Annexe 6
(art. 29 al. 1)

List of documented traditional Asian substances (TAS list)

1. General information

The TAS list contains substances from Asian medicine for which Swissmedic possesses information relating to the degree to which their traditional use is known, for which an official pharmacopoeia monograph - available in a Western language - or a monograph approved by the Agency exist or which are widely documented within specialised literature in an official language of Switzerland or in English, meaning that their safety may be considered foreseeable by specialists within the framework of an appropriate selection and dose. In addition to the Chinese Pharmacopoeia (PPRC)[1], the manuals of Bensky[2] (Material Medica) and Chen[3] have also been used as relevant reference works. The said works are a source of information on the pharmacology and toxicology of numerous substances, and are used both for training and practical purposes. The TAS list indicates which substances may be included in the composition of medicinal products that - according to Articles 26 and. 27 of the Ordinance on complementary and herbal medicinal products, (KPTPO; SR 812.212.24) - may be authorised under the simplified procedure or notification procedure. The list will be updated periodically in line with the status of knowledge and technology.

The information included in the TAS list does not release the manufacturer or the holder of the authorisation from their own responsibility to test the specific starting material and active substance used in the light of the current status of knowledge and thus to ensure that all danger for the user is excluded to the extent permitted by current scientific knowledge and provided that the preparation is used as instructed.

Regarding the herbal substances included in the TAS list, the species used are not differentiated in all cases. The corresponding instructions in the official pharmacopoeia monographs or monographs of substances approved by Swissmedic must be taken into account.

Pretreated substances appear in the TAS list after the basic variant (non-pretreated substance) and accompanied by the relevant pretreatment method. The pretreatment methods are based entirely on traditional and empirical processes from Chinese medicine. The quality of pretreated substances frequently does not correspond to the GMP standards used in the medicinal products sector and there is little scientific documentation of their safety. For this reason, the choice of pretreated substance is again left to the discretion of the doctor or therapist who has trained in the branch of Asian medicine in question.

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[1] Pharmacopoeia of the People's Republic of China; Compiled by the State Pharmacopoeia Commission of the People's Republic of China; English Edition 2000; Chemical Industry Press

[2] Dan Bensky & Andrew Gamble (1993) Chinese Herbal Medicine, Material Medica, Eastland Press, Washington, 556 pp

[3] John K. Chen & Tina Chen (2001) Chinese medical herbology and pharmacology. Art of Medicine Press Inc., City of Industry, USA

Only herbal and mineral substances are included in the TAS list. More stringent requirements are applied to substances of animal or human origin, notably regarding the safety of using these medicinal products and regarding the quality control (contamination by pathogenic germs, transmissible diseases). Medicinal products containing these substances must thus be the subject of a simplified marketing authorisation procedure in accordance with Article 26 KPTPO, with presentation of documentation on quality and safety and appropriate proof of efficacy.

The information included in the “Information on use and safety, maximum dose” columns corresponds to the knowledge and recommendations currently in Swissmedic's possession, and is not exhaustive. Specialists who have additional, relevant information relating to the safety of any of these substances are requested to pass it on to Swissmedic. We would also stress that any person manufacturing, distributing or administering medicinal products in a professional capacity is obliged to inform Swissmedic of any quality defect or adverse reaction related thereto (Article 59 TPA; SR 812.21).

2. Column "Sales category"

- Prescribing or recommending Asian medicinal products intended for an individual treatment requires in-depth knowledge of Asian medicine. Asian medicinal products intended for an individual treatment, which may be authorised within the framework of an application procedure, may therefore only be prescribed, recommended or dispensed by physicians or therapists having completed a recognised qualification programme in the type of Asian medicine concerned. Swissmedic determines the sales category.

3. Column "Information on use and safety, maximum dose

An evaluation of possible risks inherent to the use of the substances mentioned in the TAS list (notably narrow therapeutic range and overdose) is carried out in the light of the available specialised literature. In order to assist those persons prescribing them, recommending them or dispensing them to determine the maximum dose, Swissmedic has included available information. These quantitative indications are, however, for recommendation only and do not release the manufacturer, the holder of the authorisation or the doctor or therapist trained in the relevant branch of Asian medicine from their responsibility to evaluate the active substance used in the light of current scientific knowledge, to determine a maximum dose for the medicine concerned, and to include it on the packaging texts.

No systematic scientific study aimed at proving the safety of traditional Asian medicines during pregnancy or in breast-feeding mothers has as yet been carried out or is available to Swissmedic. Substances that are contraindicated during pregnancy on the basis of available literature are indicated accordingly. For medicinal products containing one of these substances, it is essential to add a warning on the packaging texts.

4. Column "Literature, comments"

This column contains supplementary comments, mainly relating to the safety of using certain substances (correct method of preparation, dose, duration of treatment, etc.) and the corresponding sources. Some additional explanations of the comments can be found below:

- *"Contains toxic PAs – respect the Guideline"*: The substance contains a toxic pyrrolizidine alkaloid (PA) with a 1.2 unsaturated necine ring. The manufacturer must declare the PA content and dose it in such a way that ensures that the maximum value recommended by the authorities of 1 µg PA per day is not exceeded when determining the dosage. Given the actual knowledge, a thermic pre-treatment of the substances has virtually no detoxifying effect on the PAs, since the 1.2 necine ring is thermostable.

- *"Contains…"*: The substances contain the components stated, which have an increased potential for adverse effects. They are mentioned in order to draw the attention of distributing companies and of persons in charge of the therapy (e.g. contains aristolochic acid).

- *"No long-term treatment"*: The substance must only be used to treat an acute ailment for a period of 1-2 weeks and not to treat chronic ailments over a longer time period (4 -6 weeks).

- *"Only use in pre-treated form"*: The drug from which the substance is extracted contains components with an increased risk of adverse effects, but according to the therapy principle of Chinese medicine, those risks can be reduced by a pre-treatment. If a highly active component is known, it is mentioned in order to draw the attention of users of the TAS list. The pre-treatment process is described in specialised literature (instructions of the PPRC, recognised reference works).

- *"Only use calcined"*: The starting substance is of animal origin and without sufficient heat treatment may under certain circumstances be contaminated by pathogenic germs or transmissible diseases. According to tradition, a calcination (Duan) that complies with the recognised reference works (e.g. PPRC, Chen) will guarantee elimination of all organic tissues.

- *"Should not be confused with*…"*:* The fact that a herbal substance is included in the list implicitly signifies that any confusion with the other species mentioned may have serious repercussions on the health (e.g. confusion between the herbs *Stephania* and *Aristolochia*).

- *"Must not be used for…"*: The substance concerned must not be used by certain groups of patients (e.g. breast-feeding infants, infants).