

**EUROPEAN COMMISSION DG XXIV
(CONSUMER POLICY AND HEALTH PROTECTION)**

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I would like to thank Professor Kemper and ESCOP of this meeting for inviting a representative from the European Commission to make a presentation at this fifth International Symposium in the session on regulatory perspectives. I am grateful for the opportunity to explain to you the new structure and responsibilities of the Directorate-General for Consumer Policy and Consumer Health Protection of the European Commission, because although the changes took place over a year ago, I am aware that there are still numerous questions to address.

The Directorate-General for Consumer Policy and Protection of Consumer Health (DG XXIV) was fundamentally restructured in May last year. In doing so, the Commission responded to criticism made following the BSE crisis that the connection between scientific advice and legislative activities was too close. It was felt that a clear separation between these two activities was needed, in order to guarantee the independence of the scientific advisory bodies. In addition to what we may call “classical consumer policy”, which is in fact my present responsibility, the area of competence of DG XXIV was broadened to include the provision of scientific advice and to inspections and control. The management of Commission scientific committees was transferred to our Directorate-General. The drafting of the legislation and the management of the procedure for its adoption by the Commission or by the Council remain under the responsibility of the different Directorates-General involved, like DG Industry, DG Agriculture or DG Environment, always in close collaboration with DG XXIV.

Before expanding further on this new organisation I would like to take the opportunity to insist on one point. The new organisation has in no way affected the traditional tasks of DG XXIV with regard to

Consumer Policy in its broadest sense. With so much emphasis now given by outsiders to the role of DG XXIV with regard to consumer **health**, it is sometimes forgotten that DG XXIV also must stand for the defence of other consumer interests, such as general product safety, economic interests, the right to information, access to justice, and so on. Yesterday, a major piece of legislation was adopted on the distant selling of financial services, which brings real added value for consumers.

After this important clarification, I now would like to come back to the new organisation of DG XXIV for the Protection of Consumer Health. It is based on three general principles, which were defined by the Commission in a formal Communication at the end of April 1997:

- First of all, it was decided that responsibility for legislation should be separate from that for scientific consultation; DG XXIV was given the management of all scientific committees, whereas the legislative responsibility remained in Directorates General responsible for the area concerned. May I add that the scientific Committees should be seen as working for all the Commission services, and not only for DG XXIV. It is indeed foreseen that their opinions should serve as a basis for any measures which have an impact with consumer health. I can quote as examples of such measures any measure relating to BSE, pesticide residues, authorisation of ingredients for cosmetics and so on. This is obviously not an exhaustive list!
- The second important new point is that responsibility for legislation should be separate from that of inspection. As regards control activities, the Food and Veterinary Office is now a Di-

rectorate within DG XXIV. Following political agreement on the location of the different Community Agencies, it is now located in Ireland. It has received a considerable increase in staff to reflect the new emphasis given to controls. Its responsibility covers the control of the correct implementation of Community veterinary and food legislation; we call this the *stable to table* approach, as it actually includes monitoring of the controls carried out by the Member States right up to the level of retail shops, canteens and so on. In the veterinary area it extends to third countries and we send regular inspection missions to those countries which import animal products into the European Union. I am aware that in the pharmaceutical sector, the Commission does not have such a direct responsibility, be it to inspect or to audit national control systems, and that inspections are carried out by the authorities of the Member States.

- The third import point relates to transparency. The Commission committed itself to greater transparency and more widely available information throughout the decision making-process and inspection measures..

Transparency has been applied to the appointment and conduct of the Scientific Committees: A public call for expression of interest was published on Internet and over one thousand applications were received. A careful selection process was carried out, based on the excellence and independence of applicants. This allowed the Commission to establish the eight Scientific Committees, of which one is of particular interest to you to-day. I will come back to this later. The eight Scientific Committees work under the supervision of the Scientific Steering Committee, which co-ordinates their work so as to avoid overlaps. The mandate and composition of the Scientific Committees is published on the Internet; so are the draft agendas of meetings and the opinions adopted by the committees. If a minority opinion was expressed by one or several members, this is also made public, so that everyone

can get a good feel of the discussions and make up their own mind.

Transparency is also applied to our control functions. All inspection reports and the statistics of the co-ordinated control programmes, where member States collaborate in an area of particular concern are on the Internet.

I believe that in the health and safety sector, the Commission can be seen as perhaps one of the most transparent bodies in the world.

The new committees include a **Scientific Committee for Medicinal Products and Medical Devices**. I would like to explain how we see the task of this Committee and how it fits into the structure established in the European Medicines Agency here in London.

First of all, it is important to underline that this Committee will in no way duplicate the tasks of the EMEA. The mandate of the Committee, adopted by a Commission Decision includes the following passage in relation to medicinal products:

Scientific and technical questions relating to Community legislation concerning medicinal products for human and veterinary use, without prejudice to specific competencies given to the Committee for Proprietary Medicinal Products (CPMP) and the Committee for Veterinary Medicinal Products (CVMP) in the context of the evaluation of medicinal products.

In the area of medical devices, the mandate reads:

Scientific and technical questions relating to Community legislation concerning medical materials and equipment.

So for the European Medicines Agency, nothing has changed: it is in charge of the evaluations of the quality, safety and efficacy of medicinal products in view of their authorisation. Whenever the EMEA transmits to the Commission an opinion on a me-

dicinal product, this opinion will normally be transposed into a formal Commission Decision giving the terms of the authorisation of the product in the European Union.

The role of the Committee will be rather to provide input or advise the Commission on broader issues, to give its opinion whenever legislation of a scientific or technical nature needs to be prepared for consumer health protection, or to give its opinion on other types of requirements such as guidelines in the area of pharmaceuticals or medical devices. In the area of medical devices, there was a lack of independent scientific expertise available to the Commission. It is in that area that the Committee has already responded to a need in adopting an opinion on the equivalency of alternatives to sutures of animal origin.

As a last point on Scientific Committee for Medicinal Products and Medical Devices, I would just like to add

- that it has 16 members with wide ranging expertise,
- that the chairman is Dr Keith Jones, Director of the Medicines Control Agency,
- that like all the other scientific committees, it is represented in the Scientific Steering Committee by its Chairman,

I have until now touched upon general questions. I think that now I should say a few words about the topic of interest to you in this meeting: Phytotherapeutic products or herbal medicines, both terms apply. We all know that in recent years, there has been a significant increase in interest in alternative medicines. Is it a kind of rejection of science and high technology, or a deep felt need for a more natural approach to health and sickness, the wish to be seen as a person and not as a dehumanised patient? In any event, the European Parliament has responded to this need by adopting a report on the status of non-conventional medicines in March 1997 which urges recognition of alternative medicines.

Being from DG XXIV, the first question I ask myself is “What do consumers want for herbal medicines?” It is certainly not as frequent a topic of discussion in my Directorate as the quality of fruit and vegetables or the safety of toys. But nevertheless, it crops up from time to time as a topic of interest and, sometimes, a concern of Consumer organisations.

There is a natural tendency for people to believe that ‘if a herbal remedy does no good, at least it will do no harm’. From time to time, we are reminded that this is not always true, sometimes with very serious consequences. On several occasions, Consumer Organisations have warned their members against this belief.

For example, one cause for concern is the risk of contamination of herbal products and here DG XXIV is from time to time involved. In DG XXIV we run a rapid alert system for food and consumer products. Some herbal products are considered as medicines, others have a less clear legal status and are considered in some Member States as food. As such, they fall within the scope of the rapid alert system and we have received reports on high levels of pesticides or heavy metals in products freely on the shelf of shops. Thanks to our rapid alert system, all Member States are warned and can take action to protect consumer health. We also immediately inform the Pharmaceutical Unit in DG III, so that there is no loophole in the system.

We are well aware that many consumers want to have access to “natural medicines”. As I said before, our remit goes beyond the purely scientific evaluation of risk and must represent consumer interests in the broadest sense. But it is not our role just to say: “Consumers want this product, so it should be available”. Our approach needs to be balanced and take account of our dual mandate which is “Consumer policy **and** protection of consumer health”. For example, we know that some consumers are in favour of the use of some substances as food supplements. We need to take this into consid-

eration, but not at the detriment of their health or economic interests. The same would be true in your special area.

Quality of herbal medicines is a pre-requisite. The existing pharmaceutical legislation correctly provides all the necessary instruments to ensure good quality.

Safety must also be ensured. We recognise that plant extracts can exert pharmacological effects; this is in fact the reason for using them as medicines! Therefore they must be authorised only once the full range of their properties has been evaluated and clearly they must be used with precautions.

Previous evaluation of effects combined with an efficient monitoring system will prevent the use of products which could be detrimental to the health of the consumer. Here again, it is true to say that the pharmaceutical legislation already provides all the necessary safeguards like quality and safety tests, good manufacturing practice, inspections by the Member States, and pharmaco-vigilance.

Finally, the **efficacy** of herbal medicines is a regular topic of debate and as I understand the situation, this criterion, which is a requirement for authorisation in the European legislation, is not always fulfilled up to the standards in force to-day. I know that to comply with these requirements, extensive (and very expensive) clinical trials under strictly controlled conditions would have to be carried out for products which have already a long existence on the market. As an alternative, DG XXIV would focus on clear labelling requirements. Consumers

would need to know to what extent efficacy has been tested and of its possible limitations, so that they may take the decision to use the product on a fully informed basis.

In relation to this point, we are contemplating in DG XXIV to propose an amendment to the Directive on misleading advertising, to cover nutritional claims, health claims and “green” claims. On this basis, consumers and other parties (such as competitors) could lodge formal complaints against **health** claims which are not substantiated by scientific evidence. Health claims are not therapeutic indications, but we certainly could not accept less for products which claim to cure than for products which claim to maintain good health!

From the point of view of DG XXIV, there are basic principles on which it is not possible to compromise, especially not when you represent both consumer policy and the protection of consumer health.

This may seem rather strict. But it is also in the interest of the industry to ensure that only safe products are placed on the market. Nature has shown itself to be an endless reservoir of molecules with therapeutic effects. We should not jeopardise the confidence consumers place in nature. The confidence and safety of consumers is the best guarantee for the health of phytotherapy and its industry and therefore I am certain that should the opportunity arise, we in the Commission and all of you here today would collaborate fruitfully towards a common objective for the benefit of consumers and patients.

Thank you for your kind attention.

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