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The Two Phytotherapies and the Laws Governing Them (**)

From this Congress it has emerged that while medicinal plants are regaining popularity as a result of cultural, economic and social pressures, the laws governing phytotherapy are outdated and incapable of sustaining and suitably orienting its developments. This problem is especially complex because of contrasting opinions and interests. It could be more easily resolved, however, by considering the two phytotherapies separately:

— *traditional phytotherapy*, based on the use of medicinal plants as such or in the form of raw extracts, and

— *modern phytotherapy*, which instead makes use of purified herbal active principles.

Traditional phytotherapy has a background of thousands of years of experience. In some cases converging indications from different countries and cultures provide, together with the data that I will deal with later on, a solid basis for the therapeutic use of some medicinal plants. Under these circumstances they are a valid alternative to new drugs with the additional benefit of not requiring pharmaco-toxicological and complex clinical studies or the enormous economic resources and sophisticated expertise these studies entail. In my opinion, medicinal plants also have the advantage of producing fewer and less important side-effects than other new drugs.

On the other hand, traditional phytotherapy has a number of drawbacks which substantially limit its application. The main ones are:

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a) the active ingredients vary according to the season and other uncontrollable factors. This characteristic renders the use of many plants, especially the highly potent ones, very risky and difficult;

b) the concentration of active ingredients is often too low to reach the level of activity necessary for a complete therapeutic effect;

c) the large-scale use of medicinal plants is problematic not only for the above reasons, but also because of the difficulty in storing, distributing and producing them at low cost and in the necessary quantities.

This explains the impotency of traditional phytotherapy in some of the most severe diseases which have afflicted or still afflict humanity. Medicinal plants are more easily applicable in the less severe pathological conditions which are nevertheless important from a social and economic viewpoint.

Modern phytotherapy was born with the isolation, identification and production in large quantities, by extraction or synthesis, of active ingredients contained in medicinal plants. Some of the limitations and disadvantages of traditional phytotherapy were therefore overcome. A new problem arose, however, which was the difficulty of transferring the experience gathered over thousands of years with medicinal plants to their pure active ingredients in view of their markedly different pharmacological and toxicological characteristics. Consequently, the latter should be treated like any other new pharmacological discovery with the delays and complications characteristic of their practical utilization.

With this picture in mind, it can be concluded that medicinal plants and their raw extracts, i.e., the instruments of traditional phytotherapy, are of both scientific and practical interest to the modern world. Their therapeutic use should, however, be limited to pathological conditions which do not require accurate dosages and a great potency of effects. The quality of the material used in therapy, whether it is the plant as such or its raw extracts, should be controlled by chemical, analytical and biological studies in order to guarantee the level of activity. Commercial packaging should contain information on the date of drug collection, conditions of storage and expiration date. The problem of therapeutic indications is more complex since the data provided by medical tradition are not always very reliable or precise. They must thus be controlled and confirmed by means of clinical trials. If laws or regulations guaranteeing these aspects existed, then the development of that "vegetable drug" which we talked about before in this congress would be justified. It should be authorized by the health authorities and considered a valid alternative to "medicinal specialties" and given the same attention concerning its prescription, distribution and acceptance by the National Health Service. Although the development of "vegetable drugs" would involve consistent efforts, they would be far less strenuous than those employed for new drugs. Since "vegetable drugs" are not patentable, the investments made for their development are presently not guaranteed. A reasonable solution would be a protection period of five years covering the first registration, similar to that applied

in Europe for medicinal specialities containing unpatented drugs. This would encourage the pharmaceutical industry to dedicate its efforts to this field.

On the other hand modern phytotherapy does not pose any particular problem from the point of view of laws and regulations because, as already mentioned, drugs made of pure substances deriving from plants are given the same treatment as that given to any new pharmacological drug regardless of whether they are obtained through synthesis or by extraction.