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Herbal medicinal products: new Committee & European dimension

Meeting on 23 September 2004 at the European Medicines Agency (EMEA) in London

Panel Paper

The spoken word applies

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The European Parliament very much appreciates the establishment of the new Committee for Herbal Medicinal Products at the European Medicines Agency (EMEA) and wishes to the Committee and its new members all success for the important work ahead.

The establishment of this committee has been a long term request of the European Parliament which came up in parliamentary debate already shortly after the creation of the EMEA in 1995. It has not been an easy development as it was not always evident to convince all stakeholders to support the establishment of such a committee. Even today, not everyone might be fully convinced of its value and therefore, the new committee is facing the challenge to prove its capability to adequately address all relevant issues around the assessment of herbal medicinal plants, and in particular those which have an interest beyond a single national or local market. I am personally convinced that the work of the new committee will be successful and that there will be a much wider availability of safe herbal medicinal products of high quality in the years to come. Let me briefly explain where my optimism is coming from.

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In light of the strong interest to have European coordination in the assessment of herbal medicinal products, the EMEA established in 1997 an ad-hoc working group on herbal medicines which later on got a permanent status. This working group did an excellent job by completely reviewing the quality standards for herbal medicinal products. It got wide appreciation from the scientific communities for their achievements. Important work has also been done with regard to the safety of herbal medicines, an area the European Parliament has always followed with particular interest. Constructive debates were also held concerning the area of efficacy, which is maybe the most difficult one in light of the frequent reference to bibliographic material and the evident lack of new clinical studies.

As the debate on the new legislative framework for herbal medicines showed, the European Parliament believes that there are many medicinal plants which are worthwhile being full part of the medicines system and by that deserve indications like any other medicine. It is not up to the European Parliament to make suggestions concerning the detailed assessment but we agreed with the Council of Ministers that a separation in those herbal medicines with full indications, often referred to as well established and those of traditional use is reasonable.

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The overall political support from all institutions in the European Union should be an encouragement for those in charge of carrying out the detailed scientific tasks to work in this direction.

Let me just remind you of a few other issues which were important for the European Parliament and which are now part of the new legislation for traditional herbal medicines:

- Concerning the composition of a traditional herbal medicine, the European Parliament advocated wider combination possibilities than originally proposed. The Council agreed on the principle and wished to permit the possibility to include vitamins and minerals provided that the action of the vitamins and minerals was ancillary to that of the herbal active ingredients. As most of the traditional combination products between a herbal and a non-herbal ingredient are indeed combinations with vitamins and minerals, this was an acceptable position from the viewpoint of the European Parliament.

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- The structure of the legal provisions made it clear that there are no EU wide legislative provisions which prohibit or restrict the use of herbals in food respectively food supplements. By July 2007, the European Commission will present a report on the advisability to include additional categories of substances into the existing legal provisions for food supplements. Possibly this will be combined with a proposal for extended legislation which may then cover categories such as herbals, amino acids and fatty acids. Until that time, the national legal provisions continue to prevail. Provided that the respective legal provisions are respected, this will allow the use of plants in medicines as well as in food respectively food supplements.

- A particularly sensitive topic during the first reading at the European Parliament was the acceptance of non-European tradition when deciding on the status of traditional herbal medicinal products. The European Parliament agreed that a minimum term of use was needed within the European Community (10 years according to the European Parliament). This is supposed to be part of a time period of use of at least 30 years preceding the date of application. The Council in line with

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the European Commission insisted on a minimum term of 15 years, however, following the concerns expressed by the European Parliament, the Council could agree to open up an additional route for products with less than 15 years of use in the European Community. After an application for a traditional use registration has been submitted, Member States may refer such an application to the Committee for Herbal Medicinal Products. The Committee shall consider the relevant documentation and decide on the establishment of a community herbal monograph, which then would allow the acceptance on the national markets. This was an acceptable compromise in a very difficult debate and will ensure an open attitude towards tradition from outside the European Union while applying the general quality, safety and efficacy standards as established for this kind of medicines in the European Union.

- While the original approach of the European Commission in relation to traditional herbal medicines was primarily looking at the acceptance on national markets, the European Parliament insisted on the possibility of mutual recognition by other Member States also for this kind of products. Both the European

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Commission and the Council took this request of the Parliament into account and the common position included the possibility of a mutual recognition for all products which are covered by a community monograph respectively a list of herbal substances. This will allow applying the general principles of mutual recognition to a large part of traditional herbal medicines and is therefore a very positive result.

- Again in line with the spirit of the amendment adopted in the European Parliament in first reading, both the Commission and the Council agreed on a far more reasonable wording with regard to labelling and advertising of traditional herbal medicines. Contrary to the original proposal advocating a quite negative disclaimer, the final agreement requires a statement on the labelling and in advertising that the product is for use in the specified indication which is exclusively based upon long standing use. This is an appropriate reflection of the reality and allows the patient and consumer to have the necessary background information on the product concerned. Such a message does not frighten the individual unnecessarily and again it is with a considerable level of satisfaction to note the move of

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the other European institutions in the direction advocated by the European Parliament.

- Finally, the Council also took into account the considerable concerns the European Parliament with regard to products not covered by the scope of the traditional herbal medicines directive. It is appreciated that the Commission will present not later than 3 years after the date of entry into force of this directive a report to the European Parliament and the Council including an assessment on the possible extension of traditional use registration to other categories of medicinal products. Further on the Council included a transition period of 7 years which allows manufacturers to make appropriate adjustments.

It is not up to the European Parliament to be involved in details of the implementation process, but we expect that the EMEA will provide all necessary support to the new committee for herbal medicinal products. This evidently starts with the appropriate resources and by that sufficient financing for the infrastructure but in particular also the provision of adequately trained staff and experts. To ensure the right communication between the new committee for herbal medicinal

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products and other committees within the agency, including in particular the committee for human medicinal products, is another important task. In all matters related to herbal medicines, the new committee is the one of primary competence. There are, however, overlapping issues which may require the need for proper coordination; in particular with regard to a possible arbitration for herbal medicines of well-established use or for herbal medicines going through the centralized procedure. It is important that the persons with the right understanding of herbal medicines are those which should have the primary say when it comes to the final assessment.

Looking at implementing measures to be developed by the European Commission in the context of the new pharmaceutical legislation, there are two areas which seem to me particularly important in the context of herbal medicines:

- The envisaged guideline on serious risks to public health should make sure that the mutual recognition process works better for all medicines including, in particular, those with well known ingredients.

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- Many manufacturers of herbal medicines are small and medium enterprises and there indeed is the need for support of these manufacturers to better cope with the European authorisation procedures. The new pharmaceutical legislation addresses this point and I am confident that the European Commission will soon come up with constructive proposals.

The EMEA will soon celebrate its 10th anniversary and it can be proud of its achievements. The 20th anniversary should be the occasion to look back at the establishment of a much more harmonized herbal medicine market ensuring a wide availability of safe herbal medicines of high quality in the European Union. It will hopefully also allow looking at progress in other therapeutic areas such as homeopathics, which have so far not received the attention on the European level which they deserve. I would encourage all those in charge to address this point, taking into account the strong support homeopathic medicinal products have in all relevant political groups of the European Parliament.

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I am sure that as part of the annual reporting of the EMEA to the European Parliament and the other institutions, all interested parties will be permanently updated on the progress of the work. This should then allow us to identify, if necessary, any deficits in the new legislation and to address it in future debates. The European Parliament will certainly very carefully monitor the developments and is looking forward to make its contribution to the further developments of the right legislative and regulatory framework for herbal medicinal products which make an important contribution to the public health of the European citizens.

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