Summary of responses to consultation MLX 286 - proposal to prohibit the sale, supply and importation of unlicensed medicines containing Kava-kava.

January 2003
1. Consultation MLX 286 on the proposal to prohibit the sale, supply and importation of unlicensed medicines ended on 27 September 2002. 51 responses were received in response to the consultation letter (attached at Annex A). A list of the organisations and individuals who responded is attached at Annex B.

2. A breakdown of the views on possible courses of action to address the issue of liver toxicity, possibly associated with the use of Kava-kava containing products is provided below in Table 1.

Table 1. Breakdown of responses to MLX 286.

<table>
<thead>
<tr>
<th>Options</th>
<th>Respondents*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Take no regulatory action at this time</td>
<td>0</td>
</tr>
<tr>
<td>Continued availability of Kava-kava with information to be made available with the product. Voluntary warnings could be added about hepatic adverse reactions in rare cases. This would be achieved by obtaining voluntary agreement with manufacturers of unlicensed products to include warning information about the risks of rare hepatic adverse reactions.</td>
<td>6</td>
</tr>
<tr>
<td>Continued availability of Kava-kava products that fall within defined parameters e.g. as to type of extract, strength, dosage, part of plant.</td>
<td>4</td>
</tr>
<tr>
<td>Continued availability of products within defined parameters and voluntary warnings</td>
<td>2</td>
</tr>
<tr>
<td>Make Kava-kava a Prescription Only Medicine (POM), limiting supply through a prescription from a doctor or dentist.</td>
<td>0</td>
</tr>
<tr>
<td>Prohibit Kava-kava in unlicensed medicines, except for external use.</td>
<td>19</td>
</tr>
<tr>
<td>No comment</td>
<td>17</td>
</tr>
</tbody>
</table>

*Three of the respondents were opposed to proposals to prohibit Kava-kava but did not state their preferred regulatory option.

3. The largest proportion (40%) of those that responded to the consultation supported the CSM’s recommendation to prohibit the sale and supply of Kava-kava in unlicensed herbal remedies, except those for external use. 36 percent of those that responded had no comments to make on the issue. Many of the responses received from the UK herbal sector consider the proposed action to be out of proportion with the level of risk. The low number of adverse reactions and potential confounding factors, such as alcohol consumption and concomitant medication featured highly in these responses.

4. A number of the major interest groups in the herbal sector considered a voluntary warning to be the most appropriate regulatory option. Some also acknowledge there may be an issue over the effectiveness of voluntary action in this area.
Synopsis of the comments received

The majority of comments received were supportive of the proposal:

The Royal College of GPs made the following observations: the adverse effects of hepatotoxicity are serious; the risks do not appear to outweigh the benefits; there is agreement that taking no action would not be appropriate; other options would not offer sufficient public protection, making Kava-kava POM would not be feasible; and the recommendation is supported.

Pharmacy Misuse Advisory Group (PharMAG) points out that some health food stores were not co-operating with the voluntary ban, suggesting there is a need for regulation of the product. It supports MCA’s decision to prevent the sale of Kava-kava. Safety is a particularly vital issue when efficacy has not been proven. Although abuse of Kava-kava has not been widely reported from UK, in the South Pacific and Australia it has been recognised as a major problem.

Royal Pharmaceutical Society of GB believe that the mechanisms of toxicity are not understood; a safe dose has not been identified because the toxicity does not appear to be dose related; some cases of hepatotoxicity were severe; there was a reported death in Australia linked to Kava-kava; and there is little evidence of health benefits.

National Pharmaceutical Association supports option 5 and expects in future, products containing Kava-kava that have received a Marketing Authorisation to be classified as P.

The Royal College of Physicians supports the plan to prohibit kava-kava in unlicensed medicines. They also ask what plans CSM have in relation to the licensed products for internal use in respect of surveillance and monitoring.

Nuffield Hospitals believe that option 5 is in the best interests of public health.

The Royal College of Physicians of Edinburgh supports the proposal due to the unpredictable risk of serious hepatotoxic effects. The college is concerned how the prohibition will be enforced and recommends that consideration be given to publishing the probable toxicity of Kava-kava to doctors and the wider public.

Cosmetic Toiletry and Perfumery Association (CTPA) state that the proposed ban does not have any impact on cosmetics. It has drawn the information to the attention of members but will not be recommending members not to use Kava-kava in topical products and therefore some topical products may reappear on market.

NHS Information Authority supports option 5 but comments that it overlooks the obvious need for a greater evidence base if the safety and efficacy of this
product is ever to be established. There must be a way of restricting supply in such a way that outcome recording is possible.

In addition, support was received from: The Royal College of Paediatrics and Child Health, NHS Greater Glasgow, UK Clinical Pharmacy Association, the Royal College of Anaesthetists, Northern Ireland Practice and Education Council for Nursing and Midwifery, Guild of Healthcare Pharmacists, Royal College of Midwives, Royal College of Nursing, Royal College of Psychiatrists and BUPA Fylde Coast Hospital.

Those expressing concerns were:

**Council for Responsible Nutrition** supports the proposals but is concerned about a blanket ban in the UK and asks MCA to review the evidence within a year to allow new data to be considered.

**National Institute of Medical Herbalists Research Group**, on behalf of the Traditional Medicines Evaluation Committee of the European Herbal Practitioners Association comments that there is no evidence that traditional preparations of Kava are unsafe. Traditional preparations of Kava have a long established traditional use; the case reports published by the MCA involved OTC preparations, and none of the case reports involved a prescribed medicine from a herbal practitioner. They report on a survey of Kava-kava usage by herbal practitioners.

**Health and Diet Company** believes that the proposals are disproportionate to the perceived risk. They highlight findings from a report by Professor Donald P Waller, Professor of Pharmacology and Toxicology at the University of Illinois, Chicago which states that there are not enough details of patient and medical information to attribute adverse reactions to Kava-kava and support a voluntary label warning for all products that contain Kava-kava.

**Health Food Manufacturers Association (HFMA)** says that the action is pre-emptory, excessive and unjustified and proposes label warnings to alert consumers of dangers.

**Quest** considers this to be an over reaction given the small numbers of adverse reactions and that the consultation document itself points out that levels of risk is likely to be rare at normal doses. They support option 2.

**Bio Health** give examples of customers that have derived considerable benefit from Kava-kava and feel that there must be an alternative to complete prohibition in the UK. Cases of toxicity have not been proven beyond doubt. They support a combination of options 2 and 3.

**Hanover Health Foods** have not been advised of any side effects other than vivid dreams. They propose remedies contain a health warning and that any other course of action would force UK sales underground, compromising quality and result in loss of control by UK regulators.
Weleda states that the reports of liver damage relates solely to herbal doses of Kava, and to their knowledge there are no known reports of such reactions to homeopathic potencies of this stock. They suggest that Article 18 of the proposal, Other Exceptions, be amended to include this class of medicine.

Consumers For Health Choice think that the evidence of risk is weak and the proposed action is unwarranted.

British Herbal Medicine Association are worried that these proposals are setting a precedent that could now be easily applied to other herbal medicinal products. They support options 2 and 3.

The National Association of Health Stores regards the proposals as disproportionate, and quotes studies by Professor Waller and Dr Schmidt. They ask for copies of information MCA is using to justify the proposals and question MCA’s risk/management decision.

International Federation of Professional Aromatherapists are concerned that the ban extends to the whole plant when the evidence was based on standardised extracts.
ANNEX A

ASGBI
Association of Independent Multiple Pharmacies
Bio-Health
British Association of Dermatologists
British Contact Dermatitis Group
British Herbal Medicines Association
British Pharmacological Society
BUPA Hospitals
CKCPA
College of Optometrists
Consumers for Health Choice
Cosmetics, Toiletry & Perfumery Association
Council for Responsible Nutrition
Drug and Therapy Committee of Nuffield Hospitals
Faculty of Pharmaceutical Medicines
George Blair
GHP
Hanover Health Foods
Health and Diet Company
Health and Safety Executive
Health Development Agency
Health Food Manufacturers Association
Help the Aged
International Federation of Professional Aromatherapists
Institute of Health Food Retailing
Joint Royal Colleges Ambulance Service Liaison Committee
Medical Protection Society
National Association of GP Co-operatives
National Association of Health Food Retailers
National Institute of Medical Herbalists
National Pharmaceutical Association
NHS Greater Glasgow
NHS Information Authority
NIPEC
PharMAG
Quest vitamins
Royal College of Anaesthetists
Royal College of GPs
Royal College of Midwives
Royal College of Nursing
Royal College of Nursing Scotland
Royal College of Physicians
Royal College of Physicians Edinburgh
Royal College of Psychiatrists
Royal Pharmaceutical Society
Scottish Consumer Council
Society of Pharmaceutical Medicine
The British Thoracic Society
Viridian
Weleda
Welsh Consumer Council
Consultation MLX 286: Proposals to prohibit the herbal ingredient Kava-kava (*Piper methysticum*) in unlicensed medicines
MLX 286: Proposals to prohibit the herbal ingredient Kava-kava
(*Piper methysticum*) in unlicensed medicines

Summary

1. On 10 July 2002, the Committee on the Safety of Medicines (CSM) advised that there was evidence that Kava-kava was associated with rare cases of hepatotoxicity which may be serious in nature. The CSM considered a number of regulatory options, and reached the provisional recommendation that the use of the plant should be prohibited in unlicensed herbal remedies.

2. Ministers have considered the advice of the CSM and are proposing to make an order under section 62 of the Medicines Act 1968 to prohibit the sale, supply or importation of unlicensed medicinal products consisting of, or containing, Kava-kava, except those for external use only. The proposed order would be made on the grounds that the prohibition of Kava-kava was necessary in the interests of safety. The proposals are set out in more detail in this consultation document and a draft order is attached at ANNEX B. Views on the proposals are invited and responses should be submitted to the MCA using the enclosed form at ANNEX D by 27 September 2002. A decision on whether to make the proposed order will be made only after careful consideration of the responses and further advice from the CSM as necessary.

Background

Kava-kava

3. The herbal ingredient Kava-kava is derived from the plant *Piper methysticum*, a member of the pepper family native to the islands in the South Pacific. It has been used widely in Europe for many years as a remedy for nervous states such as anxiety, tension and restlessness. In the UK there are a number of medicinal products consisting of, or containing, the herbal ingredient Kava-kava.

Regulation of medicines containing Kava-kava in the United Kingdom

4. As with other herbal medicines, there are two regulatory routes by which herbal medicines containing Kava-kava can reach the UK market:

   - as unlicensed herbal remedies (through an exemption from licensing under section 12 of the Medicines Act).
   - as licensed herbal medicines.

5. The MCA understands that the majority of herbal medicines containing Kava-kava reach the UK market as unlicensed herbal remedies.
Previous action on Kava-kava

6. The issue of liver toxicity was initially raised in Europe in late 2000 due to a cluster of cases in Switzerland. The issue was raised again in November 2001 due to the rapid increase in the number of reports in Germany and Switzerland. The CSM first considered the issue in December 2001. At that time, the CSM reached an initial view on the evidence available that risks appeared to outweigh possible benefits. The CSM recognised that further work was needed on the emerging safety issue before the Committee could give advice on what, if any, regulatory action may be appropriate. At that time no cases of hepatotoxicity had been reported in the UK. The herbal sector instigated a voluntary withdrawal of products containing Kava-kava while the safety concerns were further investigated, a move which was welcomed by the MCA and CSM.

7. The issue was also considered by a Working Group of the CSM, set up specifically to further assess the safety of Kava-kava. The Working Group considered additional data provided by the herbal sector and other regulatory authorities. Herbal stakeholders also attended the meeting to present their views and data to the group. The Working Group advised that the balance of risks and benefits for Kava-kava continued to be negative. In the interests of fairness and proportionality the herbal sector were asked to provide any further safety or efficacy data they wished to be considered. Subsequently, additional data was provided by the sector.

The risk to consumer health

8. Since the CSM first considered the issue, additional case reports have emerged. By July 2002, 68 case reports of liver toxicity (hepatotoxicity), possibly associated with use of Kava-kava containing products, have been received by the MCA. The case reports originated from Germany, Switzerland, France, Canada, the USA and the UK. The severity of the liver damage suffered varies and includes abnormal liver function, jaundice, hepatitis, liver failure and death. In six cases the patients suffered irreversible liver failure and received liver transplants. Three patients died, including one who had received a transplant. There have been three reported cases in the UK. None of the cases have been fatal but one patient was hospitalised for several weeks. The outcome of this case is currently unknown.

9. The available data, including the additional case reports and information submitted by the sector, was considered by the CSM on 10 July 2002 and further advice was given. On the basis of the data available, the CSM has reached the provisional view that the possible therapeutic benefits of medicines containing Kava-kava can not be considered to outweigh the safety risks. The Committee advised that Kava-kava had the potential to cause hepatotoxicity which may be serious in nature.

10. The level of risk to individuals consuming Kava-kava is not known but it is likely to be rare at normal doses. The cases reported can not be used to estimate the incidence of the suspected adverse reaction within the population, as it is likely that only a small proportion of suspected adverse reactions associated with herbal
remedies are reported. It is also not known how widespread the use of Kava-kava is in the UK. The mechanism of toxicity is also unknown and there are no clear predictors of toxicity making the onset of damage unpredictable. The CSM considered carefully evidence provided by the herbal sector but concluded that, at present, there was no evidence of a relationship between the strength, dosage, degree of processing or method of extraction of the Kava-kava and the adverse reactions.

11. The Committee gave detailed consideration to a range of regulatory options. Due to the seriousness of some of the cases and the lack of predictive factors, the Committee advised that the use of Kava-kava be prohibited in unlicensed medicines.

The proposal

12. In the light of the CSM’s recent advice, and to address the rare but serious risk of liver toxicity, Ministers are proposing to make an order under section 62 of the Medicines Act 1968 to prohibit the sale, supply and importation of unlicensed medicinal products containing the herbal ingredient Kava-kava other than products which are for external use only.

Herbal medicines affected by the proposal

13. The proposal does affect all unlicensed herbal remedies for internal use which are on the UK market under section 12 of the 1968 Medicines Act which consist of or contain any:

- part of the Kava-kava plant, and/or
- extract prepared from any part of the Kava-kava plant.

14. Unlicensed herbal remedies available over-the-counter (OTC) and those supplied through an individual such as herbalist or doctor are affected by the proposal irrespective of dosage.

15. The evidence that Kava-kava is harmful relates only to internal use. Therefore, this proposal does not affect unlicensed herbal remedies for external use only.

16. This proposal does not affect any medicinal product which has a product licence, a marketing authorisation, or a homoeopathic certificate of registration. Separate regulatory action is in progress in relation to such products.

17. Kava-kava products may be available as both medicinal products and foods. As such, responsibility for their regulation and control falls to the MCA and the Food Standards Agency (FSA), respectively. The proposal does not affect products properly classified as foods. However, the Food Standards Agency (FSA) is consulting separately on proposed legislation to ban the use of Kava-kava in food.
Other exceptions

18. In addition to the exceptions for licensed products and for remedies solely for external use, the prohibition would not apply to:

- the sale or supply to, or importation by or on behalf of, a person exercising functions in relation to the enforcement of food or medicines legislation,

- the importation from a European Economic Area (EEA) State, if the product in question originates from such a state or originates outside the EEA but is in free circulation in Member States (within the meaning of Article 23.2, when read with Article 24, of the EC Treaty), and is for re-export to another EEA State, rather than the UK market.

Timetable

19. The consultation period closes on 27 September 2002. This timetable is intended to balance the need to act promptly on a safety issue against the requirement to hold a consultation that is fair and adequate.

20. If, after careful consideration of stakeholders views, the appropriate Ministers consider the proposed prohibition to be necessary in the interests of safety, the prohibition order would be made as soon as possible.

Publication of comments

21. To help informed debate on the issues raised by this consultation exercise, and within the terms of the Code of Practice on Access to Government Information (“Open Government”), the Agency intends to make publicly available a summary of responses received to this consultation.

22. The Agency’s Information Centre at Market Towers will supply copies of the results of the consultation on request. Copies may be further reproduced. An administrative charge, to cover the cost of photocopying and postage, may be applied.

23. We will assume that your comments can be made publicly available in this way unless you indicate on the reply form that you wish all or part of them to be treated as confidential and excluded from this arrangement. Under the Code of Practice on Access to Government Information, the Agency will not release confidential replies or replies containing personal confidential information.

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1 The order would be made by the appropriate Ministers, who for these purposes are the Secretary of State for Health and the Northern Ireland Minister for Health, Social Services and Public Safety (see Section 1(1) and 62 of the Medicines Act 1968).
24. Should you have any questions regarding the proposals or the conduct of the consultation exercise, please contact Alison Daykin (Tel: 020 7273 0404, Email: alison.daykin@mca.gsi.gov.uk). If you consider there are other organisations that should be invited to comment on these proposals, please either pass a copy of the documents to them or contact the MCA and we will arrange for a consultation pack to be sent to them.
MLX 286: Proposals to prohibit Kava-kava (*Piper methysticum*)
in unlicensed medicines

**DRAFT PARTIAL REGULATORY IMPACT ASSESSMENT (RIA)**

**Purpose and intended effect of the proposal**

**Issue:**

1. Evidence has emerged that, in rare cases, members of the public consuming products containing the plant Kava-kava may suffer liver damage. To date, 68 possible reports of suspected liver toxicity, associated with the use of Kava-kava, have been received by the Medicines Control Agency. Out of these, six patients suffered irreversible liver failure and required a transplant. Three patients, including one of the transplant patients, died.

**Objective:**

2. To protect public health.

**Risk assessment**

3. 68 case reports of liver toxicity (hepatotoxicity), possibly associated with the use of Kava-kava containing products have been received by the MCA. The case reports originate from a several countries, including three from the UK. The severity of the liver damage suffered varies widely. Adverse reactions include abnormal enzyme activity with no symptoms, jaundice, hepatitis, liver failure and death. In six cases the patient suffered irreversible liver failure and received liver transplants. Three patients died, one following a transplant.

4. Advice has been sought on the issue from the Committee on the Safety of Medicines (CSM), an independent group of experts which advises the Medicines Control Agency on the safety of medicines. Following the receipt of initial case reports of liver cell damage, the CSM first considered the safety of Kava-kava in December 2001. On the available safety and efficacy (effectiveness) evidence, the CSM provisionally advised at that time that the possible therapeutic benefits of medicinal products containing the herbal ingredient can not be considered to outweigh the safety risks.

5. The CSM further considered all the latest available evidence in July 2002, including the information submitted by the herbal sector, and gave further advice. The Committee gave the provisional opinion that there was sufficient evidence that Kava-kava was associated with rare cases of hepatotoxicity which may be serious in nature. In view of the potential risk of hepatotoxicity the Committee provisionally advised that the safety risks outweighed the possible therapeutic benefits of medicinal products containing the herbal ingredient.
6. The Committee gave detailed consideration to a range of regulatory options and advised that Kava-kava be prohibited in unlicensed medicines.

7. Due to the current regulatory arrangements for unlicensed herbal remedies, the number of products in the UK and the level of use by the population are not known. The level of risk to the population can therefore not be determined. It is, however, thought likely that many of the unlicensed Kava-kava products available in the UK are equivalent in terms of form (e.g. type of extract or raw herb) and dose to the products used worldwide that have been associated with the adverse reactions. Anyone who takes Kava-kava preparations may be at risk although harm is likely to be rare under normal conditions of use.

Options

Five options have been identified for unlicensed herbal remedies:

Option 1: take no regulatory action at this time.

Option 2: continued availability of Kava-kava with information to be made available with the product. Voluntary warnings could be added about hepatic adverse reactions in rare cases. This would be achieved by obtaining voluntary agreement with manufacturers of unlicensed products to include warning information about the risks of rare hepatic adverse reactions.

Option 3: continued availability of Kava-kava products that fall within defined parameters e.g. as to type of extract, strength, dosage, part of plant.

Option 4: make Kava-kava a Prescription Only Medicine (POM), limiting supply through a prescription from a doctor or dentist

Option 5: prohibit Kava-kava in unlicensed medicines, except for external use.

Quantifying and valuing the options

Option 1 (take no regulatory action)

8. This option would not provide any public health protection and would be contrary to the advice of the CSM that Kava-kava poses a risk. There would be little direct cost to business, overall. However, if reports of adverse reactions to Kava-kava continued to mount, public confidence in herbal remedies could be damaged and this would be to the detriment of the herbals market.

Option 2 (continued availability with safety warnings)

9. Voluntary warnings would be the only means of introducing warnings for users. It is unclear whether there would be full compliance with voluntary arrangements. There would be no sanctions or means of enforcement. There would be no means
for the public to determine whether they were at risk. On the basis of the CSM’s advice this option would represent an insufficient response to the risk.

**Option 3 (continued availability within defined parameters)**

10. The CSM’s view is that on evidence currently available, data does not show any relationship between dosage or the type of preparation with hepatotoxicity. There is no scientific basis for determining a threshold below which Kava-kava does not pose a risk. There is no information to determine if different parts of the plant are free from risk.

**Option 4 (make Kava-kava a POM)**

11. As the mechanism of toxicity is not understood and the onset of liver damage is unpredictable, there are no clear factors which would allow a doctor to safely prescribe Kava-kava. On the basis of the CSM’s advice, this was not considered an appropriate option to address the rare but serious risk of liver toxicity.

**Option 5 (prohibit in unlicensed medicines)**

12. Due to the provisional advice of the CSM on the seriousness of some of the cases of hepatotoxicity and, the lack of clear evidence of efficacy, it was thought necessary to consult upon this option.

**Issues of equity or fairness**

13. A statutory prohibition would ensure that the same restrictions on sale and supply are applied to all businesses. This would not necessarily be the case with any arrangements which were voluntary.

14. A notification or ‘draft technical regulation’ (under Directive 98/34/EC) about the proposal has been issued to the European Commission. This will communicate the anticipated effects of the measure and will give other Member States and the Commission an opportunity to raise concerns about potential barriers to trade.

15. The evidence that Kava-kava is harmful relates only to internal use. In the interests of fairness and proportionality, unlicensed herbal remedies for external use which contain Kava-kava are not affected by the proposal.

**BENEFITS IDENTIFIED AND QUANTIFIED**

16. The proposed legislation will benefit public health by introducing protection against unlicensed herbal remedies containing Kava-kava. Costs to the National Health Service, for example, due to hospitalisation, required treatment for jaundice and transplantations could also be avoided.
COMPLIANCE COSTS FOR BUSINESS

Business sector affected

- Importers of the herbal material which supply manufacturers or herbalists.
- Manufacturers and importers of products containing Kava-kava.
- Wholesalers and retailers of products.
- Herbalists making and preparing herbal medicines containing Kava-kava to meet an individual patient’s specific needs.

Recurring costs, Non recurring costs and Total Compliance Costs

17. Financially, for individual businesses in particular, the impact directly relates to the amount of Kava-kava sold and the proportion of these sales in relation to total sales.

18. As the majority of medicines in the UK containing Kava-kava are supplied as unlicensed herbal remedies, the number of products on the market and the level of sales is unknown. In the short term the impact could be significant for certain businesses, some of which may be classified as small businesses. In the longer term, the impact depends on the extent to which the loss of Kava sales might be replaced by other products. Stakeholders are asked to comment on the regulatory impact during consultation and this section will be expanded upon once views have been received.

19. In the long term, the level of protection provided by the order may help maintain a high confidence in herbal medicines by consumers.

SUMMARY AND RECOMMENDATIONS

Option 1: (take no regulatory action at this time)

20. No public health protection would be provided. Given the provisional advice of the CSM this would be inappropriate.

Option 2: (continued availability of Kava-kava with information)

21. Would enable consumers to decide whether to accept the risk but would not provide a means by which consumers could minimise the risk. A voluntary labelling approach, with no sanctions, is insufficient to address the potential risk to health.
**Option 3:** (continued availability of Kava-kava products within defined parameters)

22. The data currently available does not support this as a feasible option for protecting public health. If, during consultation or in the future, further scientific evidence emerged relevant to this option the possibility would be reconsidered.

**Option 4: (make Kava-kava a POM)**

23. As the mechanism of toxicity is not understood and the onset of liver damage is unpredictable there are no clear factors which would allow a doctor to safely prescribe Kava-kava. The CSM did not think this would address the rare but serious risk of liver toxicity.

**Option 5:** (prohibit Kava-kava in unlicensed medicines)

24. In view of the nature of the risk, this is the most appropriate option. This is necessary in the interests of public health.

**ENFORCEMENT, SANCTIONS, MONITORING AND REVIEW**

25. The prohibition will be enforced by the MCA’s Enforcement Unit as part of its existing compliance and enforcement responsibilities in protecting public health. Offenders will be liable to prosecution and unlicensed medicines will be included in the Agency’s regular product monitoring programme.
MLX 286: Proposals to prohibit Kava-kava (*Piper methysticum*)
in unlicensed medicines

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**Citation, commencement and interpretation**

1. (1) This Order may be cited as the Medicines for Human Use (Kava-kava) (Prohibition) Order 2002 and shall come into force on [ ] 2002.

   (2) In this Order—

   “the Act” means the Medicines Act 1968;

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(2) 1968 c.67; the expression “the appropriate Ministers” and the expression “the Health Ministers”, which are relevant to the powers being exercised in the making of this Order, are defined in section 1 of that Act, as amended by article 2(2) of, and Schedule 1 to, S.I. 1969/388 and by article 5 of, and paragraph 1(1) of the Schedule to, S.I. 1999/3142.

(3) In the case of the Secretary of State concerned with health in England, by virtue of article 2(2) of, and Schedule 1 to, S.I. 1969/388; and articles 2(1) and 5 of, and paragraph 1(1) of the Schedule to, S.I. 1999/3142; and in the case of the Minister of Health, Social Services and Public Safety, by virtue of section 95(5) of, and paragraph 10 of Schedule 12 to, the Northern Ireland Act 1998 (c.47).

(4) Section 62(3) refers to the “appropriate committee”, which is defined in section 4(6) of the Act. The Committee on Safety of Medicines was established under section 4 of the Act, by S.I. 1970/1257, for the purposes set out in that instrument.
“EEA Agreement” means the Agreement on the European Economic Area signed at Oporto on 2nd May 1992(5) as adjusted by the Protocol signed at Brussels on 17th March 1993(6);

“EEA State” means a State which is a Contracting Party to the EEA Agreement;

“external use” means application to the skin, hair, teeth, mucosa of the mouth, throat, nose, ear, eye, vagina or anal canal when a local action only is intended and extensive systemic absorption is unlikely to occur, and references to medicinal products being “for external use” shall be read accordingly – except that such references shall not include throat sprays, throat pastilles, throat lozenges, throat tablets, nasal drops, nasal sprays, nasal inhalations or teething preparations;

“free circulation in member States” has the same meaning as in Article 23.2, as read with Article 24, of the Treaty establishing the European Community; and

“medicinal product” does not include a medicinal product which is a veterinary drug.

Prohibition of sale, supply or importation of any medicinal product consisting of or containing *Piper methysticum* (known as Kava-kava)

2. Subject to article 3 below, the sale, supply or importation of any medicinal product consisting of or containing—

(a) a plant(7) belonging to the species *Piper methysticum* (known as Kava-kava); or

(b) an extract from such a plant,

is prohibited.

Exceptions to the prohibition imposed by article 2

3. The prohibition imposed by article 2 above shall not apply where the medicinal product is—

(a) for external use only;

(b) sold or supplied to, or is imported by or on behalf of, any of the following persons—

(i) an authorised officer within the meaning of section 5(6) of the Food Safety Act 1990(8) or Article 2(2) of the Food Safety (Northern Ireland) Order 1991(9),

(ii) a food analyst or food examiner within the meaning of section 30 of the Food Safety Act 1990(10) or Article 30 or 31 of the Food Safety (Northern Ireland) Order 1991(11),

(iii) a person duly authorised by an enforcement authority under sections 111 and 112 of the Act, or

(iv) a sampling officer within the meaning of Schedule 3 to the Act(12);

(c) imported from an EEA State, if the product—

(i) originates in an EEA State, or

(ii) originates outside the European Economic Area, but is in free circulation in member States,

and is being, or is to be, exported to an EEA State other than the United Kingdom; or

(d) the subject of—

(i) a product licence(13),

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(5) OJ No. L1, 3.1.1994, p.3.
(7) “Plant” includes part of a plant; see the definition of “plant” in section 132(1) of the Act.
(8) 1990 c.16; section 5(6) was amended by paragraphs 7 and 8 of Schedule 5 to the Food Standards Act 1999 (c.28).
(9) S.I. 1991/672 (N.I. 7); article 2(2) was amended by articles 3(1) and 7(1) of the Food Safety (Amendment) (Northern Ireland) Order 1996 (S.I. 1996/1633 (N.I.12)) and paragraphs 26 and 29 of Schedule 5 to, and Schedule 6 to, the Food Standards Act 1999.
(10) Section 30 was amended by paragraphs 7 and 8 of Schedule 5 to the Food Standards Act 1999.
(11) Article 31 was amended by paragraphs 26 and 35 of Schedule 5 to the Food Standards Act 1999.
(12) Schedule 3 was amended by paragraph 12 of Schedule 3 to the Food Safety Act 1990.
(13) “Product licence” has the meaning assigned to it by section 7 of the Act.
(ii) a marketing authorization within the meaning given in regulation 1(4)(a) of the Medicines for Human Use (Marketing Authorisation Etc) Regulations 1994(14), or

(iii) a certificate of registration within the meaning given in regulation 1(2) of the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994(15).

Signed by authority of the Secretary of State for Health

Parliamentary Under Secretary of State

2002

Department of Health

2002

Minister of Health, Social Services and Public Safety

EXPLANATORY NOTE
(This note is not part of the Order)

This Order prohibits the sale, supply or importation of any medicinal product for human use which consists of or contains a plant (or part of a plant) belonging to the species *Piper methysticum* (known as Kava-kava) or an extract from such a plant.

This prohibition is subject to the following exceptions—

(a) where the product is for external use only;

(b) where the sale or supply is to, or the importation is made by or on behalf of, a person exercising functions in relation to the enforcement of food or medicines legislation;

(c) where the product is imported from an EEA State, if it originates from such a State or originates outside the EEA but is in free circulation in Member States (within the meaning of Article 23.2, when read with Article 24, of the EC Treaty), and is being, or is to be, exported to an EEA State other than the United Kingdom;

(d) where the product is the subject of a product licence, marketing authorization or homoeopathic certificate of registration.


A Regulatory Impact Assessment in relation to this Order has been placed in the libraries of both Houses of Parliament, and copies can be obtained from the Medicines Control Agency, Information Centre, Room 10-202, Market Towers, 1 Nine Elms Lane, London, SW8 5NQ.
ANNEX C

MLX 286: Proposals to prohibit Kava-kava (*Piper methysticum*) in unlicensed medicines

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- British Complementary Medicines Association
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- British Dental Association (Northern Ireland)
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- British Dental Association (Wales)
- British Dental Trade Association
- British Diabetic Association
- British Epilepsy Association
- British Flower and Vibrational Essences Association
- British Generic Manufacturers Association
- British Heart Foundation
- British Herb Trade Association
- British Herbal Medicines Association
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- British Institute of Regulatory Affairs
- British Medical Association
- British Medical Association (Northern Ireland)
- British Medical Association (Scottish Branch)
- British Medical Association (Welsh Office)
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- British Society for Rheumatology
- British Society of Gastroenterology
- British Toxicology Society
- Broadcast Advertising Clearance Centre
- BAAAP
- CARE
- Careers National Association
- CCCPH
- Central Medical Advisory Committee
- Chemical Industries Association
- Chemist & Druggist
- Chinese Medical Institute & Register
- Chiropodists Board
- CMAS
- College of Health
- College of Optometrists
- College of Pharmacy Practice
- Common Services Agency
- Commonwealth Working Group on Traditional and Complementary Health
- Community Pharmacy Magazine
- Community Practitioners and Health Visitors Association
- Community Services Pharmacists Group
- Company Chemist Association Ltd
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Overseas Doctors Association in the UK Ltd
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Pharmaceutical Contractors Committee
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Prescription Medicines Code of Practice Authority
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Quest Vitamins
Radio Advertising Clearance Centre
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Register for Chinese Herbal Medicine
Registered Nursing Home Association
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Royal College of Midwives
Royal College of Nursing
Royal College of Nursing (Northern Ireland)
Royal College of Nursing (Scotland)
Royal College of Nursing (Wales)
Royal College of Obstetricians & Gynaecologists
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Royal College of Pathologists
Royal College of Physicians & Surgeons (Glasgow)
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Royal Society for the Promotion of Health
School of Homoeopathic Medicine
Scottish Consumer Council
Scottish Executive
Scottish General Medical Services Committee
Scottish Pharmaceutical General Council
Scottish Wholesale Druggists Association
Scrip Ltd
Shadow Health Professionals Council
Social Audit
Society of Homoeopaths
Society of Pharmaceutical Medicine
Society for the Promotion of Nutritional Therapy
Solgar Vitamin and Herb
Specialist Herbal Supplies
Sterilised Suture Manufacturers Association
Surgical Dressings Manufacturers Association
TAPASI
Terrance Higgins Trust
The British Thoracic Society
The Herb Society
The Institute for Complementary Medicine
UK Central Council for Nursing, Midwifery & Health Visiting
UK Clinical Pharmacy Association
UK Homoeopathic Medical Association
UK Inter-Professional Group
Unified Register of Herbal Practitioners
University of London
Veterinary Medicines Directorate (VMD)
Weleda (UK) Ltd.
Welsh Consumer Council
Women in Medicine
MLX 286: Proposals to prohibit Kava-kava (*Piper methysticum*)
in unlicensed medicines

REPLY FORM

Please tick box as appropriate

- We have no comments to make on the proposals in MLX 286

- Our comments on the proposals in MLX 286 are below/attached

- My reply may be made freely available

- My reply is confidential

- My reply is partially confidential (indicate clearly in the text any confidential elements)

Signed:_____________________________

Date:__________________