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Ms A North  
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Dear Arielle

## **DRAFT DIRECTIVE ON TRADITIONAL MEDICINAL PRODUCTS**

1. I am writing with the Medicines Control Agency's comments in response to the Commission's first draft of a possible Directive on traditionally used medicines.
2. We welcome the early release of the draft following the discussion at the September Pharmaceutical Committee. As you are aware our Ministers would like to see early progress with the Directive and so we wish to participate constructively in further development work.

### Scope

3. The UK priority is to find a suitable regulatory regime for traditional herbal remedies. Having said that, we are aware that there are some genuinely traditional medicines which consist partly or wholly of non herbal ingredients. Once the principle of going beyond herbals is established we would then find it difficult to establish a logical reason for saying that one particular kind of ingredients (e.g. fish oils) would be permitted while another (e.g. minerals) would not. A possible approach would be to turn the question round and to consider whether there were any particular categories which should not be permitted as traditional medicines.
4. We would raise the specific issue of traditional homoeopathic medicinal products which, like many herbal medicines, have difficulty in demonstrating efficacy using conventional clinical trials. While there is, we appreciate, a separate Directive on homoeopathic medicinal products, our lawyers' current view is that Directive 92/73 Article 9.2 does not permit a traditional use scheme as such (that is, where the efficacy requirement is replaced by reference to evidence of traditional usage). If that is the case, we can see a clear case for allowing Member States to use the Directive on

traditional use medicines to permit equivalent arrangements for traditional homoeopathic medicinal products.

5. On the assumption that there may not be a common view between Member States on what they would wish to include beyond herbals we would find national discretion in this area a reasonable approach.

6. We are aware that once the Directive goes beyond traditional herbal remedies (or other relatively discrete area such as traditional homoeopathic medicines) it may become more difficult to contain the regulatory consequences. We would therefore wish to continue to review the developing shape of the Directive and the wider implications for overall medicines regulation before firmly committing ourselves to the principle of the Directive extending more widely.

#### National schemes

7. Given the current major differences in approach between Member States we think that the overall approach of the Directive is realistic, that is national schemes within EU parameters which allow a degree of flexibility but also include features which encourage a greater commonality of approach over time. To illustrate the latter point, it is likely that in drawing up our positive list envisaged under Article 5 the UK would wish to draw from the experience of other Member States in operating lists of this kind.

#### Definition of tradition

8. We would underline the importance of having a provision along the lines of Article 4(4) in relation to evidence of traditional use beyond the EU. No doubt it may be possible to improve the specific wording. There are ethnic groups in the UK, and probably elsewhere in the EU, which have medicines traditions many centuries old. It would seem arbitrary if a very longstanding traditional medicine had to be ruled out simply on the basis that it could only demonstrate it had a few years use within the EU. We recognize that some traditional medicines originating outside EU would need to be ruled out on safety grounds and that many currently would fall well short of the likely quality requirements. However, we think it better to rule out problem products where necessary on a case-by-case basis so that there is at least an opportunity and incentive for some of these medicines to come under the traditional medicines Directive. If we do not do this the likely outcome would be to drive such medicines underground, which would not protect public health or provide consumer choice.

9. It may be difficult to prove that a medicine has been used year by year “throughout” the defined period (30 years in the current draft). We can envisage a situation where there is convincing evidence that a medicine has been regarded as a traditional remedy for perhaps well over 30 years but that evidence of actual use may relate more specifically to various points within 30 years. It is not easy to define tradition, and it would be helpful to have a view on whether “throughout” would allow sufficient flexibility for national guidelines to define sensible criteria for recognizing genuine traditional use.

10. In Article 4 (3) we wonder whether the wording “one or more of the Member States” may imply that the product has to be used in at least one Member State throughout the whole 30 years. If this narrower interpretation is implied by the text this might preclude an applicant from taking evidence, partly from one Member State and partly from another. We suggest that a reasonable policy aim in 4(3) should be to allow the applicant to take evidence from the EU as a whole when seeking to demonstrate use covering the requisite period.

#### Combination products

11. Article 2(1) probably needs to include a plural reference, otherwise this might unintentionally rule out traditional herbal combinations. Perhaps a wording something like the following would be helpful: “any medicinal product which consists exclusively of one or more herbal drug or herbal preparation, or one or more such drug in combination with one or more such preparation.” We would also suggest that it may be helpful to have a discussion on the criteria for accepting medicines consisting of combinations of traditional ingredients – herbal or otherwise - since this could have a significant effect on the practical application and extent of coverage of the Directive.

#### Relationship between traditional use registrations and 65/65/EEC medicines

12. We can see difficulties with the provisions of Article 3(1) and 8(1)(f). There is a case for the policy objective that if a medicine can meet the standards of 65/65 then preferably it should do so. However, we are concerned that the provision in 3(1) “*if a medicinal product falls under the scope of [65/65/EEC or 2309/93] it can not be registered as traditional use registration*” would not be workable and could have far reaching consequences. There are likely to be numerous medicines meeting the other criteria for traditional use where there will be uncertainty as to whether the product – either in its present form, or with some lesser or greater adjustment - might meet 65/65. There is a risk that such a provision could lead to much uncertainty and could deny consumer choice

13. We can also see 8(1)(f) leading to problems. If the test is no traditional use registration where there is an “essentially similar” 65/65/EEC registration - as in the draft here - this provision could probably be evaded quite easily in practice, e.g. by slight differences in the two products. There would appear to be wide scope for legal challenges on this issue. If however, the requirement is widened so that, for example, once there is a 65/65 product on the market no traditional use medicine is permitted with the same ingredients and similar indications this could well lead to a reduction in consumer choice. If, nonetheless, there were a general view that a provision at 8(1)(f) was desirable it would seem necessary as a minimum to restrict the effect to the Member State concerned.

14. With both 3(1) and 8(1)(f) we can see some potential risk of human rights issues arising, in particular relating to companies property rights.

15. On the whole we favour differentiating between 65/65/EEC authorised medicines and traditional use registrations mainly by product information. If anyone can suggest additional ways of providing incentives or requirements to go down the

route of 65/65 where possible, we would be willing to consider them providing that this avoids other undesirable consequences.

### Safety

16. We suggest that it would be helpful to strengthen the position of the regulatory authorities. In the present draft there is the requirement for a bibliographic review of safety data and expert report in 4(3)(d); also refusal of registration if the product proves harmful in normal conditions of use in 8(1)(d). It would seem desirable also to have a provision broadly to the effect that where the competent authority in question has reasonable concerns as to the harmfulness of the product in normal conditions of use, it may require further information and, if still not satisfied, may refuse registration. In this context we note that it is likely that traditional use products will come from a variety of different routes and many may not have been previously licensed or well studied and monitored.

17. In Article 9 we assume that the main reason why there should be negative lists at European or national level would be safety. Protection of endangered species might also be a factor. It would be helpful to specify criteria in the text otherwise the provision may seem too open ended.

### Quality

18. We think that traditional medicines should meet the same quality standards – appropriately applied – as other medicines. We do not have immediate suggestions on the question raised in 6(3) about the possibility of simplified dossiers for simple products. In general, however, we suggest that the actual quality issues to be addressed will have the same scope for most products but will vary in depth and detail depending, for example, on whether the product is a simple dried herb in a teabag or an extract in a tablet.

### Product information

19. We agree the general view expressed in Pharmaceutical Committee on the importance of informing the consumer as to the meaning of a traditional use registration and distinguishing them from other medicines with a marketing authorisation. The provisions of 12(3) – (5) look likely a reasonable attempt to achieve this.

### Conclusion

20. I hope these comments are helpful. I am copying this letter to members of the Pharmaceutical Committee.

Best regards

Roy Alder  
Head of Executive Support