EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health systems and products
Medicinal products – authorisations, European Medicines Agency

PHARM 637

PHARMACEUTICAL COMMITTEE
23 October 2013

Subject: **Questions on marketing of medicinal products containing kava**

Agenda item 6a, AOB

In the framework of the African, Caribbean and Pacific (ACP) - EU Partnership the issue of products containing kava is a recurring topic.

Kava is a herbal product from the Pacific region used to treat anxiety, tension and restlessness. It became very popular in Europe in the 1990s and it was increasingly exported from some ACP countries like Fiji, Tonga and Vanuatu. In early 2000 concerns were raised about the safety of the product due to some allegations of liver toxicity in some people who had used dietary supplements containing kava extract. As a result a number of EU Member States have since 2002 either suspended or revoked marketing authorisations for medicinal products containing kava, pending the provision of conclusive evidentiary proofs of its efficacy. Switzerland, Canada and Australia banned the product.

To get an overview of medicinal products containing kava in the EU the European Commission kindly requests Member States to answer the following questions:

1. Have marketing authorisations for medicinal products containing kava been revoked or suspended in your Member State?
    a. If no,
        i. are there valid marketing authorisations for medicinal products containing kava in your Member State?
        ii. are there medicinal products containing kava marketed in your Member State?
    b. If yes,
        i. when were the marketing authorisations revoked or suspended?
        ii. on which grounds were the marketing authorisations revoked or suspended?
2. Have any applications for registration as traditional herbal medicinal product for a medicinal product containing kava in your Member State been refused?

   a. If yes, on which grounds?
3. Have registrations been granted for traditional herbal medicinal products containing kava in your Member State?

Answers should be sent to SANCO-PHARMACEUTICALS-d6@ec.europa.eu by the end of November 2013.