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Subject : "Traditional" medicinal products - brainstorming

Summary:
On the occasion of the 47th Pharmaceutical Committee, some Members suggested that specific measures could be proposed for "traditional" medicinal products (a category of products indicated for minor disorders where proof of efficacy could be replaced by a reference to "traditional use"). It was agreed to take up this issue at the 48th Pharmaceutical Committee.

It is the purpose of this brainstorming-paper to draw up possible scenarios for future legislative initiatives and to list possible costs and benefits linked to the proposed solutions.

1. Why specific measures for "traditional" medicinal products?

Arguments in favour:

-*grey/black market argument*: Traditional medicinal products without proven efficacy are and will be on the market anyhow. In order to assure a high level of safety and quality for these – potentially very hazardous – products, it is better to establish a feasible regulatory control scheme where safety and quality of the product is checked instead of banning the products completely and thereby creating an uncontrolled grey market.
-*consumer choice argument*: Even if efficacy has not been proven scientifically, patients should be given the option of having access to traditional medicines they believe in on condition that the labelling clearly indicates the lack of proof of efficacy.

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Arguments against:
-*"useless"-product argument*: Traditional medicinal products without proven efficacy are quackery and there is no point in attributing them a "medicinal product" status.
-*"easy life" argument*: Current pharmaceutical legislation (in particular after the adoption of the Commission Directive on well-established use) gives a certain flexibility to applicants and competent authorities regarding the proof of efficacy of a medicinal products. Applicants should take up this chance and update the dossiers of their "old" or "traditional" products in order to make them fully compliant with Directive 65/65. A directive on "traditional" medicinal products would discourage this development and make the life of marketing authorisation holders of old/traditional products too "easy".

2. Basic parameters:
- Community pharmaceutical legislation is based on three pillars: the proof of quality, safety and efficacy. The legislative initiative in question would do away with the third requirement (proof of efficacy) and replace it by other requirements (documentation showing traditional use; specific reference to lack of proof of efficacy in the labelling). This would be an important change of pharmaceutical legislation and the appropriate legal basis would therefore be a EP and Council Directive (and not a Commission Directive).
- The need to demonstrate quality and safety must remain unaffected.
- The legislative initiative will be a proposal for a simplified way of authorising/registering "traditional" products. It will not, in any way, affect the principle that any medicinal product (old or new, traditional or non-traditional, well-established or not, herbal or synthetic) may still be authorised under the authorisation procedures for medicinal products under Directive 65/65 if the applicant can demonstrate that the requirements of Directive 65/65; 75/318 and 75/319 (the proof of quality, safety and efficacy) are fulfilled.
- The legislative initiative will regulate "traditional medicinal products" within the framework of pharmaceutical legislation.

3. Possible approaches:

- European approach: A Directive would lay down basic Community requirements for the registration/authorisation of traditional medicines (e.g.: quality and safety must be demonstrated; limitation to OTC indications; obligatory labelling requirement: "traditional medicine - efficacy not proven"; …). In addition the Directive would provide for harmonised European criteria for "traditionally used medicines" (e.g.: harmonised lists of traditional indications, traditional substances and dosages, …).

Benefits/costs: This European approach would facilitate the free circulation of those traditional medicines which comply with the harmonised Community requirements. There may be, however, a risk that the harmonised lists of substances and indications would be quite short, because national traditions diverge widely. All those products not covered by the harmonised European lists would have to disappear from the market.

- national approach: a Directive would lay down certain basic Community requirements for the national registration/authorisation of traditional medicines (e.g.: quality and safety must be demonstrated; limitation to OTC indications; obligatory labelling requirement: "traditional medicine - efficacy not proven"; …) and leave the rest (definition of traditional use, drawing up of lists of substances, …) up to Member States.

Benefits/costs: This approach would make the free circulation and mutual recognition of traditional products in the EU difficult (if not impossible), but it would allow Member States to fully maintain their national policies/traditions.

- **mixed approach**: this approach would imply a combination of the national and the European approach in one or another way, e.g.: to create a harmonised European scheme for traditional medicines and to allow – simultaneously - national registrations for all those products which do not qualify for the European authorisation.

Benefits/costs: This approach seems to combine the benefits of both models mentioned above. It remains, however, questionable whether it is worthwhile to develop a harmonised European scheme for traditional medicines: Some think that in those cases where it is possible to agree on a harmonised European view (e.g. by endorsing generally accepted monographs on certain herbal substances) a proof of efficacy is also possible and "real" 65/65 marketing authorisations should be granted.

- zero approach: not to change legislation at all.

Benefits/costs: The benefits and costs will differ from Member State to Member State

Action to be taken:

For discussion and feedback from Member States.