clear from the proposal who would make that decision and on what basis. The decision is likely to be highly contentious, since the pharmaceutical industry will lobby for the inclusion of as broad a range of medicines as possible, while some Member States and other parties may have an interest in the cost savings arising from parallel import.

The Commission should also bear in mind the growing practice of preparing medicines for dispensing in specific doses, and also the need for pharmacists to adapt original packaging doses to the needs of patients. This practice is not linked to repackaging for parallel trade, but does involve opening packs to prepare doses. A ban on opening the seal in the terms set out in the consultation would make this impossible. Although the consultation seems to indicate that health professionals would be permitted to break the seal, there would need to be an unambiguous definition of 'end user' (including pharmacists) in the wording of any legislation.

Finally, the measure could only address counterfeit penetration at the level of repackaging itself, and not the placing in circulation of complete packs, since in the latter case the seal itself could presumably be faked.

This is another area where a through impact appraisal is vital.

4 The Dangers of Acquiring Medicines through the Internet

Finally, there is a surprising lack of consideration in the Consultation of counterfeit penetration through the internet. As is well known, it is through the internet that most counterfeit medicines reach the patient. WHO estimates that 50 per cent of 'medicines' bought through the internet are fakes. This is a problem that can hardly be ignored and which indeed has also been signalled by the Commission before[3].

The Consultation makes only passing reference to the internet, and does not explain why this should not be an issue covered by the consultation.

Paradoxically, while the Commission rightly expresses concern at the threat from counterfeit penetration, other aspects of Commission policy in the competition and internal market area are designed to encourage on line purchase (for example through the encouragement of discounting and price competition for prescription medicines, and of reimbursement for cross border purchases).

An unequivocal position from the Commission on the dangers of acquiring medicines through the internet, together with support for those EU States who wish to restrict or regulate internet trade in medicines, may be as useful as some of the more ambitious proposals in the Consultation, and certainly cheaper.

END

[3] Commission Communication (COM(2005)479)