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To: Interested organisations

25 July 2002

Dear Sir or Madam

**CONSULTATION LETTER MLX 286: PROPOSALS TO PROHIBIT THE
HERBAL INGREDIEINT KAVA-KAVA (*PIPER METHYSTICUM*) IN
UNLICENSED MEDICINES**

1. Please find the attached consultation document MLX 286. You are invited to consider and comment upon the proposals set out in the document including the draft Partial Regulatory Impact Assessment.
2. The consultation document MLX 286 contains:
 - a summary and the background to the proposal
 - ANNEX A - a draft partial Regulatory Impact Assessment (RIA)
 - ANNEX B - a draft Order
 - ANNEX C - a list of organisations being consulted
 - ANNEX D - a reply form.

3. 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).
4. Replies should arrive at the MCA **no later than 27 September 2002**. Please send your replies using the attached form to:

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London SW8 5NQ

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fax: 0207 273 0387
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5. Finally, you may wish to note that a parallel consultation is being carried out by the Food Standards Agency on a proposal to prohibit the use of Kava-kava in food.

Yours faithfully

Richard Woodfield
Group Manager Herbal Policy



CONSULTATION DOCUMENT MLX 286

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 wide spread 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 though 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 Ministers¹ 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.

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**

S T A T U T O R Y I N S T R U M E N T S

2002 No.

MEDICINES

**The Medicines for Human Use (Kava-kava) (Prohibition) Order
2002**

<i>Made</i> - - - -	2002
<i>Laid before Parliament</i>	2002
<i>Coming into force</i> - -	2002

As respects England, Wales and Scotland, the Secretary of State concerned with health in England and as respects Northern Ireland, the Minister of Health, Social Services and Public Safety, acting jointly, in exercise of the powers conferred upon them by section 62(1)(a) and (2) of the Medicines Act 1968(2) or, as the case may be, the powers conferred by those provisions and now vested in them(3), and of all other powers enabling them in that behalf, it appearing to them to be necessary in the interests of safety to make the following Order, after consulting such organisations as appear to them to be representative of interests likely to be substantially affected by the Order pursuant to section 129(6) of that Act, after consulting and taking into account the advice of the Committee on Safety of Medicines pursuant to sections 62(3) and 129(7) of that Act(4), and after taking into account the report of the Medicines Commission made under section 62(5) of that Act, hereby make the following Order:

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⁾,

⁽⁵⁾ OJ No. L1, 3.1.1994, p.3.

⁽⁶⁾ OJ No. L1, 3.1.1994, p.572.

⁽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

2002

Parliamentary Under Secretary of State
Department of Health

2002

Minister of Health, Social Services and Public Safety

⁽¹⁴⁾ S.I. 1994/3144; as amended by S.I. 1998/3105, 2000/292, 2001/795 and 2002/236 and 542.

⁽¹⁵⁾ S.I. 1994/105; as amended by S.I. 1995/541, 1996/482, 1998/574, 1999/566, 2000/592, 2001/795 and 2002/236 and 542.

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.

This Order was notified to the European Commission in accordance with Article 8 of the European Parliament and Council Directive 98/34/EC (OJ No. L204, 21.7.1998, p.37), as amended by Article 1(4) of the European Parliament and Council Directive 98/48/EC (OJ No. L217, 5.8.1998, p.18).

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.

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

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	College of Pharmacy Practice
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	Community Pharmacy Magazine
	Community Practitioners and Health Visitors Association
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 Ireland)
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 Foundation for Integrated Medicine
 General Medical Council
 General Medical Services Committee
 General Medical Services Committee (Wales)
 General Practitioners Association (NI)
 Genetic Interest Group
 GNC
 Grayshott Health Foods
 Guild of Healthcare Pharmacists
 HCSA
 Health and Diet Company
 Health & Safety Executive
 Health Development Agency
 Health Education Authority
 Health Food Manufacturer's Association
 Health Service Commissioner
 Health Which?
 Help the Aged
 Holland and Barrett
 IHRC
 Imperial Cancer Research Fund
 Independent Healthcare Association
 Independent Television Commission
 Institute of Biology
 Insulin Dependent Diabetes Trust

Internal Holistic Aromatherapy Foundation
 Institute for Optimum Nutrition
 Institute of Quality Assurance
 Institute of Health Food Retailing
 International Society of Professional
 Aromatherapists
 International Federation of Aromatherapists
 Jessop Marketing
 Joint Royal Colleges Ambulance Service
 Liaison Committee
 Local Authority Central Office of Trading
 Standards (LACOTS)
 Long-Term Medical Conditions Alliance
 Medical Defence Union
 Medical Devices Agency
 Medical Protection Society Ltd
 Medical Research Council
 Medical Women's Federation
 Medicines Commission
 MIMS (Haymarket Medical Publishing Ltd)
 Ministry of Defence
 National Asthma Campaign
 National AIDS Trust
 National Assembly for Wales
 National Association of GP Co-operatives
 National Association of Health Stores
 National Association of Primary Care
 National Association of Women Pharmacists
 National Back Pain Association
 National Board for Nursing, Midwifery and
 Health Visiting
 National Board for Nursing, Midwifery &
 Health Visiting (NI)
 National Board for Nursing, Midwifery &
 Health Visiting for Scotland
 National Consumer Council
 National Council of Women of GB
 National Eczema Society
 National Federation of Retail Newsagents
 National Federation of Women's Institutes
 National Institute of Medical Herbalists
 National Meningitis Trust
 National Pharmaceutical Association
 Natural Medicines Manufacturers' Association
 UK
 Natural Medicines Society
 NCH & SPCS
 Neonatal and Paediatric Pharmacists Group
 Neurological Alliance
 NHS Alliance
 NHS Confederation
 NHS Information Authority (Coding &
 Classification)
 NHS Pharmaceutical Quality Control
 Committee
 Northern Ireland Consumer Council
 Organic Herb Trading Company Ltd.
 OTC Bulletin
 OTC Business News (Informa Publishing
 Group Ltd)

OTC News & Market Report
 Overseas Doctors Association in the UK Ltd
 Paediatric Chief Pharmacists Group
 Patients Association
 Peter Black Healthcare Ltd.
 Pharmaceutical Contractors Committee
 (Northern Ireland)
 Pharmaceutical Journal
 Pharmaceutical Quality Group
 Pharmaceutical Services Negotiating
 Committee
 Pharmaceutical Society for Northern Ireland
 Prescription Medicines Code of Practice
 Authority
 Prescription Pricing Authority
 Proprietary Association of Great Britain
 Quest Vitamins
 Radio Advertising Clearance Centre
 Radio Authority
 Register for Chinese Herbal Medicine
 Registered Nursing Home Association
 Royal College of Anaesthetists
 Royal College of General Practitioners
 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
 Royal College of Ophthalmologists
 Royal College of Paediatrics and Child Health
 Royal College of Pathologists
 Royal College of Physicians & Surgeons
 (Glasgow)
 Royal College of Physicians (Edinburgh)
 Royal College of Physicians (London)
 Royal College of Psychiatrists
 Royal College of Radiologists
 Royal College of Surgeons (Edinburgh)
 Royal College of Surgeons (England)
 Royal College of Surgeons (Faculty of Dental
 Surgery)
 Royal Colleges of Physicians : Faculty of
 Pharmaceutical Medicine
 Royal Colleges of Physicians : Faculty of
 Public Health Medicine
 Royal Pharmaceutical Society of Great Britain
 Royal Pharmaceutical Society of Great Britain
 (Scotland)
 Royal Pharmaceutical Society of Great Britain
 (Welsh Executive)
 Royal Society of Chemistry
 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

ANNEX D

To:

Miss Alexandra Williamson
Medicines Control Agency
Room 16/131 Market Towers
1 Nine Elms Lane
LONDON SW8 5 NQ

From:

**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: _____