

G 10 Medicines

HIGH LEVEL GROUP ON INNOVATION AND PROVISION OF MEDICINES

CONSULTATION PAPER

Response of the Portuguese National Association of Pharmacies (ANF)

The Portuguese National Association of Pharmacies (Associação Nacional das Farmácias - ANF) represents a significant part of the pharmacies in Portugal, with around 2.500 pharmacies' members.

The main objectives of ANF are related with the improvement of the quality of the pharmacy service rendered to the population, the enlargement and the deepening of the pharmacy intervention areas and the reinforcement of the role and the intervention of the pharmacists in the healthcare system.

The ANF welcomes the opportunity to respond to the Consultation Paper (the paper) issued by the Enterprise Directorate General of the European Commission related with the work being developed by the G 10 Medicines Group (G 10).

This submission is in two parts: the first one presents general remarks to the whole content of the Consultation Paper and the second addresses more specific comments to the several sections of the paper.

I - General Remarks

Firstly, we find that the composition of the G 10 doesn't fulfil the dimension of the matters the group wants to deal with. Although Health Ministries are members of the group, this is not sufficiently enough to bring to the discussions the contribution of health professionals, who are also important partners of the healthcare systems of Member States.

Even recognising that the issue is of the pharmaceutical industry concern, which has the majority representation in the Group, it is also related with other health care partners as proven throughout the Consultation Paper. Therefore we believe that this fact will contribute for the lack of balance in the debate and final conclusions of the G 10 work.

Thus we request that, and in what concerns the community pharmacist profession, PGEU (Pharmaceutical Group of the EU) should be invited to nominate representatives to attend at least the workshops established to consider and comment on any topics that have

implications for community pharmacies, pharmacists and the patients they serve. The PGEU represents the community pharmacists in the 15 Member States and has the support of pharmacist representative bodies in other 12 European countries of the European Economic Area and in applicant countries for EU membership.

In second place, the whole document states the will of introducing into the market innovative medicines, which *per se* is positive. However, it seems that the paper wants to give the idea that are the patients who will support, not totally but in great share, the potential higher price of those medicines. In fact, when the paper refers to costs is always in the perspective to save in order to:

- invest (public investment) in R&D, which is an approach that will benefit at first the pharmaceutical companies;
- or to pay innovative medicines, which price is usually high, culminating in the proposal of underestimate the cost-effectiveness analysis from the process of marketing authorisation (paragraph 3.7, first bullet).

We recognise that at this point we are clearly getting away from what has been the policy followed by many Member States regarding health care.

The Member States are sovereign in matters of "pricing", which makes any recommendation against this current practice totally out of sense. In our opinion, the principle of subsidiarity should be respected in all matters.

Regarding the promotion of generic market - solution which contributes to reduce substantially the public expenses with medicines - the concerns expressed are the ones of the industry, namely the problem of the end of the patent rights and its possible extension. Although the paper stresses the importance to give incentives to generic medicines, it doesn't refer the generic prescription and also the potential intervention or role of the pharmacist in its greater use.

Concerning the main worry with the competitiveness of the European industry, the Consultation Paper never specifies in a clear way to what situation it is referring.

The European pharmaceutical industry is divided in several categories of companies. On one side, there is the small company with a traditional role which survives with difficulties and, on the other side, the small high tech company, well positioned in the market, which does not fear the global competition; and at last but not least, the pharmaceutical giants. These are perfectly integrated in the globalisation market trend and, therefore, it seems to us that it is a little bit theoretical to classify those multinationals as European, American, etc. Public data shows that they are not facing severe economic difficulties.

At last, ANF is very concerned with the approach of the G 10, which considerations seem to deal with medicines as "ordinary goods".

As a remainder of this is the fact that in the relative near future, the Council and the Parliament will be considering a new Draft Directive, following codification and

consolidation of the Directives applying to this special category of products. The Draft Directive will continue to cover every activity relating to medicines, such as licensing for manufacture, marketing authorisation, labelling and package leaflets, wholesaling, advertising and pharmacovigilance.

The G 10 should start from the premise that medicines market is unique and it should recognise that, in this special market, the objective must not be to promote maximum sales but rather to ensure that a medicine is used only when appropriate and for the shortest period required to achieve the desired therapeutic outcome. These principles must be applied to all medicines without making distinctions between prescription-only medicines and non-prescription medicines.

It is crucial that the G 10 approaches its deliberations from that perspective.

II - The Consultation Paper

1. Pricing, co-payments and reimbursement

Regarding this first section we believe that it is very important to look into this issue through the principle of subsidiarity. As community pharmacists, we think that individual Member States should continue to exercise the right to determine and implement the policies on distribution and pricing.

If a member state wishes to:

- Recognise that responsible care, including appropriate self-medication, will reduce the pressure on other health care resources and government expenditure;
- Confine availability of non-prescription medicines to pharmacies so that professional advice will always be available at the point of potential supply;
- Ensure that an effective network of pharmacies is maintained to ensure that the vast majority of EU citizens have convenient access to at least one pharmacy;

then it will recognise that distribution costs must take into account the expenses necessarily associated with these health care policies. The distribution cost structure must reflect, among other factors, that when advice is sought on self-medication, the correct and responsible professional advice often is that no medicine should be purchased but some other course of action, usually to consult another health professional, should be taken.

Should a member state decide that price controls for such medicines are not required to ensure a high level of public health protection and responsible self medication, it is vitally important, that strict controls are imposed on the ways in which these medicines can be presented and promoted to the public. Methods of presentation and promotion that would encourage members of the public to treat medicines as ordinary articles of commerce should not be permitted. This would obviously mean a continuation of the current ban on promotion of sales by the provision of free samples of medicines to the public. In addition, marketing strategies such as “buy one get one free”, “three for the price of two” or any other marketing device designed to encourage people to increase the quantity of a medicine they purchase at one time, should also be banned.

2. Information and protection of patients

The ANF is firmly in favour of the proposal in 2.10 that the existing ban on the advertising to the public of prescription-only medicines should be maintained.

However, in paragraph 2.12 is mentioned the "proposed opening up of the Advertising Directive as part of the review of the pharmaceutical legislation". In our opinion, the way the Commission intends to "open up" the Advertising Directive (Directive 92/28/EEC) will lead to confusion rather than clarity on the distinction between advertising and patient information.

The experience of the US should be brought here to highlight the risks of this issue. The Food and Drug Administration (FDA) sparked the recent rapid growth in the mass media marketing of prescription-only medicines when, in 1997, it clarified rules pertaining to such ads. The action made it easier for companies to launch TV, print, and radio ad campaigns.

Pharmaceutical companies spent \$1,8 billion on mass media advertising (also called direct-to-consumer advertising or DTCA), up 38,5% from the \$1,3 billion spent in 1998. Television ads accounted for the bulk - \$1,1 billion - of the expenditure, up 70% from 1998.¹

Presently in the US, the top selling prescription-only medicines, in a short period of time after its marketing authorisation, are the ones that are advertised directly to the consumer.

According to figure in Annex 1 (Top Selling DTC promoted drugs), the 25 drugs that contributed most to the increase in retail sales of pharmaceuticals in 1999 accounted for 40,7% of the overall \$17,7 billion rise in spending. Most of these medicines were heavily advertised to the public and experienced a sharp growth in sales - an aggregated 43% in a single year. In contrast the growth in sales for all other prescription-only medicines from 1998 to 1999 was 13,3%. For all medicines combined, spending rose 18,5%.²

Still in 1999, the DTCA was responsible for 27% of the \$6,6 billions that pharmaceutical industry spent to promote directly its products to doctors and consumers.³

We think that, in practice, it would prove to be impossible to control adequately "the information" about prescription-only medicines provided by manufacturers (2.4) and the experience of the US highlights well this difficulty. The pharmaceutical industry cannot be seen as the correct source of reliable, factual and balanced information about medicines, in the absence of a pre-vetting of the information to be provided for general access, by a national authority or the EMEA. This is the best way to ensure what is pointed out in paragraph 2.4 "properly regulated European information".

In paragraph 2.6, it is recognised that "the prescriber and the pharmacist will continue to play an important role in providing patients with independent and objective information on medicines and their treatments." Therefore official sources of information could include on each SPC and package leaflet text, advice to consult a pharmacist or physician if more information is required, as the direct contact between patient and pharmacist serves to ensure that information is well understood by the patient.

Finally, in paragraph 2.14, which refers to the need of reviewing arrangements for post-marketing surveillance, we agree that it is important to have co-ordinated processes in place in each Member State to collect data on adverse events and patient safety. The integration of community pharmacists in pharmacovigilance schemes would be very useful to improve

¹ "Prescription Drugs and Mass Media Advertising, Research brief, NIHCM Foundation, September 2000, page 1.

² Idem, page 3.

³ Idem, page 1.

these schemes. Pharmacists are in a privileged position to report adverse events for both prescription-only medicines and non-prescription medicines, especially those recently switched from prescription control. This happens already in some Member States, but unfortunately not all.

3. Evaluating cost-effectiveness

Regarding section 3, the statement in paragraph 3.7 must be weighed. The criteria of safety, quality and efficacy of a medicine is undoubtedly important but the cost-effectiveness criterion must not be underestimated.

We consider this a useful criterion and its use falls under the principle of subsidiarity.

4. The Science Base

Concerning specifically:

- paragraph 4.8 (*Improved technology transfer, industry / academia liaison, etc*)
- paragraph 4.8.1 (*Foster the exchange of human and financial resources between the public and private sectors through increased industry/academia links*)
- and paragraph 4.10.1 (*...promote bilateral and multilateral research co-operation*),

there is no doubt that one should recognise the importance of this interaction between the public R&D (financed with public resources) and the private R&D.

However, it is also very important to establish clear background rules that can protect the public interest related with R&D financing.

If public health protection remains the priority at all times, special attention should be given to this kind of co-operation which is financed by European citizens who should benefit from a fair price in innovative medicines discovered with public funds help.

5. Competitiveness, benchmarking and innovation

The paragraph 5.5 states that *"there is a risk that the implementation of the Bolar provision could significantly alter this balance without appropriate measures to increase protection of new indications"*. We believe that the level of the present intellectual property protection should not be increased. The industry has been benefit from a fair protection period of time given by patents. If patent life is extended, that will delay the introduction of generic medicines into the market. This kind of policy is the one that affects the public interest and raises the expenses of citizens and health care services.

For certain regions of the world and diseases and in case of emergency and/or public health reasons, we also support the reduction of patent life, in order to permit the production of

generics. We are very supportive of the Doha Declaration on the TRIPS_Agreement and Public Health, which has resulted from the last Ministerial Conference of the WTO.

Continuing with the comparison with the US and Japan, the G 10 Consultation Paper stresses once more that health policies should promote the introduction of innovative medicines. It is important to highlight that health policies should focus on the Member State needs at first place and only after on the benchmarking process, as the solution for the problems of the health care systems in Europe (having the US and Japan like role models).

If any workshop, working group or other type of meeting is created to debate benchmarking of any aspect of the work of the G 10 that has implications for the professional services provided by community pharmacists and other health professionals, we believe that PGEU should be invited to participate. It is very important that experts from the community pharmacy sector should be in a position to contribute to discussions when ideas are being formulated rather than at the stage of consultation when a document is already prepared.

The regulatory structure for medicines, their classification, distribution policies and pharmacovigilance are all topics of vital importance to the community pharmacy sector.

Regarding paragraph 5.7 (*last bullet related with the institution of a European pharmacovigilance institute*), ANF fully supports this project.

6. Single market and fragmentation

The proposal made in paragraph 6.13 (*Allowing direct access to the non-reimbursed market after licensing at a price determined by the manufacturers without delay*) seems to transform this sector in a purely commercial one, without having in mind any public health concern. Once again the licensing systems for medicines is an issue that belongs to the scope of action of Member States (principle of subsidiarity).

There are social, economic and financial reasons that justify the sovereignty of Member States on these issues.

In paragraph 6.15, the promotion of generic prescribing and dispensing is raised as it is in 1.8. ANF recognises that the promotion of the market share of generic medicines can be an important factor in cost containment within the expenditure on pharmaceuticals. Member States may therefore wish to promote increased use of these medicines, by encouraging generic prescribing or by other means. Community pharmacists in several Member States are already making a significant contribution to cost containment exercising their professional expertise by dispensing generic medicines.

Community pharmacists know from experience that for a patient on long term medication, any alteration in the appearance of a medicine from that obtained previously can raise concern and doubts about the equivalence of the product newly supplied. Pharmacists have an important role to play in reassuring patients and thus maintaining the confidence that is

essential to ensure successful treatment. The representatives of community pharmacists should therefore be involved from the outset in discussions at Member State level on any scheme that is intended to encourage greater use of generic medicines, including schemes to promote generic prescribing.

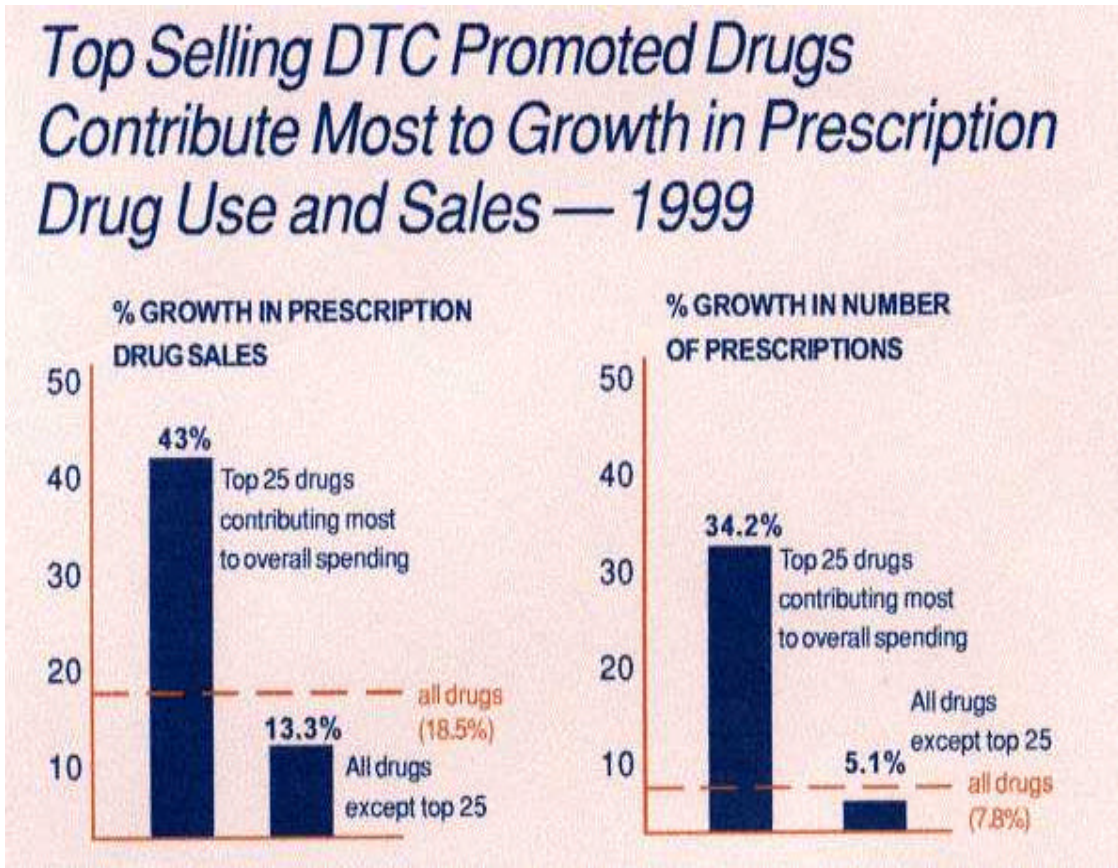
7. Generics

Although great savings in secondary healthcare costs have resulted from the introduction of innovative medicines, for example for the treatment of gastric and duodenal ulcers and hypertension, we think that generics will have a decisive importance in cost containment.

We would go further and state that every effort should be made to assess savings in social care or social security expenditure resulting from the introduction of breakthrough medicines and reflect these in the setting of the budget for expenditure on medicines.

We are somewhat puzzled about the insertion in this particular section of the distribution costs concern (7.5, last bullet), as this particular sector may assume a vital importance in the promotion of the generics use, for what was already mentioned before.

ANNEX 1



Source: "Prescription Drugs and Mass Media Advertising" NIHCM, September 2000.