

General enquiries

26 May 2005

To herbal interest groups

Dear Colleague

Important Safety Information: Acute poisoning from *Coleus forskohlii* containing products

The Medicines and Healthcare products Regulatory Agency (MHRA) has received information from the Italian Regulatory Authority, that certain products containing *Coleus forskohlii* have been associated with four cases of acute atropine like poisoning (agitation, confusion, hallucination, tachycardia, mydriasis and past amnesia) following their ingestion. Two additional adverse drug reaction (ADR) reports of tremor, asthenia, visual disturbance and confusion have also been related to the use of *Coleus forskohlii* containing products in Italy.

The Italian authorities suspect a possible batch contamination. Whilst it has not been confirmed, it is possible that *Coleus forskohlii* may have been substituted or adulterated with a member of the *Solanaceae* family. This is a family which includes a number of poisonous and psychoactive plants, and includes *Atropa Belladonna* (Deadly Nightshade). Many members of the family contain tropane alkaloids such as atropine.

A list of specific products associated with the cases of acute poisoning is provided below. Although we have not received any ADR reports indicative of atropine like poisoning associated with *Coleus forskohlii* in the UK, it is possible these products may have found their way onto our market and potentially pose a risk to public health. **If you or any of your members have stocks of any of these products please quarantine them, cease distribution and notify the MHRA.** It is unclear at this stage whether only the named products are affected or whether contamination of a harvest of *Coleus* may have occurred at source. An update will be provided when further information becomes available.

I am grateful for your assistance in this matter.

Dr Alison Daykin



Senior Herbal Policy Manager

Product	Manufacturer/ Exporter
Coleus forskohlii 20 %	INDOWORLD PRATING COORPORATION (INDIA)
	GALENO SRL
	ALCHEM INTERNATIONAL LTD (INDIA)
	EPO SRL
Coleus forskohlii 10%	EPO SRL
	GALENO SRL