

ANNEX

To the Quality Manual for the Herbal Medicinal Products

GUIDELINES for the Group Naming of the Herbal Medicinal Products

1. For the herbal medicinal products presented as the packed herbal pharmaceutical raw materials and for the herbal medicines presented in a dosage form of the cut-extruded granules manufactured from a medicinal herb of the same genus (medicinal products of the monospecies), a group name should derive from the generic and specific names of the parent plant in Russian in conjunction with a specified morphologic group of a part of the herb used e.g. “pot marigold blossom”, “common Saint-John's wort herb/herba hyperic”.

2. Should a manufacturing of the herbal medicines presented as the packed herbal pharmaceutical raw materials require a relevant pharmacopeial monograph to use multiple types of the same genus of the parent plant, then in such cases a group name shall only derive from its generic name e.g. “**haw** berry”, “**haw** blossom”.

Should the various species of a medicinal herb relative to the same genus drive production of the medicinal products with a different range of pharmacological effect, then a group name in addition to the generic name must include a specific name of the parent plant e.g. for the herbal medicinal products manufactured from the herbal medicines with the same generic name “**knotweed**”, but possessing different pharmacologic effects: “waterpepper **smartweed** herb” with a hemostatic action and “**doorweed**

herb” with a diuretic effect. The group naming requires indication of a specific name (name of the species): “waterpepper smart**weed** herb” in the first case and “door**weed** herb” in the second case.

3. Should the contents of a medicinal product of a herbal origin include a complex of a certain group of the biologically active substances of the same pharmacologic effect as its active ingredient, then a group name shall derive based on the generic and if so required – a specific name of the parent plant in Russian in conjunction with a name of the total deliverable amount of the biologically active substances e.g. for the medicinal product “Flamin” a group naming shall be defined as “the total flavonoids of the sandy everlasting blossom”.

4. Should the contents of a medicinal product include an individual substance of a herbal origin as its active component, then its group naming will derive as based on the International Non-Proprietary Name (INN) if an available group naming (a chemical name) of the discriminated individual component e.g. for a medicinal product containing bioflavonoid diosmin, a group name shall be defined as “diosmin”.

5. For the herbal medicines in the dosage form “tinctures”, “liquid extracts”, “juices” a group naming shall derive from a generic and if so required – a specific name of the parent plant in Russian in conjunction with a name of a morphologic group of a herbal part along with a name of the delivered product e.g. a tincture, an extract, a juice:

a) for a medicinal product under a trade name of “valerian tea” a group naming must be indicated as “a tincture of *Valeriana officinalis* rootstock with root”;

б) for a medicinal product under a trade name of “camomile liquid extract” a group naming shall be “Blue Chamomile Blossom Extract”.

6. For a collection of starting materials of a herbal origin (a tea) as well as for the other polycomponent medicinal products manufactured as based on the herbal pharmaceutical substances, a group naming shall be formed pursuant to their group names laid out in an alphabetical order with a symbol «+». However, should either a tincture or an extract, juice, etc., be used as a herbal pharmaceutical substance, then for such a substance a group naming shall consist of a generic - if so required then a specific name of a medicinal herb indicated in Russian in conjunction with a name of “the delivered product” (a tincture, extract, juice, etc.)

For example,

a) for a medicinal product under a trade name “Vitamin Tea No 2” that consists of the milled berries of shrubbery of different breeds of rose hips and rowan tree berries, a group naming shall be presented in a version of “Rowan Tree Berries + Rose Hip Berries”;

б) for a medicinal product under a trade name “Pectoral Species No 1” that consists of althaea root and Armenian marsh-mallow, leaves of Farfara and marjoram grass, a group naming shall be presented in a version “Althaea root + Marjoram grass + leaves of Farfara”.

в) for a medicinal product under a trade name “Lily-of-the-valley – valerian drops, oral drops”, consisting of a lily-of-the-valley tincture and valerian tincture, a group name shall be formed as based on the names of the active components – “a tincture of *Valeriana officinalis* rootstock with root + lily-of-the-valley grass tincture”.

г) for a medicinal product under a trade name “Pertussin syrup” that consists of a liquid thyme extract and potassium bromide, a group naming shall be a combination of “Potassium Bromide + Creeping Thyme Grass Extract”.

7. Should a manufacturing of medicinal products engage pharmaceutical substances of a herbal origin as well as the substances with the appropriated International Non-Proprietary Names (INN's) upon its availability (a group naming, a chemical name), then a group naming of a medicinal product must consist of the group names of the pharmaceutical substances of a herbal origin and International Non-Proprietary Name (INN) (a group naming, a chemical name) of the pharmaceutical substances laid out in an alphabetical order via symbol «+».