التاريخ : ٢٨/ ٦ / ٢٠٢٠ المرجع : م ص Ref. : Date : / /

قرار وزاري رقم ١٠ / لسنة ٢٠٢٠

بشأن اعادة تنظيم تسجيل وتداول الأدوية النباتية والمستحضرات العشبية

وزير الصحة:

- بعد الاطلاع علي أحكام القانون رقم 28 لسنة 1996 في شأن تنظيم مهنة الصيدلة وتداول الأدوية وتعديلاته ولائحته التنفيذية الصادرة بالقرار الوزاري رقم 395 لسنة 1997 والقرارات المنفذة والمكملة لها.
- وعلى القرار الوزاري رقم 319 لسنة 2005 بإعادة تنظيم جهاز الرقابة الدوائية والغذائية بالوزارة.
- وعلى القرار الوزاري رقم 201 لسنة 1997 في شأن تسجيل وتداول واستيراد الأدوية النباتية.
- وعلى القرار الوزاري رقم 278 لسنة2019 بشأن اعتماد اسعار واجور الخدمات التي تقدمها وزارة الصحة .
- وعلى توصيات اجتماع اللجنة الفنية لدراسة وتحديث القرارات الوزارية الخاصة بمراقبة التسجيل والافراج بإدارة تسجيل ومراقبة الأدوية الطبية والنباتية المشكلة بالقرار الإداري رقم 7 لسنة 2020، وما عرضه علينا السيد / الوكيل المساعد لشئون الرقابة الدوائية والغذائية بالكتاب رقم 136-2020 المؤرخ 2020/5/5.
- ورغبة في اعادة تنظيم تسجيل وتداول واستيراد الأدوية النباتية والمستحضرات العشبية.
- وبناءً على مقتضيات المصلحة العامة، وما عرضه علينا السيد / وكيل الوزارة.

- قـــرر -

مادة أولى: يقصد بالمصطلحات التالية المعنى المبين قرين كل من:

- الدواء النباتي / المستحضر العشبي: المنتج الذي يحتوي على مادة فعالة مكونة من عشبة أو مجموعة من الأعشاب تستخدم للعلاج أو الوقاية من الأمراض، ويستخدم للاستعمال الداخلي أو الخارجي.

*يندرج شاي الأعشاب ضمن المستحضرات العشبية بشرط أن يحتوي على ادعاء طبي.

*لا يسمح للدواء النباتي / المستحضر العشبي باستعماله عن طريق الحقن.

*لا يعتبر دواء نباتي / مستحضر عشبي في حال إذا كانت المادة المستخلصة من النباتات مصنفة كدواء طبي بشري.

- الوكيل المحلي: هي الشركة الممثلة لواحد أو أكثر من الشركات المصنعة / المسوقة للأدوية النباتية والمستحضرات العشبية والمرخص لها ببيع المنتج في دولة الكويت، والمسئولة عن جميع الإجراءات

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القانونية المتعلقة بالمنتج من بيع أو سحب أو إتلاف أو رصد ومتابعة الأعراض الجانبية وخلافه داخل دولة الكويت.

- الشركة المصنعة: هي المنشأة التي يتم فيها تصنيع المنتج وفقا لأسس التصنيع الجيد.
- الشركة المالكة لحق التسويق: هي الشركة التي تتولى تسويق المنتج سواء كانت الشركة المصنعة أو المتعهدة بالتسويق، وتكون مسئولة مسئولية كاملة عن جودة المنتج ومأمونيته وفعاليته ومتابعته بعد التسويق وجميع الإجراءات القانونية المتعلقة بالمنتج من بيع أو سحب أو إتلاف أو رصد ومتابعة الأعراض الجانبية وخلافه في جميع الدول التي يسوق فيها المنتج.
- شهادة المستحضر الصيدلاني CPP: شهادة صادرة من السلطات الصحية المختصة في بلد المنشأ التي يتم فيها التصنيع كاملا أو جزء من التصنيع أو مالكة لحق تسويق المنتج.
- بلد المنشأ: هي بلد الشركة المصنعة أو الحائزة على حق تسويق المنتج الذي تصدر سلطاته الصحية الرقابية شهادة المستحضر الصيدلاني.

مادة ثانية: تخضع للتسجيل جميع الأدوية النباتية والمستحضرات العشبية المراد تسويقها في دولة الكويت وفقا لهذا القرار.

مادة ثالثة: يشترط أن يكون المنتج المقدم للتسجيل مسجل ويتم تسويقه في بلد المنشأ، وفي حال عدم تسويقه يتم توضيح الأسباب ومن ثم يتم تقييمها من قبل إدارة تسجيل ومراقبة الأدوية الطبية والنباتية للموافقة أو الرفض على طلب التسجيل.

مادة رابعة: يشترط لتسجيل الأدوية النباتية والمستحضرات العشبية التالي:

1. **المتطلبات الخاصة بالوكيل المحلي:**

- ترخيص مزاولة نشاط بيع الأدوية النباتية والمستحضرات العشبية أو ما يعادله صادر من وزارة التجارة والصناعة .
- ترخيص مستودع طبي صادر من وزارة الصحة.
- تفويض توقيع ممثلي الشركة صادر من غرفة التجارة والصناعة.
- صور عن البطاقة المدنية لممثلي الشركة.

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2. المتطلبات الخاصة بالشركة المالكة لحق التسويق:

- خطاب الوكالة الحصرية يوضح العلاقة التجارية بين الوكيل المحلي والشركة.
- شهادة ترخيص الشركة صادرة من السلطات الصحية في بلد المنشأ.
- شهادة تطبيق أسس التصنيع الجيد(GMP) للشركة صادرة من السلطات الصحية في بلد المنشأ أو شهادة الجودة (ISO) صادرة من الجهات المعتمدة.
- تقديم ملف تفصيلي عن الشركة يتضمن:

2.1 نوع ونشاط الشركة وتاريخ تأسيسها ونبذة عن الشركة والمالكين للشركة في حال كانت الشركة ذات ملكية خاصة.

2.2 عدد المصانع المملوكة للشركة وعناوينها إن وجدت.

2.3 رأس مال الشركة وأرباح آخر ثلاث سنوات.

2.4 رسم تخطيطي مبسط (كروكي) لمباني المصنع وسير خطوط العمل فيها.

2.5 الهيكل التنظيمي الوظيفي للمصنع يوضح الأقسام المختلفة وعدد العاملين فيها مع ذكر مؤهلات مدراء أقسام الإنتاج ومراقبة الجودة والبحث والتطوير والمدير الفني للمصنع.

2.6 نبذة عن نشاط الشركة في مجال الأبحاث والتطوير.

2.7 قائمة بالأدوية النباتية والمستحضرات العشبية التي ينتجها المصنع سواء كانت باسمه أو لحسابه أو عن طريق التصنيع التعاقدي لشركات أخرى.

2.8 قائمة بأسماء البلدان المسجل بها منتجات الشركة وتواريخ تسجيلها وتسويقها.

2.9 المشاكل المتعلقة بالتوزيع والشكاوى الواردة للشركة وأخطاء التصنيع والسحب الطوعي والسحب الصادر عن السلطات الصحية الرقابية في بلد المنشأ والدول المسجل بها والمسوق فيها منتجات الشركة.

2.10 طرق التواصل مع الشركة.

2.11 الملف التفصيلي عن نظام التيقظ الدوائي للشركة.

2.12 صور عن شهادات تسجيل للمصنع صادرة من هيئات رقابية عالمية مثل إدارة الدواء والغذاء الأمريكية FDA أو الاتحاد الأوروبي أو مجلس الصحة الخليجي وغيرها من الجهات الرقابية المرجعية المعتمدة.

2.13 تقديم ملف تسجيل لمنتج واحد أو أكثر.

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*يتوجب تقديم أصول شهادات حديثة وسارية المفعول وتصديقها من سفارة دولة الكويت – قنصلية دولة الكويت (في حال عدم وجودهم تصدق من سفارة أو قنصلية إحدى دول مجلس التعاون الخليجي) وغرفة التجارة في بلد المنشأ.

- ملاحظة: يحق لإدارة تسجيل ومراقبة الأدوية الطبية والنباتية القيام بزيارة الشركة المصنعة للتأكد من تطبيق أسس التصنيع الجيد (GMP) متى ما ارتأت ذلك.

3. **المتطلبات الخاصة بالشركة المصنعة في حال اختلافها عن الشركة المالكة لحق التسويق:**

- شهادة ترخيص الشركة المصنعة صادرة من السلطات الصحية المختصة في بلد المنشأ.
- شهادة تطبيق أسس التصنيع الجيد للشركة المصنعة صادرة من السلطات الصحية المختصة في بلد المنشأ أو شهادة الجودة (ISO) صادرة من الجهات المعتمدة .
- شهادة توضح العلاقة بين الشركة المصنعة والشركة المالكة لحق التسويق صادرة من الأخيرة.

*يتوجب تقديم أصول شهادات حديثة وسارية المفعول وتصديقها من سفارة دولة الكويت قنصلية دولة الكويت (في حال عدم وجودهم تصدق من سفارة أو قنصلية إحدى دول مجلس التعاون الخليجي) وغرفة التجارة في بلد المنشأ.

مادة خامسة: يجب على مقدم طلب التسجيل (الوكيل المحلي) تقديم كتاب تعهد من الشركة المالكة لحق التسويق يضمن الالتزام بإبلاغ إدارة تسجيل ومراقبة الأدوية الطبية والنباتية بوزارة الصحة في حالة صدور أي تحذير من أي من الجهات الرقابية الدولية بشأن سلامة ومأمونية استخدام المنتج.

مادة سادسة: يحق لإدارة تسجيل ومراقبة الأدوية الطبية والنباتية طلب أي مستندات أو دراسات إضافية أو اجراء أي تحاليل مخبرية تعتبرها مكملة لإجراءات التسجيل، وعلى الشركات الإلتزام بذلك.

مادة سابعة: تعتبر متطلبات التسجيل المذكورة باللغة الإنجليزية كذلك في ملحق القرار جزء لا يتجزأ من متطلبات التسجيل .

مادة ثامنة: يجب على الشركة المصنعة إخطار إدارة تسجيل ومراقبة الأدوية الطبية والنباتية بأي تغيير أو تعديل يطرأ على المنتج على أن لا يتم تطبيق هذا التغيير أو التعديل إلا بعد الحصول على موافقة الإدارة.

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مادة تاسعة: مدة صلاحية شهادة تسجيل المنتج خمس سنوات من تاريخ إصدار الشهادة.

مادة عاشرة: إدارة تسجيل ومراقبة الأدوية الطبية والنباتية هي الجهة المخولة بإصدار شهادات مستحضر صيدلاني / حرية التداول، ترخيص التصنيع للشركة المصنعة أو المالكة لحق التسويق وشهادة أسس التصنيع الجيد وجميع الشهادات المتعلقة بتسجيل المنتج المصنع محلياً أو حق تسويقه مملوك لصالح شركة محلية.

مادة حادية عشر: يجب إعادة تجديد تسجيل المنتج والشركة المصنعة، على أن يقدم طالب التجديد المستندات المطلوبة من قبل الإدارة قبل ستة أشهر من انتهاء مدة صلاحية شهادة التسجيل.

مادة ثانية عشر: يجب عند نقل وكالة الشركة المالكة لحق التسويق من وكيل محلي إلى آخر تقديم المستندات التالية:

1. شهادة الوكالة الحصرية صادرة من الشركة المالكة لحق التسويق تفيد بتعيين وكيل محلي جديد لها.
2. شهادة إلغاء الوكالة الممنوحة للوكيل السابق من الشركة المالكة لحق التسويق موضحاً بها تاريخ إلغاء الوكالة.
3. قائمة بالمنتجات الخاضعة لنقل الوكالة صادرة من الشركة المالكة لحق التسويق موضح فيها الاسم التجاري للمنتج، التركيز، الشكل الدوائي، الشركة المصنعة.

*يتوجب تقديم أصول شهادات حديثة وسارية المفعول وتصديقها من سفارة دولة الكويت -- قنصلية دولة الكويت (في حال عدم وجودهم تصدق من سفارة أو قنصلية إحدى دول مجلس التعاون الخليجي) وغرفة التجارة في بلد المنشأ.

مادة ثالثة عشر: يحظر استيراد وتسجيل الأدوية النباتية والمستحضرات العشبية التي تحتوي على نباتات واردة في الجدول رقم ١ والمرفق في ملحق القرار باللغة الإنجليزية والذي يحتوي على نباتات مخدرة وسامة.

مادة رابعة عشر: يجوز الترخيص لاستيراد الأدوية النباتية والمستحضرات العشبية التي تحتوي على نباتات واردة في الجدول رقم ٢ المرفق في ملحق هذا القرار باللغة الإنجليزية، والذي يتضمن التراكيز والجرعات المحددة وضوابط الاستخدام.

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مادة خامسة عشر: يحظر استيراد النباتات الأولية الواردة في الجداول أرقام ٢،١ المرفقة في القرار باللغة الإنجليزية إلا في أغراض التصنيع الدوائي فقط، ولا يسمح بالإتجار بهذه المواد بشكلها الأولي بعد استيرادها في البلاد إلا بعد موافقة إدارة تسجيل ومراقبة الأدوية الطبية والنباتية.

مادة سادسة عشر: على كل من يرغب في استيراد أي من المواد الواردة بالجداول أرقام ٢،١ المرفقة في ملحق القرار باللغة الإنجليزية بغرض التصنيع الدوائي، أن يتقدم بطلب لإدارة تسجيل ومراقبة الأدوية الطبية والنباتية مرفق به المتطلبات التالية: –

1. اسم النبات المراد استيراده باللغة العربية أو الإنجليزية والاسم العلمي ومنشأه والمنتج المراد تصنيعه منه، مع الأخذ بعين الاعتبار الحصول على ترخيص تصنيع المنتج من إدارة تسجيل ومراقبة الأدوية الطبية والنباتية.
2. الكمية المطلوب استيرادها وشهادة من بلد منشأ تحمل اسم وتاريخ الإنتاج وتاريخ انتهاء الصلاحية ورقم التشغيلة للنبات.
3. المواصفات القياسية وطريقة التحليل واسم المرجع العلمي إذا كان النبات دستوريا أو مذكورا في أحد المراجع العلمية.
4. شهادة تحليل معتمدة من الشركة المصنعة.
5. عينة كافية للتحليل في مختبرات الإدارة.

مادة سابعة عشر: يحق لإدارة تسجيل ومراقبة الأدوية الطبية والنباتية تعليق تسجيل أي منتج أو شركة مالكة لحق التسويق أو الشركة المصنعة وذلك إذا ثبت للإدارة ما يلي:

أ. إذا صدر قرار بتعليق أو حظر المنتج أو الشركة من قبل السلطات الصحية الرقابية في بلد المنشأ.

ب. إذا ثبت عدم فعالية ومأمونية استخدام المنتج.

ت. إذا ثبت التلاعب في المستندات المقدمة لإدارة تسجيل ومراقبة الأدوية الطبية والنباتية.

ث. إذا ثبت مخالفة الشركة لنظم ولوائح إدارة تسجيل ومراقبة الأدوية الطبية والنباتية.

ج. إذا ثبت عدم استمرار الشركة باتباع أسس التصنيع الجيد.

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ح. تكرار عدم اجتياز المنتج للتحليل لدى مختبرات إدارة تسجيل ومراقبة الأدوية الطبية والنباتية.

خ. بناءً على طلب الشركة المصنعة مع ذكر الأسباب.

د. في حال عدم ابلاغ الوكيل المحلي إدارة تسجيل ومراقبة الأدوية الطبية والنباتية عن صدور أي تحذيرات تخص المستحضر أو الشركة المصنعة من الهيئات الصحية المعتمدة.

مادة ثامنة عشر: يحق لإدارة تسجيل ومراقبة الأدوية الطبية والنباتية إلغاء تسجيل أي منتج أو شركة مالكة لحق التسويق أو الشركة المصنعة وذلك إذا ثبت للإدارة ما يلي:

أ. إذا تم الغاء تسجيل المنتج أو الشركة في بلد المنشأ.

ب. إذا ثبت احتواء المنتج على ماده كيميائية صيدلانية غير معلن عنها.

ت. عدم مطابقة المنتج للمواصفات الفنية المعتمدة.

ث. بناء على طلب الشركة المصنعة.

ج. إذا صدر قرار بإلغاء تسجيل المنتج أو الشركة من قبل السلطات الرقابية العالمية المعتمدة.

ح. إذا ثبت للإدارة حسب المراجع العلمية المعتمدة عدم سلامة وأمان استخدام المنتج.

خ. عدم تجديد التسجيل في الفترة المحددة.

د. إذا ثبت التزوير أو التلاعب في المستندات المقدمة للتسجيل.

ذ. في حال عدم مطابقة المنتج أو الشركة لمتطلبات هذا القرار.

ر. إذا مضت سنتان من تاريخ تسجيل المنتج من دون استيراده أو من تاريخ آخر استيراد له الى دولة الكويت.

مادة تاسعة عشر: يحق لإدارة تسجيل ومراقبة الأدوية الطبية والنباتية تأجيل أو رفض أو تعليق أو إلغاء تسجيل أي منتج أو شركة المصنعة مع ذكر الأسباب التي أدت إلى ذلك.

مادة عشرون: يحق للوكيل المحلي التظلم على قرار الإدارة في رفض التسجيل أو تعليق التسجيل أو إلغاؤه خلال مدة أقصاها ثلاثة أشهر من تاريخ العلم بصدور القرار، وعليه يعتبر القرار نافذاً بعد دراسة التظلم.

مادة واحد وعشرون: يخضع تسجيل الأدوية النباتية والمستحضرات العشبية والشركات المصنعة للرسوم المقررة في القرار الوزاري المنظم لأسعار وأجور الخدمات الصحية .

الكويت - الصليبخات - ص. ب. : (٥) - الرمز البريدي13001 - تلفون : ٢٤٨٦٣٦٨٦ - ٢٤٨٦٣٥٧٤ - فاكس : ٢٤٨٦٣٤٥٧ - برقياً : صحة الكويت
Kuwait - Sulaibikhat - P.O.Box: (5) - Postal Code: 13001 - Tel : 24863686- 24863574 - Fax : 24863457 - Cable : Health Kuwait

مادة اثنان وعشرون: الموافقة على إفراج وتداول الأدوية النباتية والمستحضرات العشبية وفقا للقرار الوزاري الخاص بذلك.

مادة ثلاثة وعشرون: لا يتم الإعلان عن الأدوية النباتية والمستحضرات العشبية إلا بعد الحصول على الموافقات اللازمة من وزارة الصحة.

مادة أربعة وعشرون: يُبلغ هذا القرار من يلزم لتنفيذه، ويعمل به اعتباراً من تاريخ صدوره ، ويلغى أي قرار أو نص يتعارض مع أحكام هذا القرار ، وينشر في الجريدة الرسمية .

الدكتور / باسل حمود الصباح

ALSABAH

وزير الصحة

د. باسل حمود الصباح
وزير الصحة

الكويت - الصليبخات - ص. ب. : (٥) - الرمز البريدي13001 - تلفون : ٢٤٨٦٣٦٨٦ - ٢٤٨٦٣٥٧٤ - فاكس : ٢٤٨٦٣٤٥٧ - برقياً : صحة الكويت
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القرار الوزاري بإعادة تنظيم وتسجيل وتداول الأدوية النباتية والمستحضرات العشبية

STATE OF KUWAIT
MINISTRY OF HEALTH
DRUG AND FOOD CONTROL

Pharmaceutical & Herbal Medicines Registration & Control Administration

MINISTERIAL DECREE FOR THE REGISTRATION OF HERBAL MEDICINES AND HERBAL PREPARATIONS

M.D. (١٥١) /2020

د. عبدالله منجد البدر
وكيل وزارة الصحة المساعد
لشئون الرقابة الدوائية والغذائية

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Abbreviations

BP	British Pharmacopeia
BSE	Bovine Spongiform Encephalopathy
CIF	Cost Insurance and Freight
CPP	Certificate of Pharmaceutical Product
EMA	European Medicines Agency
FSC	Free Sale Certificate
GCC	Gulf Cooperation Council
GMP	Good Manufacturing Practice
HM	Herbal medicine
M.D.	Ministerial Decree
MAH	Marketing Authorization Holder
MHRA	Medicines and Healthcare products Regulatory Agency
PIL	Patient Information Leaflet
RH	Relative Humidity
TCM	Traditional Chinese Medicine
THM	Traditional Herbal Medicine
TSE	Transmissible Spongiform Encephalopathy
USFDA	United States Food and Drug Administration
USP	Unites States Pharmacopeia
CoA	Certificate of Analysis
WHO	World Health Organization

Glossary of Terms

Local agent: for a pharmaceutical company to access the local market, it must appoint a local agent to represent it in Kuwait. This is a one-off process that is required as a prerequisite for the registration of all company's products. Therefore, before submitting any product of a new manufacturing company, the local agent must present an original letter of appointment from the pharmaceutical company, which must be authenticated by Kuwait Embassy or Consulate in the country of origin. The letter of appointment must clearly state that the selected local agent is the company's sole/exclusive agent in Kuwait. This is critical to define the legal status of the product and the officially responsible representative of the principal manufacturer in Kuwait.

Marketing Authorization Holder (MAH): the pharmaceutical company that legally holds the right and responsibility of marketing the product in Kuwait.

Finished product: a medicinal product, which has undergone all stages of production, including packaging in its final container.

Certificate of Pharmaceutical Product (CPP): is an internationally recognised certificate by drug regulatory authorities for establishing the status of a pharmaceutical product registration elsewhere. This document provides evidence that the medicinal product was produced under a comprehensive system of quality assurance, conforming to Good Manufacturing Practice (GMP) standards as mandated by the World Health Organisation (WHO). It contains specific information such as the name of the product, the formulation, the manufacturer, packager, product license holder, and whether the product is marketed in the country where the CPP was issued.

Free Sale Certificate (FSC): is a certificate that indicates a particular product is marketed in the country of origin or is eligible for export. It contains specific information such as the name of the product, the formulation, the manufacturer, packager, and whether the product is marketed in the country where the FSC was issued.

Good Manufacturing Practice (GMP) certificate: this certificate states that the manufacturer is periodically inspected by the relevant authorized health authority and that it follows strict current Good Manufacturing Practice (cGMP) guidelines to ensure the production of products with the desired quality standard.

Country of origin: it is the country where the product has been released with certificate of analysis signed by the responsible qualified person in that country.

Traditional Chinese medicine (TCM): is a combination of practices and remedies that were originated in ancient China, and has evolved over thousands of years. TCM practitioners uses herbal preparations and various mind and body practices, such as acupuncture and tai chai, to treat or prevent health problems.

Ayurvedic medicine: is a traditional practice based on ancient writings that rely on a "natural" and holistic approach to physical and mental health. Ayurvedic medicine is one of the world's oldest medical systems and remains one of India's traditional healthcare systems. Ayurvedic treatment combines products mainly derived from plants but may also include animal, metal, mineral, diet, exercise and lifestyle.

Summary of product characteristics: the definitive description of the product.

Patient information leaflet (PIL): the leaflet is the product's information provided in the pack. It should be drawn up in accordance with the summary of the product characteristics.

Adverse effect: any unfavourable and unintended sign in a patient or clinical investigation of a subject administered including a symptom or disease associated with the use of a product with a therapeutic affect and which does not necessarily have a causal relationship with this treatment.

The form of 30: the price of the product in 30 countries listed in the Gulf Cooperation Council Guidance for Submission.

Ex-factory price: the cost of the finished product in the country of origin at the time of batch release before adding other expenses, such as shipment, insurance, wholesaler profit, and pharmacy profit.

Wholesale price: ex-factory price in the country of origin added to it the wholesaler's profit.

Cost, insurance and freight (CIF) price: the ex-factory price added to it the costs of insurance and shipping.

Specification: is a list of tests, references to analytical procedures, appropriate acceptance criteria and reference of each tested parameter (e.g. United States Pharmacopeia, British Pharmacopeia, in-house… etc.).

Clinical trial: any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product, and/or to identify any adverse reactions to an investigational product, and/or to study the absorption, distribution, metabolism and excretion of an investigational product, with the objective of ascertaining its safety and/or efficacy.

Stability study: is a study that contains information on storage conditions, batch number, batch size, container closure system and completed (and proposed) test intervals, results and conclusions with respect to storage conditions and retest date or shelf-life, as appropriate.

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Introduction

In accordance with the Pharmacy Law in the State of Kuwait, a pharmaceutical product including herbal products and herbal teas can only be placed in the local market if registered by the Pharmaceutical and Herbal Medicines Registration and Control Administration. The information in this Ministerial Decree (M.D.) is meant to provide assistance to industry and professionals on how the Pharmaceutical and Herbal Medicines Registration and Control Administration mandates.

Each and every herbal product/ herbal tea must be represented by a local pharmaceutical company that is referred to as a local agent. The local agent is responsible for providing the documents set by this M.D. in order to finalize the registration of the herbal product/ herbal tea and its manufacturing company.

This M.D is divided into four sections; Section I provides registration requirements of new local agents, marketing authorization holders (MAHs) and manufacturing companies, Section II provides definitions, classifications and registration requirements of herbal products for human use, Section III provides the definition and registration requirements of herbal teas for human use, and Section IV provides requirements for variation, transfer of agency and cancellation of a herbal product/ herbal tea. This M.D. is to be implemented in a manner that is fair, consistent and effective.

In some cases, when necessary, the Administration will provide the agent with a customized set of requirements to comply with via memos.

Section I: Local agent, Marketing Authorization Holder (MAH) and Manufacturing Company Registration Requirements

The following requirements are considered minimum at the time of submission and are subject to change. The Herbal Department at the Administration reserves the right to request additional documents on a case-by-case basis.

1.1 Local agent registration requirements

If the local agent is a new local pharmaceutical company, the following must be submitted for herbal products/ herbal teas:

1. Copy of valid license from the Ministry of Commerce in which the company activity include the sale of medicines.
2. Copy of valid store license issued from the Drug Inspection Administration.
3. Copy of authorized personal signatures.

1.2 Marketing Authorization Holder (MAH) registration requirements

When first registering a new MAH for a herbal product/ herbal tea the following must be submitted:

1. Legalized letter of appointment from the MAH stating that the local agent is the sole and/or exclusive agent in the State of Kuwait.
2. Original legalized manufacturing license from the country of origin for each manufacturing site issued from the Ministry of Health or the concerned authorized authority in the country of origin.
3. Original legalized Good Manufacturing Practice (GMP) certificate from the country of origin.

- **N.B** For herbal teas, the submission of either a GMP certificate or an International Organization for Standardization (ISO 22716) certification or equivalent is accepted.

4. List of herbal products/ herbal teas manufactured by the company.
5. Site master file (for herbal products only) which contain the following:
    a. General information and history of the company.
    b. Capital and turnover for the past three years.
    c. Layout and diagrams of manufacturing sites.
    d. Quality control unite and quality management.

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e. Personnel information including number of employees in each department and their qualification.
f. Premises and equipment, including manufacturing sites owned by the company, manufacturing lines, and manufacturing machines.
g. List of products manufactured by the company and exporting countries.
h. Distribution problems, complaints, product defects and recalls from any authorities worldwide.
i. Contract manufacturing information.
j. Pharmacovigilance Master File.
k. Recognized global approvals for the company such as the United States Food and Drug Administration (USFDA), European Medicines Agency (EMA), Medicines and Healthcare products Regulatory Authority (MHRA) or a drug regulatory authority in one of the Gulf Cooperation Council (GCC) countries.

1.3 Manufacturing site registration requirements (If the manufacturer is different than the MAH)

If the manufacturer is different than the MAH, the following must be submitted:

1. A letter issued from the MAH explaining the relationship between the MAH and the manufacturer.
2. GMP certificate of the manufacturer.
3. Manufacturing license of the manufacturer.

❖ **N.B** Legalization must be done by the following:

1. Kuwait Embassy/Consulate in the country of origin, and when it is not possible, legalization may be provided by an authorized Arabian Embassy/Consulate in the country. Except when the country of origin is a GCC country.
2. Arab Chamber of Commerce of the country of origin or Kuwait Chamber of Commerce.

❖ **N.B** The Administration may request a GMP inspection visit for any manufacturing site.

Section II: Herbal Products

2.1 Definition of a herbal product

- Any medicinal product, exclusively containing active ingredients consisting of one or more herbal substances or herbal preparations, or such herbal substances in combination with such herbal preparations that are intended for prophylactic, therapeutic, or other human health benefits.
    - Herbal substances consists of fragmented or cut plants, plant parts, algae, fungi, lichen in unprocessed, usually dried form, but sometimes fresh. Certain exudates that have not been subjected to a specific treatment are also considered to be herbal substances. Herbal substances are precisely defined by the plant part used and the botanical name according to the binomial system (genus, species, variety and author). Herbal active substances that has been chemically altered, including synthetic compounds from herbal material, are not considered herbal.
    - Herbal preparations are preparations that are obtained by subjecting herbal substances to treatments such as extractions, distillation, expression, fractionation, purification, concentration or fermentation. These include comminuted or powdered herbal substances, tinctures, extracts, essential oils, expressed juice and processed exudates.

❖ **N.B**

1. A herbal product cannot be sterile or be administered by injection.
2. The presence of normal flora in the herbal product will prevent the product from being eligible for registration as a herbal product; e.g. Probiotics.
3. The presence of vitamins or minerals in the herbal product will not prevent the product from being eligible for registration under the Herbal Department, provided that the action of vitamins or minerals is ancillary to that of the herbal active ingredients regarding the specified claimed indication.

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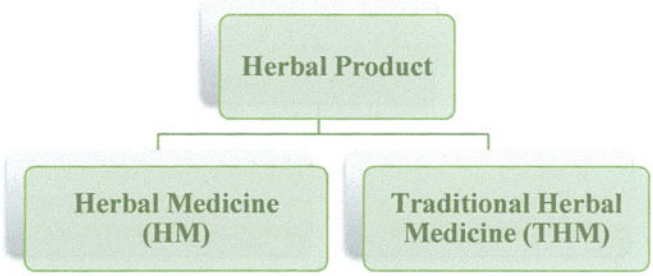
2.2 Classification of herbal products

The Administration has classified herbal products that fall under this M.D. into two categories:

- Herbal Medicines (HMs)
- Traditional Herbal Medicines (THMs)



2.2.1 Herbal Medicine (HM)

The classification of a herbal product as a HM suggests that the product is assessed as a herbal medicine with well-established use. This means that herbal products under this classification require their safety and efficacy to be demonstrated through data obtained from clinical trials.

2.2.2 Traditional Herbal Medicine (THM)

Traditional medicine refers to the knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures (e.g. Traditional Chinese Medicine, Ayurvedic Medicine, etc.). The traditional herbal registration is to provide a simplified registration option for herbal products not fulfilling the requirements of efficacy for HMs. Therefore, no clinical tests and trials on efficacy are required as long as sufficient safety data and 'plausible efficacy' are demonstrated based on evidence of long-standing use (i.e. a period of at least 30 consecutive years of traditional use. The dose and method of preparation must be the same as those traditionally used).

THMs must only contain claims or therapeutic indications based on long-standing traditional use. Any indications added to the product that is not supported by long-

standing traditional use evidence requires the product to be registered as a HM, requiring the submission of clinical studies for the presented indication.

2.3. Requirements for the registration of a herbal product

The following requirements are considered minimum at the time of submission and are subject to change. The Herbal Department at the Administration reserves the right to request additional documents on a case-by-case basis.

2.3.1 Regional administrative registration requirements for both THM and HM

1. Covering letter: the applicant should include a covering letter for each submission with local agent letterhead, including the herbal product trade name, concentration, MAH, manufacturing company, and a complete list of documents submitted for registration.
2. Application form: should be submitted filled, signed and stamped by the applicant.
3. Original legalized free sale certificate (FSC) or Certificate of Pharmaceutical Product (CPP) issued from the Ministry of Health or from the concerned authorized health authority at the country of origin for each herbal product showing that it is registered and marketed in the country of origin. The certificate should be legalized from Kuwait Embassy and Arab Chamber of Commerce in the country of origin. The FSC/CPP should include the following:
    a) The date and registration number of the product in the country of origin.
    b) The herbal product submitted for registration should be with the same composition and strength as the one registered in the country of origin.

4. Original legalized price certificate stating the Ex-factory price, Wholesale and Retail prices and the Cost, Insurance and Freight (CIF) prices for Kuwait and other countries (in the form of 30).

❖ **N.B** Submission of the price certificate does not apply to THMs.

5. Product information:

- Include summary of product characteristics if available.
- Label.
- Patient information leaflet (PIL) in English or (English and Arabic).
- The leaflet must include the following details:
  a) Composition
  b) Indication
  c) Dosage
  d) Side effects
  e) Warnings
  f) Contraindications
  g) Major drug-drug interactions should be mentioned in the leaflet.

6. Declaration of alcohol content: a declaration letter from the pharmaceutical company stating the alcohol content of the product. If the product does not contain any alcohol content, a letter from the pharmaceutical company stating that the product is free from alcohol.

❖ **N.B** The maximum alcohol concentrations should be aligned with the concerned M.D. for importing and handling ethyl alcohol and any material that is manufactured with it.

7. Pork- free declaration: A declaration letter from the pharmaceutical company stating that the product is free from any materials of pork/porcine source.
8. Artwork of the outer pack:
   - Allergens and warnings should be mentioned on the outer pack
   - Storage conditions
   - Manufacturing date and expiry date
   - Batch number
   - Indication
   - Trade name
   - Composition
   - In-use shelf life (whenever applicable)
9. Finished product sample.
10. List of countries where the product is registered with registration dates and numbers.

2.3.2 Technical quality registration requirements for both THM and HM

radioactive materials, pathological microorganisms and parts of insects, and potentially artificial or chemical active pharmacological substances.

2. Certificate of Analysis (CoA) and specifications of the active herbal substances stating the percentage of heavy metals (e.g. lead, mercury, cadmium, arsenic, etc.) according to approved reference international standards (e.g. European Pharmacopeia (Eur. Ph.), British Pharmacopeia (BP), etc.).
3. Summary of the risk assessment covering the risk evaluation for elemental impurities.
4. Evidence to show that the levels of elemental impurities are controlled during the manufacturing process.
5. Complete stability studies on two pilot scale batches and one smaller scale batch. The studies must include all the tests that are mentioned in the finished product specification including:
   - Long-term stability studies over the COMPLETE SHELF LIFE of the product at 30°C ±2 & 65% relative humidity (RH) ±5. (Long-term stability study performed at storage condition 25°C ±2 & 60 % (RH) ±5 can be accepted).
   - Accelerated stability studies at 40°C±2 & 75%RH ±5 over a period of 6 months.
6. Finished Product Specifications must include all following parameters and their limits:
   - Description
   - weight content
   - Weight variation
   - Solubility in water
   - Identification of the active ingredients of the finished products
   - Assay in full details of the active ingredients
   - Microbiological tests and impurities should be mentioned
   - ❖ **N.B** Reference pharmacopoeia must be mentioned.

7. CoA of finished product with the same batch number as the sample(s) submitted. The certificate should include all following parameters with the limits and results:

➢ In case of solid dosage forms: -

a) Description

a) Description
b) Weight content / Weight variation (results should be in numerical values)
c) Identification of the active ingredients of the finished products
d) Assay in full details of the active ingredients (results should be in numerical values)
e) Impurities (results should be in numerical values)
f) Microbiological tests (results should be in numerical values)
g) Dissolution (results should be in numerical values)

➢ In case of liquid dosage forms: -

a) Description
b) Identification of the active ingredients of the finished products
c) Assay in full details of the active ingredients (results should be in numerical values)
d) Impurities (results should be in numerical values)
e) Microbiological tests (results should be in numerical values)

➢ In case of suppositories: -

a) Description
b) Disintegration
c) Identification of the active ingredients of the finished products
d) Assay in full details of the active ingredients (results should be in numerical values)
e) Impurities (results should be in numerical values)
f) Microbiological tests (results should be in numerical values)

➢ In case of ointments and creams: -

a) Description
b) Identification of the active ingredients of the finished products
c) Assay in full details of the active ingredients (results should be in numerical values)
d) Impurities (results should be in numerical values)
e) Viscosity
f) PH (results should be in numerical values)
g) Water content

h) Uniformity of dosage unit
i) Microbiological tests (results should be in numerical values)
j) Particle size

6. For products containing substances extracted from an animal source, certificate of suitability for Transmissible Spongiform Encephalopathy (TSE)/Bovine Spongiform Encephalopathy (BSE) should be submitted.
7. Manufacturing process should be mentioned with a flow chart/diagram.

2.3.3 Technical safety and efficacy registration requirements

Applicants must submit studies from all relevant sources to support the safety and efficacy of the product. The required evidence will vary depending on the type of claim as well as the type of the product:

2.3.3.1 Technical safety and efficacy registration requirements for HMs

1. Toxicological and safety studies, precautions and side effects (if any) for the product should be submitted. Clinical studies should be submitted.
2. A scientific reference supporting the pharmacological claim (e.g. Pharmacopeia, scientific book or scientific journal).
3. A study showing the pharmacological action of the product including its action and effects on the major organ systems of the human body.
4. When available, information based on previous marketing experience of a finished product may be provided to supplement the evidence supporting the safety of the product.

2.3.3.2 Technical safety and efficacy registration requirements for THMs

For a herbal product to be eligible for a THM registration, the product should meet the following criteria:

- Have a period of at least 30 consecutive years of traditional use.
- The dose and method of preparation must be same as those traditionally used.
- Evidence of safety.
- Adherence to appropriate manufacturing standards.
- Provision of appropriate product information to users.

❖ **N.B** The supporting evidence for a THM must show that the product has been used in practice for at least 30 consecutive years. Reference to a source published 30 years ago is not sufficient, as this simply demonstrates that the product was in used 30 years ago. There must be a connection between the duration of use and the claimed use.

THMs are divided into two sub categories according to the evidence provided:

A) Pharmacopeial evidence for traditional products.

B) Non – Pharmacopeial evidence for traditional products.

A) Pharmacopeial evidence for THMs

Product meeting this criterion only require one Pharmacopeial reference. The applicant must show that the following items in the dossier are identical to the Pharmacopeial references in the following aspects:

- Medicinal ingredients.
- Quantity of crude material equivalent.
- Recommended dose.
- Recommended route of administration.
- Recommended duration of use.
- Dosage form.
- Directions of use.
- Risk information.
- Method of preparation.
- Applicant should submit copies of the relevant pages from a recognized Pharmacopeia as supporting evidence.

❖ **N.B.** Official expert committee reports or monographs from learned societies (e.g. Commission E, European Herbal Substances Community List, European Herbal Substances Community Monographs, European Scientific Cooperative on Phytotherapy (ESCOP), etc.) are accepted.

B) Non –Pharmacopeial evidence for THMs

Applicants who submits a product claiming that it is a THM, but is unable to provide a Pharmacopeial evidence must provide at least two independent references. The references must be reliable and from reputable sources. For example:

- Scientific book or/and scientific journal (e.g. published peer-reviewed scientific literature, Martindale, Potter's New Cyclopaedia of Botanical Drugs and Preparations etc.).

❖ **N.B** For both HMs and THMs, the applicant has the responsibility to report to the Administration any up-to-date post-marketing surveillance and adverse effect monitoring of the herbal product that occurred locally or/and internationally.

2.4 Requirements for the renewal of a registered herbal product

The registration of a herbal product must be renewed every 5 years from the date of issuing the registration certificate. The agent must submit the renewal file 6 months prior to pharmaceutical registration expiration. The following requirements are considered minimum at the time of submission and are subject to change. The Herbal Department at the Administration reserves the right to request additional documents on a case-by-case basis:

1. Covering letter: the applicant should include a covering letter for each submission indicating the request for renewal of registration.
2. Original legalized FSC or CPP issued from the Ministry of Health or from the concerned authorized health authority at the country of origin for each herbal product, and should include the following:
   a) The date and registration number in the country of origin.
   b) The herbal product submitted for registration should be with the same composition and strength as the one registered in the country of origin.
3. Complete stability study on 2 production batches. The stability study should include finished products specifications parameters for:
   - Long term stability study over the COMPLETE SHELF LIFE of the product at 30°C ±2 & 65%RH ±5. (Long-term stability study performed at storage condition 25°C ±2 & 60 % (RH) ±5 can be accepted).
   - Accelerated stability study at 40°C±2 & 75%RH ±5 over a period of 6 months.

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6. Evidence to show that the levels of elemental impurities are controlled during the manufacturing process.
7. Declaration letter stating that there is no change in the registered product submitted for registration renewal.
8. Approved CIF price in Kuwait.

❖ **N.B** Submission of the price certificate does apply to THMs.

9. One sample of the product should be submitted. Information of the product on the outer and inner pack sample must be in English or (English and Arabic) Information should include:

- Allergens and warnings should be mentioned on the outer pack
- Storage conditions
- Manufacturing date and expiry date
- Batch number
- Indication
- Trade name
- Composition
- In-use shelf life (whenever applicable)

10. Samples for analysis might be requested by the Administration, during registration process or at any time after registration.

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Section III: Herbal Teas

3.1 Definition of a herbal tea

Herbal tea is a herbal product (refer to **2.1 Definition of a herbal product**). Herbal tea is used in many traditional medicine systems as a dosage form. Herbal materials (for example, dried roots, leaves or flowers) are packed into paper or cloth bags or sachets, each containing ground herbal materials (a single herb or a mixture of different herbs) sufficient for one dose for making into an infusion. Herbal tea bags should be free from bleach, gluten and dioxin. Herbal tea that is not packed in a tea bag or sachet (i.e. loose), should specify an exact dose and instruction for use. Herbal tea should include a clear medical/therapeutic indication explaining its purpose.

3.2 Requirements for the registration of a herbal tea

The following requirements are considered minimum at the time of submission and are subject to change. The Herbal Department at the Administration reserves the right to request additional documents on a case-by-case basis.

3.2.1 Regional administrative registration requirements for a herbal tea

1. Covering letter: the applicant should include a covering letter for each submission with local agent letterhead, including the herbal tea trade name, concentration, MAH, manufacturing company (if different than MAH), and a complete list of documents submitted for registration.
2. Original FSC issued from the Ministry of Health or from the concerned authorized health authority at the country of origin, legalized by Kuwait Embassy. The FSC must include the following information:

- Trade name
- Scientific name
- Indications
- Detailed composition for the active and inactive ingredients

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3. Status of registration of the product in the country of origin.
4. List of countries where the product is registered with registration dates and numbers.
5. Finished product sample. Information of the product on the outer and inner pack sample must be in English or (English and Arabic) and satisfy the requirements of Ministry of Commerce of State of Kuwait. Information should include:

- Name
- Composition
- Uses
- Batch No.
- Manufacturing date
- Expiry Date
- Storage Conditions
- Indication

3.2.2 Technical quality registration requirements for a herbal tea

1. Finished product specifications and CoA of the finished product (with the same batch number as the one(s) submitted as sample(s). The CoA should include all the tests (total Ash, Acid insoluble Ash, moisture content at 110°C and microbiology) mentioned in the finished product specifications, including the limits and results (if applicable).

   ❖ **N.B** For herbal teas where fresh herbal substances are used, finished product specifications and CoA must include the testing of heavy metals.

2. CoA and specifications of the active herbal substances stating the percentage of heavy metals (e.g. lead, mercury, cadmium, arsenic, etc.) according to approved reference international standards (e.g. European Pharmacopeia (Eur. Ph.), British Pharmacopeia (BP), etc.).
3. Evidence to show that the levels of elemental impurities are controlled during the manufacturing process.

3.2.3 Technical safety and efficacy registration requirements for a herbal tea

1. Safety and efficacy studies from competent international authorities (Annex II) (and/or evidence of traditional use (refer to section **2.3.3.2**) or clinical studies (refer to section **2.3.3.1)** if applicable).

- **N.B** The number of active substances in a herbal tea indicated to increase the amount of urine to achieve flushing of the urinary tract should be limited to a maximum of **4 active substances**. Further herbal substances may be added as excipients.
- **N.B** The applicant has the responsibility to report to the Administration any up-to-date post-marketing surveillance and adverse effect monitoring of the herbal tea that occurred locally or/and internationally.

3.3 Requirements for the renewal of a registered herbal tea

The registration of a herbal tea must be renewed every 5 years from the date of issuing the registration certificate. The agent must submit the renewal file 6 months prior to the herbal tea registration expiration. The following requirements are considered minimum at the time of submission and are subject to change. The Herbal Department at the Administration reserves the right to request additional documents on a case-by-case basis:

1. Covering letter: the applicant should include a covering letter for each submission indicating the request for renewal of registration.
2. Original legalized FSC issued from the Ministry of Health or from the concerned authorized health authority at the country of origin for each herbal tea, and should include the following:
   a) The date and registration number in the country of origin.
   b) The herbal product submitted for registration should be with the same composition and strength as the one registered in the country of origin.
3. Declaration letter stating that there is no change in the registered product submitted for registration renewal.
4. One sample of the product should be submitted. Information of the product on the outer and inner pack sample must be in English or (English and Arabic) and satisfy the requirements of Ministry of Commerce of State of Kuwait. Information should include:

- Name
- Composition
- Uses
- Batch No.
- Manufacturing date
- Expiry Date
- Storage Conditions
- Indication

9. Samples for analysis might be requested by the Administration, during registration process or at any time after registration.

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Section IV: Variation, Transfer of Agency and Cancellation of a Herbal Product/ Herbal Tea

4.1 Variation requirements for a registered herbal product/ herbal tea

- Any changes/ additions made to a registered herbal product/ herbal tea must be submitted to the administration for review and approval.
- Such changes/ additions cannot be implemented without prior approval from the administration.
- Covering letter: the applicant should include a covering letter indicating the requested changes.
- Specific requirements will be set for each type of change/ addition as a memo.

4.2 Transfer of Agency

- Legalized original letter of appointment for the new local agent issued from the MAH.
- Termination letter issued from the MAH mentioning the date of termination of the previous local agent.
- List of products that are affected by the transfer, including product name, concentration, dosage form, and manufacturing company if defers from the MAH.

4.3 Herbal product/ herbal tea suspension

Pharmaceutical and herbal medicines registration and control administration reserve the right to suspend the registration of a herbal product/ herbal tea or company in the following circumstances:

- If the product or the manufacturing company is suspended in country of origin.
- Lack of safety or efficacy of the product. If the company does not comply with the current GMP standards.

- If the product does not comply with the specification issued by the manufacturer or by the pharmacopoeial specification, upon repeated analysis.
- If discrepancy in the documents submitted were observed.
- As per marketing authorization holder request.
- Non compliance to Pharmaceutical and Herbal Medicines Registration and Control Administration laws and regulations.
- If the Pharmaceutical and Herbal Medicine Control and Registration administration come to know by any circumstances other than agent about any warning issued for a specific drug or manufacturing site by FDA, EMA, WHO, GCC or any other International Health Forums.

4.4 Herbal product/ herbal tea cancellation

Pharmaceutical and herbal medicines registration and control administration reserve the right to Cancel the registration of a herbal product/ herbal tea or company in the following circumstances:

- Two years passed without importing the registered product.
- The herbal product/ herbal tea is banned or suspended in the country of origin or in any country due to safety, quality, issue or lack of efficacy, or if the product is proved to have toxic or serious adverse effects.
- Submitted documents are false or if it is proven to have different data from those submitted for registration.
- If there is any chemical active ingredient(s) in the herbal product/ herbal tea that was not declared.
- If the herbal product/ herbal tea does not comply with the specifications submitted by the manufacturer.
- As per the instruction from the manufacturer to cancel the product, the product will be cancelled.
- A product is liable to cancellation if the agent fails to renew the product registration within 6 months of the expiry of the registration certificate.
- The Pharmaceutical and Herbal Medicines Registration and Control Administration reserves the right to cancel the registration of the product if it fails to comply with this M.D.

LIST OF ANNEXES

Annex I: Lists of banned and restricted herbs

Manufacturers and local agents must ensure any herbal products/ herbal teas they place on the market do not contain banned ingredients. They must also ensure that restricted ingredients are used legally. The following tables includes banned and restricted lists that has been extracted from various competent regulatory authorities, and others based on Kuwait Ministry of Health M.D.

Table 1 consists of narcotic and poisonous herbs that are banned and cannot be included in herbal products/ herbal teas submitted for registration.

Table 2 consists of herbal ingredients that are subject to specific restrictions (i.e. precautions for their use, indications, maximum acceptable limits etc.). Some herbal ingredients are subject to more than one set of restrictions. Restrictions may be added or removed at any time.

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Table 1: List of banned herbs in herbal products/ herbal teas

A. Narcotics
1-Cannabis, Indian hemp, Marihuana or pot. Cannabis sativa
2- Coca or Coca leaves Erythromylum coca (Huamuco coca), E.Truxillense (Truxillo coca).
3- Opium or gum opium, papaver somniferum, Poppy straw.
4- Khat or Abyssinian tea, Catha edulis.
5-Datura Stramonium, James Town Weed, Datura Innoxia. (hallucinogenic and euphoric due to presence of tropane alkaloids, also very toxic)
6-Peyote or Mescal Buttons, Lophophora williamsii (Psychotropic drug & Very poisonous)
7- Catharanthus, Vinca Rosea
B. Poisonous herbs
1-Aristolochia species ❖ Aristolochia Clematis ❖ Aristolochia Contorta ❖ Aristolochia Debelis ❖ Aristolochia Fang-chi ❖ Aristolochia Manshuriensis ❖ Aristolochia Serpentaria
2-Amygdalin
3-Cantharides, Cantharis Vesicatoria, dried insect
4-Curare or South American arrow poison, Strychnos Castelnaei, S.Toxifera, S.Crevauxii
5-Cicuta Spp. (Water Hemlock), C. Maculata
6-Chinaberry tree, Melia Azedarach, White Cedar

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7-Canada Moon seed, Menispermum canadense
8-Colocynth, Citrullus Colocynth
9- English Holly Ilex Aquifolium
10-Euphorbia species; Asthmaplant, Chamaesyce hirta, Euforbia, Euphorbe, Euphorbia hirta, Euphorbia capitulata, Euphorbia pilulifera, Euphorbium Officinarum, Pillbearing Spurge, Snakeweed.
11-Jequirity (Abrus Precatorius)
12-Lilly of the vally, Covallaria Majalis
13-Lanata, Lanata Camara
14-Mandragora species ,Mandagora officinarum, Atropa Mandagora,Mandagora autumnalis, M.Acaulis , M.Foemina, M.Hispanica, M.Hausskenchtii, M.Vernalis, M.neglecta, M.praecox
15-Metopium Toxiferum (Poison Wood Tree)
16-Narcissus species (Narcissus, Daffodil, Jonquil)
17-Nerium Oleander (Oleander)
18-Nux Vomica, Strychnous Nux Vomica
19-Peganum Harmala
20-Physic Nut, Jatropha Curcas, Poison Nut, Barbados Nut
21-Phystigma, Calabar Beam or Ordeal Beam, Phyostigma Venensosum
22-Red yeast rice (Poisionous dye Sudan Red G)
23-Red squill or V.Maritama or squil bulb
24-South American arrow Poison or Curare, Strychnous Castelnaui, S.Toxifera, S.Cervauxii
25-Solanum Nigrum , Solanum Dulcamara
26-white Hellebore or European Hellebore, Veratrum Album
27-White Snake root or Rich Weed, Eupatorium Rugosum
28- Senecio (Pyrrolizidine Alkaloids)
29- Atropa Belladonna or Deadly Nightshade, Belladonna Herb

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30- Areca Catchu **(M.D 199/1997)**

Table 2: Restricted herbal ingredients in herbal products/ herbal teas

1-Aconitum spp. (Aconite, Monkshood): all Aconitum species including: Aconitum napellus, Aconitum stoerkianum, Aconitum uncinatum var japonicum, Aconitum deinorrhizum, Aconitum balfourii, Aconitum chasmanthum,Aconitum spicatum, Aconitum lycoctonum Restrictions: Internal use: no permitted dose unless made available by a prescription from a registered doctor or dentist (POM). External use: max. dose 1.3%.
2- Adhatoda Vasica Restrictions: The following precaution should be added on the outer pack and leaflet: "Do not take if you are pregnant or breast-feeding".
3- Egyptian Henbane, Hyoscyamus niger, Hyoscyamus albus, Hyoscyamus muticus Restrictions: Internal use: 100 mg (maximum dose), 300 mg (maximum daily dose). External use: can only be sold in registered pharmacies and by or under the supervision of a pharmacist.
4-Ergot, Rye Ergot or Secale Conutum dried sclerotum of Claviceps Purpurea or prepared Ergot of Rye; Smut of Rye; Spurred Rye Restrictions: Internal and external use: can only be made available by a prescription from a registered doctor or dentist (POM).
5-Gelsemium sempervirens, Yellow Jessamine, Gelsemium

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Restrictions:

Internal use: maximum dose 25 mg, maximum daily dose 75 mg.

External use: can only be sold in premises which are registered pharmacies and by or under the supervision of a pharmacist.

6-Ipecac, Caphaelus Ipecacuanhua, Carapichea ipecacuanha (Rio or Brazilian Ipecac), C.Acuminata (Cartagena ipecac)

Restrictions:

- The USFDA recommends that it is in the interest of the public health for ipecac syrup to be available for sale without prescription, provided that it is packaged in a quantity of 1 fluid ounce (30 milliliters), and its label bears, in addition to other required label information, the following, in a prominent and conspicuous manner:

(1) A statement conspicuously boxed and in red letters, to the effect: "For emergency use to cause vomiting in poisoning. Before using, call physician, or hospital emergency room immediately for advice."

(2) A warning to the effect: "Warning--Keep out of reach of children. Do not use in unconscious persons. Ordinarily, this drug should not be used if strychnine, corrosives such as alkalies (lye) and strong acids, or petroleum distillates such as kerosine, gasoline, coal oil, fuel oil, paint thinner, or cleaning fluid have been ingested."

(3) Usual dosage: 1 tablespoon (15 milliliters) in persons over 1 year of age. UNSAFE when used in high doses or in children under the age of one year.

- Registered in the UK with minimal ingredient as a combination product syrup under the traditional herbal medicine registration, indicated for the relief of sore throats and chesty coughs only.

7- Lobelia or Indian Tobacco, Lobelia Inflata

Restrictions:

Internal use: max. dose 200 mg, max. daily dose 600.

External use: can only be sold in premises which are registered pharmacies and by or under the supervision of a pharmacist.

8- Poison Hemlock (Conium Maculatum)

Restrictions:

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For external use only: max. 7.0 %.
9- Piper Methysticum (Kava Kava) Restrictions: For external use only.
10- Adonis Vernalis (pheasant's eye) Restrictions: For internal use only: max. dose 100 mg, max. daily dose 300 mg.
11- Cinchona officinalis, Cinchona bark, Peruvian bark, Cinchona Succirubra, (Red Cinchona), C. Calisaya (Calisaya bark), Cinchona Micrantha Restrictions: Internal use: max. dose 250 mg, max. daily dose 750 mg. External use: can only be sold in premises which are registered pharmacies and by or under the supervision of a pharmacist.
12- Colchicum Autumnale, Colchicum corm Restrictions: Internal use: max. dose 100 mg, max. daily dose 300 mg. External use: can only be sold in premises which are registered pharmacies and by or under the supervision of a pharmacist.
13-Cascara sagarda or Rhamanus purchiana Bark Restrictions: Internal use: max. daily dose 30 mg to be taken once daily at night. If presented as a herbal tea, amount of comminuted herbal substance (equivalent to not more than 30 mg hydroxyanthracene derivatives) in 150 ml of boiling water as herbal infusion. - The use in children under 12 years of age is contraindicated. - Contraindicated during pregnancy. - Not to be used for more than 1 week.
14-English Ivy ,Hedra Helix

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Restrictions:

Adolescents, adults and elderly

a) Single dose: 15-65 mg, one to three times daily

Daily dose: 45-105 mg

(Note: maximum daily dose for ethanolcontaining finished products :67 mg;

corresponding to 420 mg herbal substance)

b) Single dose: 14-18 mg three times daily

Daily dose: 42-54 mg

c) Single dose: 33 mg two times daily

Daily dose: 66 mg

d) Single dose: 100 mg three times daily

Daily dose: 300 mg

e) Single dose: 40 mg three times daily

Daily dose: 120 mg

Children between 6-11 years of age

a) Single dose: 11-35 mg, two to three times daily

Daily dose: 33-70 mg.

(Note: maximum daily dose for ethanolcontaining finished products: 34 mg;

corresponding to 210 mg herbal substance)

b) Single dose: 9-18 mg, one to three times daily

Daily dose: 15-40 mg

c) Single dose: 25 mg, two times daily

Daily dose: 50mg

d) Single dose: 75 mg, three times daily

Daily dose: 225 mg

e) Single dose: 20-26 mg, three to four times Daily

Daily dose: maximum of 80 mg

Children between 2-5 years of age

a) Single dose: 8-18 mg, two to three times daily

Daily dose: 24-36 mg

(Note: maximum daily dose for ethanolcontaining finished products: 24 mg;

corresponding to 150 mg herbal substance)

b) Single dose: 7-9 mg, two to three times daily

Daily dose: 14-27 mg

c) Single dose: 17 mg, two times daily

Daily dose 34 mg

e) Single dose: 20 mg, three times daily

Daily dose: 60 mg

The use in children under 2 years of age is contraindicated.

15- Nutmeg Myrestica fragrance

Restrictions:

Maximum dose 1mg/kg body weight

16- Rhamnus Frangula

Restrictions:

Internal use: max. daily dose 30 mg, to be taken once daily at night. If presented as a herbal tea: amount of comminuted herbal substance equivalent to not more than 30 mg hydroxyanthracene derivatives in 150 ml of boiling water as herbal infusion.

- The use in children under 12 years of age is contraindicated.

- Not to be used for more than 1 week. - Not suitable during pregnancy.
17- Hyoscymus Muticus (Egyptian Henbane), Hyoscymus Niger (Black Henbane), Hyoscymus Albus Restrictions: Internal use: max. dose 100 mg, max. daily dose 300 mg. External use: can only be sold in premises which are registered pharmacies and by or under the supervision of a pharmacist.
18- Ephedra sinica, Ephedra equisetina, Ephedra distachya, Ephedra intermedia, Ephedra gerardiana Restrictions: Internal use: max. dose 600 mg, max. daily dose 1800 mg External use: can only be sold in premises which are registered pharmacies and by or under the supervision of a pharmacist

❖ **N.B** In addition to the herbs and plants listed above in Tables 1 and 2, the Ministry of Health has the right to ban/restrict any herb or plant if proven harmful for human use in any way, or if there is any warning for its use released by a health organization or a national health regulatory authority (e.g. USFDA, MHRA, World Health Organization (WHO), etc.)

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Annex II: List of reference competent national health regulatory authorities

1. Saudi Food and Drug Administration (SFDA).
2. Gulf Council Corporation – Central Registration (GCC-DR).
3. United States Food and Drug Administration (USFDA).
4. Therapeutic Goods Administration Australia (TGA).
5. Health Canada.
6. Ministry of Health, labor and welfare, Japan.
7. Med safe, New Zealand.
8. Swiss medic, Switzerland.
9. European Medicine Agency (EMA).
10. Medicines and Healthcare products Regulatory Agency, UK (MHRA).
11. Federal institute for Drugs and Medical Devices, Germany (in German: Bundesinstitut fur Arzneimittel and Medizinprodukte- BfArM).
12. National Agency for the Safety of Medicine and Health Products, France (ANSM).
13. Health Products Regulatory Authority, Ireland (HPRA).
14. Medicine Evaluation Board, Netherlands.
15. Medical Product Agency, Sweden.
16. Danish Medicines, Agency, Denmark.
17. Federal Agency for Medicine and Health Products, Belgium.

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References

1. EMA, as described in the '' Guideline on the use of the CTD format in the preparation of a registration application for traditional herbal medicinal products (2008)''
2. OFFICIAL JOURNAL OF THE EUROPEAN UNION DIRECTIVE 2001/83/EC on the community code relating to medicinal products for human use '' L 136/86 , L 136/87 , L 136/88 ''
3. HOUSE OF COMMONS LIBRARY ''Regulations of herbal medicine standard note SN/SC/6002 (12 FEB 2014)''
4. MHRA, Traditional Herbal Medicines Registration scheme: key requirements.
5. MEDICINES& HEALTH PRODUCTS REGULATORY AGENCY,BANNED AND RESTRICTED HERBAL INGREDIENTS published 18th of December 2014
6. SAUDI FOOD AND Drug AUTHORITY ''Guidance for products classification''
7. SAUDI FOOD AND Drug AUTHORITY ''Data requirements for herbal & health products submission''
8. SULTANATE OF OMAN MINISTRY OF HEALTH DIRECTORATE GENERAL OF PHARMACEUTICAL AFFAIRS AND DRUG CONTROL MUSCAT CIRCULAR NO. 28/2008 (01-03-1429) (07-4-2008).
9. HEALTH SCIENCES AUTHORITY REGULATORY GUIDANCE revised august 2017 (Health supplements guidelines).
10. Food and Drug Administration. Part 328- Over the counter drug products intended for oral ingestion that contain ethanol. Title 21- Food and Drugs. Rockville, MD: Department of Health and Human Services (US), Food and Drug Administration; 006.
11. World Health Organization, Swiatowa Organizacja Zdrowia. WHO guidelines on good agricultural and collection practices [GACP] for medicinal plants. World Health Organization; 2003 Dec 16.

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List of restricted herbs with specific restrictions as per competent national health regulatory authorities and Ministerial Decrees

Restricted herbal ingredients in herbal products/ herbal teas registered in the Herbal Section
1-Aconitum spp. (Aconite, Monkshood): all Aconitum species including: Aconitum napellus, Aconitum stoerkianum, Aconitum uncinatum var japonicum, Aconitum deinorrhizum, Aconitum balfourii, Aconitum chasmanthum,Aconitum spicatum, Aconitum lycoctonum Restrictions: Internal use: no permitted dose unless made available by a prescription from a registered doctor or dentist (POM). External use: max. dose 1.3%. Source: MHRA, available at: **https://www.gov.uk/government/publications/list-of-banned-or-restricted-herbal-ingredients-for-medicinal-use/banned-and-restricted-herbal-ingredients**
2- Adhatoda Vasica Restrictions: The following precaution should be added on the outer pack and leaflet: "Do not take if you are pregnant or breast-feeding". Source: EMA, available at: **https://www.ema.europa.eu/en/documents/public-statement/final-public-statement-adhatoda-vasica-nees-folium-first-version_en.pdf**
3- Egyptian Henbane, Hyoscyamus niger, Hyoscyamus albus, Hyoscyamus muticus Restrictions: Internal use: 100 mg (maximum dose), 300 mg (maximum daily dose). External use: can only be sold in registered pharmacies and by or under the supervision of a pharmacist. Source: MHRA. Available at: **https://www.gov.uk/government/publications/list-of-banned-or-restricted-herbal-ingredients-for-medicinal-use/banned-and-restricted-herbal-ingredients**

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4-Ergot, Rye Ergot or Secale Conutum dried sclerotum of Claviceps Purpurea or prepared Ergot of Rye; Smut of Rye; Spurred Rye

Restrictions:
Internal and external use: can only be made available by a prescription from a registered doctor or dentist (POM).

Source: MHRA. Available at: **https://www.gov.uk/government/publications/list-of-banned-or-restricted-herbal-ingredients-for-medicinal-use/banned-and-restricted-herbal-ingredients**

5-Gelsemium sempervirens, Yellow Jessamine, Gelsemium

Restrictions:

Internal use: maximum dose 25 mg, maximum daily dose 75 mg.
External use: can only be sold in premises which are registered pharmacies and by or under the supervision of a pharmacist.

Source: MHRA. Available at: **https://www.gov.uk/government/publications/list-of-banned-or-restricted-herbal-ingredients-for-medicinal-use/banned-and-restricted-herbal-ingredients**

6-Ipecac, Caphaelus Ipecacuanhua, Carapichea ipecacuanha (Rio or Brazilian Ipecac), C.Acuminata (Cartagena ipecac)

Restrictions:
The USFDA recommends that it is in the interest of the public health for ipecac syrup to be available for sale without prescription, provided that it is packaged in a quantity of 1 fluid ounce (30 milliliters), and its label bears, in addition to other required label information, the following, in a prominent and conspicuous manner:
(1) A statement conspicuously boxed and in red letters, to the effect: "For emergency use to cause vomiting in poisoning. Before using, call physician, or hospital emergency room immediately for advice."
(2) A warning to the effect: "Warning--Keep out of reach of children. Do not use in unconscious persons. Ordinarily, this drug should not be used if strychnine, corrosives such as alkalies (lye) and strong acids, or petroleum distillates such as kerosine, gasoline, coal oil, fuel oil, paint thinner, or cleaning fluid have been ingested."
(3) Usual dosage: 1 tablespoon (15 milliliters) in persons over 1 year of age. UNSAFE when used in high doses or in children under the age of one year.

Source: USFDA. Available at:
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=201.308

Registered in the UK with minimal ingredient as a combination product syrup under the traditional herbal medicine registration, indicated for the relief of sore throats and chesty coughs

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only.

Source: MHRA. Available at: **https://www.gov.uk/government/publications/herbal-medicines-granted-a-traditional-herbal-registration-thr/herbal-medicines-granted-a-traditional-herbal-registration**

7- Lobelia or Indian Tobacco, Lobelia Inflata

Restrictions:
Internal use: max. dose 200 mg, max. daily dose 600.
External use: can only be sold in premises which are registered pharmacies and by or under the supervision of a pharmacist.
Source: MHRA. Available at: **https://www.gov.uk/government/publications/list-of-banned-or-restricted-herbal-ingredients-for-medicinal-use/banned-and-restricted-herbal-ingredients**

8- Poison Hemlock (Conium Maculatum)

Restrictions:
For external use only: max. 7.0 %.

Source: MHRA. Available at: **https://www.gov.uk/government/publications/list-of-banned-or-restricted-herbal-ingredients-for-medicinal-use/banned-and-restricted-herbal-ingredients**

9- Piper Methysticum (Kava Kava)

Restrictions:
For external use only.

Source: MHRA. Available at: **https://www.gov.uk/government/publications/list-of-banned-or-restricted-herbal-ingredients-for-medicinal-use/banned-and-restricted-herbal-ingredients**

10- Adonis Vernalis (pheasant's eye)

Restrictions:
Internal use: max. dose 100 mg, max. daily dose 300 mg.
External use: no dose permitted.

Source: MHRA. Available at: **https://www.gov.uk/government/publications/list-of-banned-or-restricted-herbal-ingredients-for-medicinal-use/banned-and-restricted-herbal-ingredients**

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11- Cinchona officinalis, Cinchona bark, Peruvian bark, Cinchona Succirubra (Red Cinchona), C. Calisaya (Calisaya bark) ,Cinchona Micrantha

Restrictions:
Internal use: max. dose 250 mg, max. daily dose 750 mg.
External use: can only be sold in premises which are registered pharmacies and by or under the supervision of a pharmacist.

Source: MHRA. Available at: **https://www.gov.uk/government/publications/list-of-banned-or-restricted-herbal-ingredients-for-medicinal-use/banned-and-restricted-herbal-ingredients**

12- Colchicum Autumnale, Colchicum corm

Restrictions:
Internal use: max. dose 100 mg, max. daily dose 300 mg.
External use: can only be sold in premises which are registered pharmacies and by or under the supervision of a pharmacist.

Source: MHRA. Available at: **https://www.gov.uk/government/publications/list-of-banned-or-restricted-herbal-ingredients-for-medicinal-use/banned-and-restricted-herbal-ingredients**

13-Cascara sagarda or Rhamanus purchiana Bark

Restrictions:
Max. daily dose 30 mg to be taken once daily at night.
Herbal tea: amount of comminuted herbal substance (equivalent to not more than 30 mg hydroxyanthracene derivatives) in 150 ml of boiling water as herbal infusion.
The use in children under 12 years of age is contraindicated.
Contraindicated during pregnancy.
Not to be used for more than 1 week.

Source: EMA. Available at: **https://www.ema.europa.eu/en/documents/herbal-monograph/draft-european-union-herbal-monograph-rhamnus-purshiana-dc-cortex-revision-1_en.pdf**

14-English Ivy ,Hedra Helix

Restrictions:
Adolescents, adults and elderly
a) Single dose: 15-65 mg, one to three times daily
Daily dose: 45-105 mg
(Note: maximum daily dose for ethanolcontaining finished products :67 mg; corresponding to 420 mg herbal substance)
b) Single dose: 14-18 mg three times daily

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Daily dose: 42-54 mg
c) Single dose: 33 mg two times daily
Daily dose: 66 mg
d) Single dose: 100 mg three times daily
Daily dose: 300 mg
e) Single dose: 40 mg three times daily
Daily dose: 120 mg

Children between 6-11 years of age
a) Single dose: 11-35 mg, two to three times daily
Daily dose: 33-70 mg.
(Note: maximum daily dose for ethanolcontaining finished products: 34 mg; corresponding to 210 mg herbal substance)
b) Single dose: 9-18 mg, one to three times daily
Daily dose: 15-40 mg
c) Single dose: 25 mg, two times daily
Daily dose: 50mg
d) Single dose: 75 mg, three times daily
Daily dose: 225 mg
e) Single dose: 20-26 mg, three to four times Daily
Daily dose: maximum of 80 mg

Children between 2-5 years of age
a) Single dose: 8-18 mg, two to three times daily
Daily dose: 24-36 mg
(Note: maximum daily dose for ethanolcontaining finished products: 24 mg; corresponding to 150 mg herbal substance)
b) Single dose: 7-9 mg, two to three times daily
Daily dose: 14-27 mg
c) Single dose: 17 mg, two times daily
Daily dose 34 mg
e) Single dose: 20 mg, three times daily
Daily dose: 60 mg
The use in children under 2 years of age is contraindicated

Source: EMA. Available at: **https://www.ema.europa.eu/en/documents/herbal-monograph/final-european-union-herbal-monograph-hedera-helix-l-folium-revision-2_en.pdf**

15- Nutmeg Myrestica fragrance

Restrictions:
Maximum dose 1mg/kg body weight

Source: **file:///C:/Users/aalostad/Downloads/ToxicityOfNutmegMyristicinAReview.pdf**

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16- Rhamnus Frangula

Restrictions:
Max. daily dose 30 mg, to be taken once daily at night.
Herbal tea: amount of comminuted herbal substance equivalent to not more than 30 mg hydroxyanthracene derivatives in 150 ml of boiling water as herbal infusion.
The use in children under 12 years of age is contraindicated.
Not to be used for more than 1 week.
Not suitable during pregnancy.

Source: EMA. Available at: **https://www.ema.europa.eu/en/documents/herbal-monograph/european-union-herbal-monograph-rhamnus-frangula-l-cortex-revision-1_en.pdf**

17- Hyoscymus Muticus (Egyptian Henbane), Hyoscymus Niger (Black Henbane), Hyoscymus Albus

Restrictions:
Internal use: max. dose 100 mg, max. daily dose 300 mg.
External use: can only be sold in premises which are registered pharmacies and by or under the supervision of a pharmacist.

Source: MHRA. Available at: **https://www.gov.uk/government/publications/list-of-banned-or-restricted-herbal-ingredients-for-medicinal-use/banned-and-restricted-herbal-ingredients**

18- Ephedra sinica, Ephedra equisetina, Ephedra distachya, Ephedra intermedia, Ephedra gerardiana

Restrictions:
Internal use: max. dose 600 mg, max. daily dose 1800 mg
External use: can only be sold in premises which are registered pharmacies and by or under the supervision of a pharmacist

Source: MHRA. Available at: **https://www.gov.uk/government/publications/list-of-banned-or-restricted-herbal-ingredients-for-medicinal-use/banned-and-restricted-herbal-ingredients**
(and restricted as per M.D 342/1996)

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