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PGEU Comments

PUBLIC CONSULTATION ON THE EC LEGAL PROPOSAL ON INFORMATION TO PATIENTS

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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 160.000 pharmacies, to an estimated 46 million European citizens daily.

PGEU's objective is to promote the role of pharmacists as key players in healthcare systems throughout Europe and to ensure that the views of the pharmacy profession are taken into account in the EU decision-making process.

PGEU welcomes the opportunity to respond to the Commission's proposal for a legislative change in relation to patient information relating to medicines.

However, following the consultation processes undertaken during 2007, the parallel ongoing impact assessment to which PGEU has contributed, and also the extensive work in this area undertaken by the Pharmaceutical Forum PGEU believes the proposals do not fairly reflect the range and depth of debate that has taken place.

In the view of PGEU, the proposal is severely flawed. In our response, we set out our view of the principal weaknesses of the proposal.

2. Basic Principles

PGEU acknowledges that some patients look to a variety of sources for information regarding their medicines, including the internet, and that some patients have specific information needs that cannot be always met from traditional sources. The fact remains (as the consultation and numerous surveys also recognize) that health professionals such as pharmacists and doctors remain the primary source of easily accessible and reliable information in relation to medicines. It is crucial that any legislative developments in this area support and sustain that role.

In particular, information provided to patients generally, (for example through mass media channels), will not address the specific needs and circumstances of individual patients.

However, if the legislation is to be changed in this area, in particular if the pharmaceutical industry is to be given more scope to 'push' information to patients – an option the PGEU rejects -, then it is of fundamental importance that public confidence in the integrity of information provided in this way is maintained. In particular, such information should conform to established quality principles, and be subject to validation, prior to dissemination (ex ante). The pushing of information by the industry should never be a proxy form of promotion or advertising, although we would argue that in under the Commission's proposals as they currently stand, it inevitably will be.

Finally, the sole justification of any change in this area can only be to help patients, and not to grant more commercial freedom to the pharmaceutical industry. The consultation gives the impression that that principle has been overlooked.

3. Comments to the Commission's Proposal

(1) Sanctions

The proposals do not envisage a system of validation. Ex Ante actions are specifically ruled out (paragraph 3.3.2). Instead, the only substantial obligation vis a vis the National Co-Regulatory Body will be to 'announce information activities' (it is not clear whether this means each particular episode of information 'pushing' or a general pushing with regard to a particular medicine).

If the information breaches the Quality Criteria, then the Commission envisages a system of sanctions. The first sanction appears to be public embarrassment, followed by presumably fines for 'repeated and severe cases of non-compliance'.

Therefore although the proposals reject self regulation as a solution (footnote 2), there is a strong reliance on the willingness of the industry to exercise self restraint. This is particularly so as the benefits from dissemination of promotional information may be greater than any threatened public embarrassment (particularly where such 'embarrassment' comes months after the event, and receives little press coverage). Given that the proposals envisage dissemination of information in the mass media, the risk benefit structure might be highly attractive to the industry.

This assumes of course that the industry is interested in the promotion of its products, and would contemplate breaching codes of conduct and the like. The first assumption is undeniable, and well documented. The second is also borne out by the experience of some countries with self regulation. Breaches in the UK, to name but one, were so common for example that in 2005 an investigation by the UK Parliament into the industry concluded that:

"…..the examples cited to us of breaches of advertising regulations, cover up of negative medicines information and provision of misleading information to prescribers, suggest that self regulation is not working satisfactorily."
(The Influence of the Pharmaceutical Industry report of the House of Commons Health Committee 2005, para 227)

While the Commission is not proposing self regulation, by excluding a system of validation, and proposing a weakened sanctions system for a first offence, it opens the door to abuse.

(2) The Pharmaceutical industry as judge in its own cause
The weakness of the sanction system set out in the proposals is compounded by the fact that the proposals specifically provide that the pharmaceutical industry should form part of the national co-regulatory body. Although the more severe sanctions would be imposed by the national competent authority, it remains true that industry representatives would determine the initial disciplinary measures against its own members. This is the case of course with self regulatory systems, and as mentioned above, the experience has not always been a happy one.

It is suggested that the place of the pharmaceutical industry in the co-regulatory body is justified by the fact that industry has a collective interest in ensuring that its members do not breach the rules, both because the industry as a whole suffers reputational damage as a result, and because breaching the rules may bestow a competitive advantage on the parties willing to do it.

But this is flawed, because while individual instances of malpractice may be unacceptable to the industry as a whole, there is a collective interest in encouraging a weakening of the

rules. There is clearly a danger that the industry will encourage a relaxed view of breaches as a strategy to weaken the system of sanctions as a whole.

(3) Quality Criteria

The scope of the information that might be provided under a 'pushing' system is fundamentally important. PGEU welcomes the fact that in the Commission's view the information provided should not go beyond -the 'key elements' in the Patient Information Leaflet. It is disappointing to see that the Commission contemplates additional categories of information, including scientific studies and prices. If scientific studies are to be included, then the industry must be required to disclose who funded the studies, since industry influence on such studies is well attested, and their tendency to partiality well known .It is not at all clear why prices are relevant (prices to whom? Governments and insurers? Co-payers?)

There are two other significant problems in this area. First, paragraph 3.2 states that 'Communication not covered by the definition of advertising should be regarded as information'. This is precisely the wrong way round, and cannot be correct since there is effectively an extended definition of information, but only a vague definition of advertising. Clearly the working principle should be that anything which does not comply with the quality criteria is advertising, otherwise compliance with the quality criteria would be meaningless.

Worse, while PGEU welcomes the incorporation of the quality criteria adopted by the Pharmaceutical Forum, we do not understand why they have been adulterated. These criteria, let us recall, were adopted by the full Pharmaceutical Forum (members of each member state plus stakeholders, including the industry). Industry approved them. What possible justification can there be therefore for excluding the definition of unbiased, which was robust, and replacing it with a new category of 'non-promotional' with a very weak definition. The definition states that information should 'focus on guiding patients to the correct and safe use of medicines'. Apart from the fact that the word 'focus' implies only that some elements of the information (non-focal ones) should be non-promotional, the definition is clearly compatible with medicines promotion, because promotional presentation of the product can take place within a general statement about correct use. This is true of any product, from food to detergent.

It would be interesting to know why the collective opinion of Europe's governments and stakeholders is not good enough.

(4) Inequalities and Subsidiarity

The Commission bases its proposals on the basis that there are inequalities between member states with regard to access to information (paragraph 2.1).

This does not of course justify the particular proposals put forward, because it does not follow that increasing equality of access requires a push mechanism for industry. What the Commission is proposing goes beyond what would be necessary to ensure greater equality, or even wider dissemination of information, because neither of those objectives requires direct industry involvement in the pushing of information.

While it is true that patients who do not read English or are not computer literate have fewer options for sourcing information, (a problem within Member States as much as between them) the variation in rules and practices between Member States referred to in

paragraph 2.1 line 13 is equally a reflection of legitimately differing national approaches to the issue, and is a common feature of any nationally implanted European rules. After all, it is the Member States and not the EU who must manage and finance their health systems, and who therefore may be in a better position to make judgments about how information is disseminated.

In fact however, the only way to have the kind of uniformity which would minimize inequalities between Member States would be to have a system totally managed and implemented at European level. The Commission must know that this is legally and practically impossible. What the consultation proposes however is a confusing hybrid system, in which it is unclear where power lies.

Thus, the Advisory Committee described in section 5 must be consulted but appears to have absolutely no powers. It exists in a legal limbo, dispensing advice but unable to compel. But what useful advice on national situations could such a body provide? There is no scientific element, as the consultation admits. If the purpose of the body is to ensure even interpretation of the law, then that is better left to the Courts.

The National Co-Regulatory bodies could in fact adopt codes of conduct that are variable and even mutually incompatible. If the real aim of the proposal is to promote equality, this is a serious weakness.

4. Cross-linking the Information to Patient proposal with the Pharmacovigilance proposal

The EC legal proposal for a strategy to better protect public health by strengthening and rationalising EU Pharmacovigilance is significantly simplifying existing requirements in order to shorten as much as possible entry to market of new medicines or medicines with new indications, trusting on the robustness of the post-authorisation pharmacovigilance.

If this proposal is linked with the proposal to allow push information, PGEU has serious concerns about the protection of public health. There is nothing in both legal proposals that will prevent the marketing authorisation holder to refrain from pushing information to patients on newly authorised medicines, though they are included in a “list of intensively monitored medicines” due to the fact that their benefit-risk profiles have not been sufficiently tested. In our opinion this should be considered carefully as there must be certainty that removal of delays does not involve any degree of extra risk for the patient.

5. Conclusion

The Commission’s proposals are a missed opportunity. The legitimate concerns of patients could have been addressed while recognising the well founded concern about industry involvement in this area. Instead they offer a future in which the pharmaceutical industry can freely communicate information about its products in the mass media, but with a system of weak sanctions, conflicts of interest at national level, and a watered down system of quality criteria.

It reads as a document which has little to do with the needs of Europe’s patients, and everything to do with the agenda of the pharmaceutical industry.

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