

Welcome address of Dr. Dieter Thomae
Member of the German Parliament and
Spokesman in the Area of Health Policies of the
Liberal Party of the German Parliament,

during the Reception of the ESCOP Symposium in Bonn on 10 May 2001

Dear Professor Kemper, dear members of ESCOP and guests of this symposium,

I am very happy that ESCOP invited me to hold a welcome address on this important congress. ESCOP has substantially contributed to the scientific assessment of herbal medicinal products on a European level, their monographs being able to form the scientific basis for a European-wide assessment of medicinal plants and their preparations. Thus, several years ago, the Working Group at the EMEA stated that your monographs offer a valuable and updated overview on published scientific literature which may be used in support of the demonstration of safety and efficacy of a medicinal product in a bibliographical application. Well-documented scientific monographs are therefore in the position to fulfil the requirements of the Directive on well-established medicinal use, in contrast to preparations which can be registered as traditionally used medicinal products in Member States with a 30-year tradition and without scientific proof of efficacy.

However, on a European level, the developments in the area of food supplements must be carefully observed. Widening the scope of this draft Directive to substances with a nutritional or physiological function would allow herbal preparations to be marketed as food supplements as far as they are included in a specific list. This would enable products currently classified as medicinal products being attached to the food supplements category. This sounds very simple but does have comprehensive consequences. Regulations of drug safety and liability would no longer be applicable to these products, and the pharmacy-only status existing in many countries would no longer be upheld. Considering the role of

today's health policy, I expressly object to politics which, in an inappropriate and exaggerated way, exclude herbal medicinal products from the area of medicinal products and intend to define them as food supplements.

One of the most important demands of our liberal health policy is making available all kinds of medicinal products including natural medicines for professional therapy as well as for self-medication. Self-responsibility as part of our healthcare system is intended to contribute effectively to the principle of solidarity which our healthcare system is built on.

A further problem politicians are confronted with is the scheduled Positive List which will restrict the number of medicinal products reimbursable by the State health insurances. Publication of the draft list has just been postponed due to political decisions of the Ministry of Health, but a department of the ministry as well as a specific commission have been working on the assessment of respective medicinal products for several months. True, several years ago, our former government, a conservative / liberal coalition, had intended to establish a Positive List. A draft was prepared but finally abandoned because we saw that a Positive List would have resulted in nothing but disadvantages for all people and institutions involved in our health system. Nowadays, the social-democratic / green government is going to make the same mistake which we had realised and avoided years ago. Severe concerns are justified as to how far herbal medicinal products can be included in the Positive List in an appropriate way. Due to the current legal provisions, herbal medicinal products are reimbursable to the same extent as chemical medicines are, as far as the indication fields

themselves are reimbursable. The companies, however, have to contribute to this option by providing scientific data in accordance to the current scientific knowledge.

Depending on the therapeutic claims and taking into account the overall scientific progress, reference to a long-term use of a medicinal product and the experience of patients and physicians no longer seem to be sufficient. In addition, herbal medicinal products are expected to provide scientific confirmation of efficacy and safety as chemically defined medicinal products have to do. For this reason, sound clinical research may strengthen the importance of herbal medicinal products and provide the option to search for new indication fields taking into consideration the long-term experience and the medicinal use of well-known plants. ESCOP as a scientific organisation may contribute to the scientific progress and stimulate clinical research for modern herbal medicinal products as part of the European healthcare systems.

You have chosen an optimum venue for your symposium, not only because of the beautiful view to the romantic Rhine - we are exactly on the border-line between the lower and the middle part of the Rhine, the river which brings European harmonisation forward by linking Switzerland, France, Germany and the Netherlands - but also because you are in the centre of a growing science

and health region between the river Rhine and the river Ahr.

In the city of Bonn, our former federal capital, you will not only find the Ministry of Health (which did not move to Berlin) and the BfArM, the Federal Institute for Drugs and Medical Devices (which, during the past few months, has successively moved from Berlin to Bonn), but also the University with its well-known institutes of natural science, clinical medicine and agriculture as well as further scientific research institutions. Also BAH, the German Medicines Manufacturers Association, is situated in Bonn.

In the area of the river Ahr - and that is where I come from - we have a high density of expert clinics and spas as well as further research institutions working close together with the pharmaceutical industry. Regarding agriculture, we are trying to establish a model region for cultivation of medicinal plants and spices with the financial support of public funds.

Last but not least, our region is also a gastronomic one, and our red wines belong to the most famous ones in Germany because they can benefit from the warm sun shining on the vineyards of the Ahr valley. If you find the time after the symposium, you are invited to come to this beautiful region and enjoy the nice landscape and the red wine - a product which has been traditionally used in phytotherapy. But first of all: enjoy this evening.

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