

Submission to the Medicines Classification Committee

Request to refine the wording of the Aloes entry in the First Schedule to the Medicines Regulations 1984

Reason for Request

It has come to Medsafe's attention that several companies are marketing *Aloe vera* drinks and capsules as dietary supplements. The products are readily available in supermarkets, health shops, pharmacies and on-line.

Medsafe believes that these products are derived from the gel of *Aloe vera* rather than from the sap. The sap, not the gel, contains the hydroxyanthracene derivatives responsible for the stimulant laxative effect that led to the scheduling of Aloes.

Medsafe therefore recommends refining the wording of the Aloes for internal use entry in the Schedule to ensure that these gel-based products are not classified as pharmacy-only.

Classification status of Aloes

Aloes has been classified as a pharmacy-only medicine (for internal use) since at least 1984 due to concerns about its use as a stimulant laxative. The Medicines Classification Committee (MCC) reaffirmed its classification as a pharmacy-only medicine at their 24th meeting (November 2000) and at their 38th meeting (December 2007) as part of discussions on stimulant laxatives.

Aloin, an hydroxyanthracene derivative, is one of the major components responsible for the laxative effect in species of *Aloe*. Aloin is also scheduled as a pharmacy-only medicine.

Preparations from Aloe species

The *Aloe* leaf yields two products which are commercially used – a gel and a residue obtained by drying the juice (also known as latex or sap) of the leaves. This sap is contained in pericyclic cells of the leaf while the gel consists of mucilage from the polyhedral cells of the central region of the leaf (1).

Several references stress that the sap is not to be confused with the *Aloe vera* gel (2, 3). This is because the gel should not include any sap and it is the sap that contains the hydroxyanthracene derivatives responsible for the stimulant laxative effect. Aloin is a chief constituent of *Aloe* sap. The gel consists primarily of water and polysaccharides (pectins, hemicelluloses, glucomannan, acemannan and mannose derivatives).

Status of Aloes in Australia

Aloe barbadensis (synonym of *Aloe vera*), *Aloe ferox* and *Aloe peryi* are listed as substances that may be used in Listed Medicines in Australia. Warning statements about the laxative effect are required if the product is indicated for this purpose and/or the quantity of hydroxyanthracene derivatives is greater than 10 mg per maximum recommended daily dose.

Recommendation

The part of the *Aloe* plant responsible for the laxative effect (the sap) should remain scheduled in New Zealand but the Aloes definition should be refined to enable gel-based products to remain on the market as dietary supplements.

Medsafe therefore recommends refining the wording of Aloes (for internal use) in the schedule to:

Aloe spp – pharmacy-only for internal use, except when derived from the mucilaginous gel obtained from the leaves of *Aloe vera*.

References

- 1) Bruneton J. (1999). Pharmacognosy. Phytochemistry of medicinal plants. 2nd edition. Lavoisier Publishing. Paris.
- 2) World Health Organization. (1999). WHO monographs on selected medicinal plants. Volume 1. World Health Organization. Geneva.
- 3) Sweetman SC. (2007). Martindale: The complete drug reference. 35th edition. Pharmaceutical Press. London.