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Answer to the consultation paper of the G10 Medicines Group (See CP 2001/151 – Compilation of comments)

Réponse à la consultation du groupe « Médicament » appelé G10 (Voir CP 2001/151 – Compilation de commentaires)

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Comments on the consultation paper of the G10 Medicines Group

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2. Information to patients
3. Evaluating cost-effectiveness
4. The science-base
5. Competitiveness, benchmarking and innovation
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1. Pricing, co-payments and reimbursement

In principle, it has to be stated that the distribution and the pricing of medicines and medicinal products do not constitute a medical problem, as long as medicines, which are needed for the therapy of patients, are available to them. Due to their specific nature and their national legislation, national health care systems play an important role, as they reimburse costs in nearly all European countries, partly with patient co-payment. Rapid developments in medical and pharmaceutical research and the development of new, increasingly specialised medicinal products and medicines have made the health care market one of the sectors with the largest growth potential. This fact as well as demographical developments as such, contribute to the phenomenon of sharply rising costs in the health care sector of all European States. Irregardless of the different financing modes of the European health care systems, it has to be stated from the medical point of view:

1. The use of generic medicines

The decision about which medicine is the most appropriate in a given therapy is jointly made between the physician and patient.

Physicians should have the freedom to prescribe the most appropriate medicines for their patients. In doing so, they must also discharge their responsibility to use resources as effectively as possible.

The most important points to consider when discussing the use of generic medicines are :

1. the need to guarantee that generic medicines are of the same pharmaceutical quality as branded medicines
2. the need to designate generic medicines by their international non-proprietary name (INN)
3. to establish formularies of generic medicines which may be dispensed by pharmacists when the doctor and the patient agree

4. to encourage the acceptance by both doctors and patients of prescription by INN

2. Self-medication

From the economic point of view, it is obvious that the pharmaceutical industry has strong interest in the promotion of self-medication.
From the medical point of view, however the risks related to self-medication also need to be pointed out clearly. Incompetent self-medication risks adverse reactions and may increase treatment costs. Patients, who are not medically trained may not always be able to consider possible interactions with other medicines. In addition, a generous liberalisation of the OTC market may lead too easily to a situation, where patients lacking information, have a higher consumption of medicines, which perhaps remain without effect or have a harmful effect. From the medical point of view, medicines shall by no means become consumption goods, they have to be used according to their nature, as substance for specific use for alleviating and treating diseases.
In the CP document 96/136 Final, "The common position of the CP, UEMO, UEMS on self-medication in Europe explicitely refers to the risks involved in self-medication, pointed out in detail in the above mentioned document.

2. Information to patients

The following remarks refer to the different paragraphs of Section 2.

2.1 – It is indeed necessary to insist on the fact that if patients are better informed then there is likely to be a better relationship between patients and doctors, and that it has been demonstrated that this relationship of confidence, based on an exchange of information, has a correlation with greater compliance with medicine use and dosage instructions and that, in all probability, it will lead to more efficient use of available health resources.

2.2 – It is clear that the pharmaceutical industry has the material and scientific means to provide reliable, factual and balanced information.
The industry currently has two major concerns which occupy it almost exclusively: on the one hand, innovation in sectors with high potential and, on the other hand, marketing activities using the most traditional means of the trade. Under these conditions, can we really hope for a spontaneous positive development towards providing information to patients that is reliable, factual and balanced? It would still be necessary to lay down rules on this subject and to supervise their application. This necessary development should be one of the objectives of the revision of European pharmaceutical legislation.

2.3 – It is quite correct that insufficient information is the main cause not only of patient dissatisfaction but also of legal actions against doctors. It is important to insist on the fact that information should in particular emphasise the benefits which can be reasonably expected from the treatment. Because of their failure to envisage the limits of this treatment, doctors have great difficulties themselves in managing the inevitable disappointments or treatment failures.

2.4 – The information contained in this article is quite correct. It refers to the need to revise European legislation on the subject.

2.5 – The question of changing the name of medicines when they change from prescription to non-prescription status is controversial. Each option has its advantages and disadvantages.

2.7 – This refers to the need to supervise closely direct communication between pharmaceutical companies and patients.

2.8 – This list can effectively be used as an outline for such regulation. It is important not to be limited to giving “indications” for medicines but to give details, with statistics if possible, of the benefit that one has the right to expect from such or such a treatment, in this case, from taking such or such a medicine. This is in no way part of the culture of the doctor-patient relationship, but the introduction and observance of this rule would indicate considerable progress in that relationship.

2.9 –CP is extremely wary of relaxing any of the constraints surrounding the advertising of "non-listed" medicines, that is to say those which can be obtained without prescription. Maintaining a priori controls, in countries which have them, is absolutely indispensable. Indeed, European legislation should impose a generalisation of such a priori controls if this has not already been done.

2.10 – This point is vitally important. The G10 is clearly distinguishing itself from the decisions of the FDA which for several years has authorised consumer advertising for prescription-only medicines. The most visible result of this measure is a near doubling of promotion expenses for these medicines, which has measurable consequences on the level of health expenditure in the United States. Patients' and consumers' associations themselves are now proving to be critical of it. What patients want is information, not advertising. In no way whatever can we consider that the liberalising of advertising for prescription medicines has improved communication and the relationship of confidence between patients and doctors. We cannot hide the fact that the opposite is more to be feared especially since consumer advertising of prescription-only medicines tends to annoy doctors.

CP supports the G10's firm position on maintaining current European regulation which does not allow consumer advertising of prescription-only medicines.

2.11 – The criticisms about the content of the "leaflets" included in packs of medicines for patients' and consumers' information are not new and on the whole are justified. Writing these leaflets is an extremely difficult exercise, particularly because of the different levels of interest and comprehension of their intended readership. As in all forms of information about medicines, there is a drift towards "defensive information" in the domain of leaflets too. The information provider is becoming increasingly worried about not being exposed to the complaint of having hidden such or such an aspect of the product which might lay him open one day to legal action. The spectre of medicine being brought within the jurisdiction of the courts hangs over the modest leaflet also.

The current rules set by European legislation, which are of a basically technical and regulatory inspiration, should effectively be reviewed in favour of a design and mode of writing and presentation which are defined in cooperation with representatives of patients and consumers.

2.12 – This point has already been mentioned in paragraph 2.10. It should be emphasised that the guidelines put forward by AESGP could of course be applied only to medicines that can be obtained without prescription.

The idea of setting up a European structure comparable to the American CDC seems an excellent one: such a centre would help to fill in gaps and correct the regrettable heterogeneity of European statistics as well as bring to light regional variations the knowledge of which is extremely important for medical research and for well-advised decisions concerning healthcare systems.

In quite a few circumstances, EU decision makers think or act in what may be an inappropriate manner by unwisely extrapolating information from data – notably epidemiological data – collected in North America. However, epidemiological data is a very fragile commodity which travels very badly!

3. Evaluation of cost-effectiveness

In general, CP considers the evaluation of cost-effectiveness of medicines useful and sensible, but is sceptical as to the result of the results, furthermore, as they are evaluated differently by each country. In this way, CP advocates the harmonisation of net-prices of medicines as a concrete target to follow.

4. The Science Base

The CP can only approve the content of Section 4 (The Science Base). Particular emphasis is placed on:

- the development of a veritable EU policy in the domain of public-funded research, especially in the biotechnology section. This would be a real innovation in a domain where initiatives continue to come very predominantly from private companies. However, as the document emphasises, even though there are as many European companies as there are American ones, their average size is much smaller which prohibits their having the same ambitions;
- the need for a public debate on the priority objectives of such a policy;
- the need to link it with the research and development carried out by private firms, which traditionally have made nearly all the investment in pharmaceutical research;
- the need to clarify the measures of directive 98/44.

This last point is absolutely essential as the current situation is untenable. The final positions taken by the EU are likely to be different from those adopted in this domain by the United States. The G10 cannot remain silent on this prospect. On the contrary, it must anticipate future difficulties and propose a course to follow to harmonise the EU's positions and those of the United States. In the absence of any harmonisation of the rules for the patentability of biotechnological inventions, there is a risk of extreme confusion in this sector which would discourage many initiatives.

It would be good if, on following up their reflection, the G10 were to study the very recent decision of the European Court of Justice (made on 9 October) on the interpretation of directive 98/44 in response to the case introduced by the Netherlands. There is a fear in fact that the substance of this decision will be strongly contested, particularly in Member States which have taken a clear stand against the patentability of genomic sequences the description of which is, quite unambiguously, a discovery and not an invention.

Lastly, it is necessary to emphasise the value of creating networks which connect centres of excellence in fundamental and applied research under the aegis of the EU and with its financial backing.

5. Competitiveness, benchmarking and innovation

The paper recognises that Europe is losing competitiveness and R & D to the USA, but fails to comment on the consolidation within the industry with companies becoming larger by take-overs by US companies of European ones. There is then a process of closing facilities in Europe and concentrating in the US.

Secondly, cost of R & D increases exponentially and again it is in the States that finance is available. Of course, it is now possible to analyse potential products using computer models much easier than in the past and the use of genetic manipulation (again rights often held in US) to produce new entities also increases. The industry makes great play on such costs but glosses over that it spends 10x as much on marketing.

5.3 is important and should be supported but the size of the major companies means that they will have most facilities in house.

TRIPS – the intellectual property rights is a major factor by the companies in securing exclusivity in a range of areas and we have been particularly concerned re the genome but there are other areas. Europe should certainly ensure that its industry is not disadvantaged by US domination in this field and their resort to expensive legislation in the courts to exclude smaller companies.

Benchmarking against other blocs (US and Japan) are important but access to innovative products must depend on proper trials and evidence-based assessment. Cost will be a major factor and it is interesting the reaction to the compulsory revelation of price-markups of anti-AIDS drugs in the South African court has resulted in a drastic reduction by the companies concerned.

Taking into account the cost of research and the need for a fair profit, excessive profiteering is against proper medical care and reduces the available money for other health care – ultimately, in one form or another, it is the patient who pays.

The CP finds that the comments on enlargement are sound and wonders whether there is exists a proper infrastructure to support a research-based industry in these countries. However, it recognises that they are producers of generics although in the past there was some question as to quality. They are prepared to do clinical trials on products at competitive rates (a criticism of the medical academic institutions in Western Europe is that their clinical research has been too slow and been too expensive).

6. Single market and fragmentation

The CP warmly welcomes European Commission's attempt to improve authorisation, procedures of pharmaceuticals both centralised and mutual in order to avoid delays in market access of pharmaceuticals as stated in points 6.8.-6.14 of the consultation paper. The CP strongly argues that it should not be acceptable, that the fragmentation of European pharmaceutical markets, even though due to country specific reasons, put European patients into unequal position for example by causing unfair delays. Patients must have rapid access to safe, effective and high quality medicinal products regardless of the location of the patient.

Fast authorisation procedure is in general strongly supported by the CP. A specific fast track procedure deserves further discussion. The way to detect and agree upon unmet medical need should be established. The body determining this kind of need must be as impartial as possible in order not to bias the concurrence between products.

The CP has some reservations of promotion of generic prescribing and dispensing of generic medicines in order to reduce pharmaceutical spending.

The CP emphasises that the chose of any medication has to be always adjusted to the needs of a individual patient and finally must test on the experience and responsibility of the prescribing doctor.

7. Generics

It should be pointed that a strong generic base does not stimulate innovation – in deed, in those countries in the EU with a strong tradition of generics there is hardly a research-based company.

The problem with generics is that with increased patent time to 20 years, many are old hat by the time of release. Also the companies will often change a specification to say an isomer just before the end thus effectively extending patent.

Price and licensing are the key with doctors having the right to prescribe a propriatory product for good reasons but accepting that he may be challenged on cost grounds if there is a cheap, high-quality generic alternative. The medical profession supports cost-effective, evidence-based medicine. For this reason CP is concerned at extension of OTC (over the counter) and P (pharmacy-only) classifications since illness requires a proper diagnosis (after a history, examination and any necessary tests) by a trained physician prior to treatment which others are not trained to do and this is essential for patient/consumer protection.