

قرار وزاري رقم (389) لسنة 2025

بشأن تنظيم تسجيل وتداول الأدوية النباتية والمستحضرات العشبية

وزير الصحة:

- بعد الاطلاع على أحكام المرسومين بقانون ونظام الخدمة المدنية وتعديلاتهما.

- وعلى أحكام القانون رقم 28 لسنة 1996 في شأن تنظيم مهنة الصيدلة وتداول الأدوية والمعدل بالقانون رقم 30 لسنة 2016 ولائحتهما التنفيذية.

- وعلى أحكام القانون رقم 159 لسنة 2025 في شأن مكافحة المخدرات والمؤثرات العقلية وتنظيم استعمالها والإتجار فيها.

- وعلى القرار الوزاري رقم 101 لسنة 2020 بشأن إعادة تنظيم وتسجيل وتداول الأدوية النباتية والمستحضرات العشبية.

- وعلى القرار الوزاري رقم 9 لسنة 2025 بشأن ضوابط ولوائح تنظيم عملية الإعلانات الطبية للمراكز الصيدلانية وأماكن ومحال البيع في القطاع الأهلي.

- وعلى القرار الوزاري رقم (340) لسنة 2025 في شأن تنظيم إجراءات الإفراج والتداول للمنتجات المستوردة الخاضعة لرقابة إدارة تسجيل ورقابة الأدوية والمنتجات الطبية.

- ورغبة في تحديث تنظيم تسجيل الأدوية النباتية والمستحضرات العشبية.

- وبناء على مقتضيات مصلحة العمل وما عرضه علينا السيد/ وكيل الوزارة.

- قرر -

مادة أولى:

يُقصد بالمصطلحات التالية المعنى المبين قرين كل من:

الدواء النباتي: **Herbal Medicine (HM)** المستحضر الصيدلاني الذي يحتوي على مواد فعالة مكونة من عشبة أو مجموعة من الأعشاب تحمل ادعاء طبي بحيث يكون للعلاج أو الوقاية من الأمراض، ويستخدم للاستعمال الداخلي أو الخارجي.

المكمل النباتي الطبيعي **Herbal Natural (HNS)** **Supplement**: المنتج الذي يحتوي على مواد عشبية لا تستخدم لأغراض علاجية أو طبية وإنما تستخدم لغرض الصحة العامة ويعتبر من المستحضرات العشبية.

الدواء النباتي التقليدي **Tradition Herbal (THM)** **Medicine**: هو منتج عشبي ناتج عن ممارسات وخبرات متوارثة عبر ثقافات مختلفة مثل الدواء الصيني التقليدي **Traditional Chinese medicine** (دواء الأيورفيدا) **Ayurvedic**

Medicine) وثبتت السلامة والفعالية بالاستناد إلى الاستخدام التقليدي لمدة لا تقل عن (30 عاماً على التوالي).

الوكيل المحلي: هي الشركة الدوائية المحلية الممثلة للشركة صاحبة حق التسويق والمرخص لها بيع الأدوية النباتية والمستحضرات العشبية في دولة الكويت ومسئولة عن جميع الإجراءات القانونية المتعلقة بهذه المنتجات من بيع أو سحب أو إتلاف أو متابعة الأعراض الجانبية وخلافاً داخل دولة الكويت.

المكتب العلمي: هو المركز الصيدلي الذي يقوم بتمثيل الشركة صاحبة حق التسويق في دولة الكويت ومسؤول عن المعلومات والإجراءات العلمية والفنية والتسويقية للأدوية والمنتجات الطبية.

الممثل المعتمد: هو الوكيل المحلي أو المكتب العلمي المعتمد أو فرع الشركة صاحبة حق التسويق المرخص من وزارة الصحة.

الشركة المصنعة: المنشأة التي يتم فيها تصنيع المنتج وفقاً لأسس التصنيع الجيد.

الشركة صاحبة حق التسويق: هي الشركة التي تتولى تسويق المنتج سواء كانت الشركة المصنعة أو المتعهدة بالتسويق، وتكون مسؤولة مسؤولية كاملة عن جودة المنتج وأمنيته وفعالته 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 **Certificate of a Pharmaceutical Product (CPP)**:

هي شهادة صادرة من السلطات الصحية المختصة في بلد المنشأ التي يتم فيها التصنيع كاملاً أو جزء من التصنيع أو صاحبة حق تسويق المنتج.

بلد المنشأ: هي بلد الشركة المصنعة أو الحائزة على حق تسويق المنتج الذي تصدر سلطاته الصحية الرقابية شهادة المستحضر الصيدلاني.

السلطات الرقابية المرجعية: تشمل السلطات الرقابية العالمية الصارمة مثل إدارة الغذاء والدواء الأمريكية (USFDA)، الوكالة الأوروبية للأدوية (EMA)، وزارة الصحة الكندية (Health Canada)، وكالة تنظيم الأدوية ومنتجات الرعاية الصحية البريطانية (MHRA)، وكالة الأدوية والأجهزة الطبية اليابانية (PMDA)، الهيئة السويسرية للدواء (Swissmedic)، إدارة المنتجات العلاجية الأسترالية (TGA)، وغيرها من السلطات التنظيمية الحاصلة على اعتراف منظمة الصحة العالمية (WHO) بأنها تعمل في المستوى الرابع من النضج التنظيمي، أو مدرجة من قبل منظمة الصحة العالمية كسلطة تنظيمية صارمة (WLA).

مادة ثانية

تخضع للتسجيل جميع الأدوية النباتية والمستحضرات العشبية المراد

تسويقها في دولة الكويت وفقاً لهذا القرار.

مادة ثالثة

الأدوية النباتية والمستحضرات العشبية التي تدرج في نطاق هذا القرار تشمل:

1. الأدوية النباتية.
2. المكملات النباتية الطبيعية.
3. الأدوية النباتية التقليدية.
4. شاي الأعشاب المحتوي على ادعاء طبي.

مادة رابعة

اشتراطات تسجيل الأدوية النباتية والمستحضرات العشبية:

1. 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 ورقابة الأدوية والمنتجات الطبية للموافقة أو الرفض على طلب التسجيل.
2. يجب أن تكون جرعة وطريقة تحضير الدواء النباتي التقليدي مطابقة للمصادر المعتمدة.

3. يسمح للدواء النباتي التقليدي أن يحتوي على الادعاءات المثبتة في الاستخدام التقليدي فقط وأي ادعاءات تُضاف إلى المنتج ولا يدعمها دليل كافٍ على الاستخدام التقليدي، تتطلب تسجيل المنتج كدواء عشبي، مما يستوجب تقديم دراسات سريرية لدعم الادعاء.
4. لا يسمح للدواء النباتي/ المستحضر العشبي بالاستعمال عن طريق الحقن.

5. يمكن للدواء النباتي أو المستحضر العشبي أن يحتوي على أملاح أو معادن أو فيتامينات، شريطة أن يكون التأثير العلاجي الأساسي ناتجاً عن المكونات العشبية، وأن تكون أي إضافات غير عشبية ذات طبيعة تكميلية فقط وبنسب أقل من الجرعات العلاجية المعتمدة لهذه الإضافات.

6. لا يعتبر المنتج دواء نباتي أو مستحضر عشبي في حال كانت المادة المستخلصة من النباتات مصنفة كدواء طبي بشري.

مادة خامسة

يشترط لتسجيل الأدوية النباتية والمستحضرات العشبية التالي:

1. المتطلبات الخاصة بالوكيل المحلي:

- 1.1 ترخيص مزاولة نشاط بيع الأدوية النباتية والمستحضرات العشبية أو ما يعادله صادر من وزارة التجارة والصناعة.
- 1.2 ترخيص الشركة لاستيراد الأدوية صادر من وزارة الصحة.
- 1.3 ترخيص مستودع طبي صادر من وزارة الصحة.
- 1.4 تفويض توقيع ممثلي الشركة صادر من غرفة التجارة والصناعة.
- 1.5 صور عن البطاقة المدنية للممثلي الشركة.

2. المتطلبات الخاصة بالمكتب العلمي أو فرع الشركة صاحبة حق التسويق:

- 2.1 ترخيص مزاولة نشاط مكتب علمي أو فرع للشركة صاحبة حق التسويق صادر من وزارة التجارة والصناعة.
- 2.2 ترخيص مكتب علمي أو فرع للشركة صاحبة حق التسويق صادر من وزارة الصحة.
- 2.3 تفويض توقيع ممثلي الشركة صادر من غرفة التجارة والصناعة.
- 2.4 صور عن البطاقة المدنية للممثلي الشركة.
3. المتطلبات الخاصة بالشركة صاحبة حق التسويق:

- 3.1 خطاب الوكالة الحصرية يوضح العلاقة التجارية بين الوكيل المحلي والشركة¹.

- 3.2 شهادة ترخيص الشركة صادرة من السلطات الصحية في بلد المنشأ.

- 3.3 شهادة تطبيق أسس التصنيع الجيد Good Manufacturing Practice (GMP) للشركة صادرة من السلطات المختصة في بلد المنشأ أو شهادة الجودة (ISO) صادرة من الجهات المعتمدة¹.

- 3.4 تقديم ملف تفصيلي عن الشركة يتضمن التالي:

1. نوع ونشاط الشركة وتاريخ تأسيسها ونبذة عن الشركة والمالكين للشركة في حال كانت الشركة ذات ملكية خاصة.
2. عدد المصانع المملوكة للشركة وعناوينها إن وجدت.
3. رأس مال الشركة وأرباح آخر ثلاث سنوات.
4. رسم تخطيطي مبسط (كروكي) لمباني المصنع وسير خطوط العمل فيها.
5. الهيكل التنظيمي الوظيفي للمصنع يوضح الأقسام المختلفة وعدد العاملين فيها مع ذكر مؤهلات مدراء أقسام الإنتاج ومراقبة الجودة والبحث والتطوير والمدير الفني للمصنع.
6. نبذة عن نشاط الشركة في مجال الأبحاث والتطوير.
7. قائمة بالأدوية النباتية والمستحضرات العشبية التي ينتجها المصنع سواء كانت باسمه أو لحسابه أو عن طريق التصنيع التعاقدى لشركات أخرى.

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

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.

10. طرق التواصل مع الشركة، تتضمن أرقام الهواتف والبريد الإلكتروني أو وسيلة تواصل أخرى.

الأدوية والمنتجات الطبية بوزارة الصحة في حالة صدور أي تحذير من أي من الجهات الرقابية الدولية بشأن سلامة وأمنية استخدام المنتج.

مادة ثامنة

يحق لإدارة تسجيل ورقابة الأدوية والمنتجات الطبية طلب أي مستندات أو دراسات إضافية أو إجراء أي تحاليل مخبرية تعتبرها مكتملة لإجراءات التسجيل، وعلى الشركات الالتزام بذلك.

مادة تاسعة

يتضمن ملحق القرار باللغة الإنجليزية تفصيل كامل للمتطلبات والشروط التي يجب توافرها في ملف التسجيل المقدم إلى إدارة تسجيل ورقابة الأدوية والمنتجات الطبية.

مادة عاشرة

يجب على الشركة المصنعة إخطار إدارة تسجيل ورقابة الأدوية والمنتجات الطبية بأي تغيير أو تعديل يطرأ على المنتج على ألا يتم تطبيق هذا التغيير أو التعديل إلا بعد الحصول على موافقة الإدارة.

مادة حادية عشر

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

مادة ثمانية عشر

إدارة تسجيل ورقابة الأدوية والمنتجات الطبية هي الجهة المخولة بإصدار شهادات مستحضر صيدلاني حرية التداول، شهادة تسجيل التصنيع للشركة المصنعة أو صاحبة حق التسويق وشهادة أسس التصنيع الجيد وجميع الشهادات المتعلقة بتسجيل المنتج المصنع محلياً أو حق تسويقه مملوك لصالح شركة محلية.

مادة ثالثة 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 رابعة عشر

يجب عند نقل وكالة الشركة صاحبة حق التسويق من وكيل محلي إلى آخر تقديم المستندات التالية:

1. شهادة الوكالة صادرة من الشركة صاحبة حق التسويق تفيد بتعيين وكيل محلي جديد لها¹.
2. شهادة إلغاء الوكالة الممنوحة للوكيل السابق من الشركة صاحبة حق التسويق موضحاً بما تاريخ إلغاء الوكالة¹.
3. قائمة بالمنتجات الخاضعة لنقل الوكالة صادرة من الشركة صاحبة حق التسويق موضح فيها الاسم التجاري للمنتج التركيز، الشكل الدوائي، الشركة المصنعة.

• ¹ يتوجب تقديم أصول هذه الشهادات وتصديقها كما هو

11. الملف التفصيلي عن نظام التيقظ الدوائي للشركة.

12. صور عن شهادات تسجيل للمصنع صادرة من هيئات رقابية عالمية مثل هيئة الدواء والغذاء الأمريكية أو الاتحاد الأوروبي أو مجلس الصحة الخليجي وغيرها من الجهات الرقابية المرجعية المعتمدة إن وجدت.

13. تقديم ملف تسجيل لمنتج واحد أو أكثر.

• ¹ يتوجب تقديم أصول هذه الشهادات وتصديقها كما هو وارد في المادة السادسة من هذا القرار.

ملاحظة: يحق لإدارة تسجيل ورقابة الأدوية الطبية والنباتية القيام بزيارة الشركة المصنعة للتأكد من تطبيق أسس التصنيع الجيد (Good Manufacturing Practice (GMP متى ما ارتأت ذلك.

4. المتطلبات الخاصة بالشركة المصنعة في حال اختلافها عن الشركة صاحبة حق التسويق:

4.1 شهادة ترخيص الشركة المصنعة صادرة من السلطات الصحية المختصة في بلد المنشأ¹.

4.2 شهادة تطبيق أسس التصنيع الجيد (GMP) للشركة المصنعة صادرة من السلطات المختصة في بلد المنشأ أو شهادة الجودة (ISO) صادرة من الجهات المعتمدة¹.

4.3 شهادة توضح العلاقة بين الشركة المصنعة والشركة صاحبة حق التسويق صادرة من الأخيرة.

• ¹ يتوجب تقديم أصول هذه الشهادات وتصديقها كما هو وارد في المادة السادسة من هذا القرار.

مادة سادسة

يُعتمد التحقق الإلكتروني Electronic Verification للشهادات إن وجد دون الحاجة إلى التصديق الورقي من الجهات المعنية وفق الشروط التالية:

1. في حال عدم وجود التحقق الإلكتروني يتوجب على الشركات تصديق الشهادات من سفارة/ قنصلية دولة الكويت من بلد المنشأ أو في سفارة / قنصلية خليجية في حال عدم وجود سفارة لدولة الكويت في بلد المنشأ.

2. يتوجب تصديق شهادة الوكالة بين الوكيل المحلي والشركة صاحبة حق التسويق للمنتجات الطبية أو شهادة إلغاء الوكالة من سفارة / قنصلية دولة الكويت من بلد المنشأ أو في سفارة/ قنصلية خليجية في حال عدم وجود سفارة لدولة الكويت في بلد المنشأ بالإضافة إلى غرفة التجارة في بلد المنشأ.

مادة سابعة

يجب على مقدم طلب التسجيل تقديم كتاب تعهد من الشركة صاحبة حق التسويق يضمن الالتزام بإبلاغ إدارة تسجيل ورقابة

وارد في المادة السادسة من هذا القرار.

مادة خامسة عشر

يحظر استيراد وتسجيل الأدوية النباتية والمستحضرات العشبية التي تحتوي على نباتات واردة في الجدول رقم (1) المرفق بهذا القرار كما يحظر استيراد وتسجيل الأدوية النباتية والمستحضرات العشبية التي تحتوي على نباتات أو مواد واردة في جداول القانون رقم 159 لسنة 2025 في شأن مكافحة المخدرات والمؤثرات العقلية وتنظيم استعمالها والإتجار فيها.

مادة سادسة عشر

يجوز الترخيص لاستيراد الأدوية النباتية والمستحضرات العشبية التي تحتوي على نباتات واردة في الجدول رقم (2) المرفق في ملحق هذا القرار باللغة الإنجليزية والذي يتضمن التراكيز والجرعات المحددة وضوابط الاستخدام.

مادة سابعة عشر

يحظر استيراد النباتات الأولية الواردة في الجدول رقم (1) المرفق في هذا القرار إلا في أغراض التصنيع الدوائي فقط، وليس كمستحضر عشبي وذلك بعد الحصول على موافقة وزارة الصحة ولا يسمح بالإتجار بهذه المواد بشكلها الأولي بعد استيرادها في البلاد.

مادة ثامنة عشر

يحظر استيراد النباتات الأولية الواردة في جداول القانون رقم (159) لسنة 2025 في شأن مكافحة المخدرات والمؤثرات العقلية وتنظيم استعمالها والاتجار فيها، إلا في أغراض التصنيع الدوائي فقط، وليس كمستحضر عشبي، وذلك بعد الحصول على ترخيص استيراد صادر من مراقبة تراخيص المواد والمستحضرات المخدرة والمؤثرات العقلية وفقاً للقانون رقم (159) لسنة 2025 والقرارات الوزارية الصادرة تنفيذاً له ، ولا يسمح بالإتجار بهذه المواد بشكلها الأولي بعد استيرادها في البلاد.

مادة تاسعة عشر

على الشركة المستوردة للأعشاب الطبية بشكل نبات أولية بغرض التصنيع الدوائي أو البحث العلمي، أن يتقدم بطلب لإدارة تسجيل ورقابة الأدوية والمنتجات الطبية 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 ورقابة الأدوية والمنتجات الطبية.
2. الكمية المطلوب استيرادها وشهادة من بلد منشأ تحمل اسم وتاريخ الإنتاج وتاريخ انتهاء الصلاحية ورقم التشغيل للنبات.
3. المواصفات القياسية وطريقة التحليل واسم المرجع العلمي إذا كان النبات دستورياً أو مذكوراً في أحد المراجع العلمية.
4. شهادة تحليل معتمدة من الشركة المصنعة.

مادة عشرون

الإشتراطات والضوابط المنظمة لتعليق التسجيل:

يحق لإدارة تسجيل ورقابة الأدوية والمنتجات الطبية تعليق تسجيل أي منتج أو شركة صاحبة حق التسويق أو الشركة المصنعة وذلك إذا ثبت للإدارة ما يلي:

1. إذا صدر قرار بتعليق أو حظر المنتج أو الشركة من قبل السلطات الصحية الرقابية في بلد المنشأ.
2. إذا ثبت عدم فعالية وأمنية استخدام المنتج.
3. إذا ثبت التلاعب في المستندات المقدمة لإدارة تسجيل ورقابة الأدوية والمنتجات الطبية.
4. إذا ثبت مخالفة الشركة لنظم ولوائح إدارة تسجيل ورقابة الأدوية والمنتجات الطبية.
5. إذا ثبت عدم استمرار الشركة باتباع أسس التصنيع الجيد.
6. تكرار عدم اجتياز المنتج للتحليل لدى إدارة فحص الأدوية والمنتجات الطبية.
7. في حال عدم إبلاغ الممثل المعتمد لدى إدارة تسجيل ورقابة الأدوية والمنتجات الطبية عن صدور أي تحذيرات تخص المستحضر أو الشركة المصنعة من الهيئات الصحية المعتمدة.

مادة حادية وعشرون

الإشتراطات والضوابط لإلغاء التسجيل:

يحق لإدارة تسجيل ورقابة الأدوية والمنتجات الطبية إلغاء تسجيل أي منتج أو شركة صاحبة حق التسويق أو الشركة المصنعة وذلك إذا ثبت للإدارة ما يلي:

1. إذا تم إلغاء تسجيل المنتج أو الشركة في بلد المنشأ.
2. إذا ثبت احتواء المنتج على مادة كيميائية صيدلانية غير معلن عنها.
3. عدم مطابقة المنتج للمواصفات الفنية المعتمدة في ملف التسجيل.
4. بناء على طلب الشركة صاحبة حق التسويق.
5. إذا صدر قرار بإلغاء تسجيل المنتج أو الشركة من قبل السلطات الرقابية العالمية المعتمدة
6. إذا ثبت للإدارة حسب المراجع العلمية المعتمدة عدم سلامة وأمان استخدام المنتج
7. عدم تجديد التسجيل في الفترة المحددة.
8. إذا ثبت التزوير أو التلاعب في المستندات المقدمة للتسجيل.
9. في حال عدم مطابقة المنتج أو الشركة لمتطلبات هذا القرار.
10. إذا مضت سنتان من تاريخ تسجيل المنتج من دون استيراده أو من تاريخ آخر استيراد له إلى دولة الكويت.
11. تكرار عدم اجتياز الجهاز أو المستلزم الطبي للتحليل لدى مختبرات إدارة تسجيل ورقابة الأدوية والمنتجات الطبية بحد أقصى 5 مرات.

| الجدول رقم (1) الأعشاب المخطورة التي لا يجوز إدراجها ضمن المنتجات العشبية أو الشاي العشبي |
|---|
| 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 Castelnai, S. Toxifera, S. Crevauxii |
| 5-Cicuta Spp. (Water Hemlock), C. Maculata |
| 6-Chinaberry tree, Melia Azedarach, White Cedar |
| 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 Officinatum, 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 |

مادة ثانية وعشرون

يحق لإدارة تسجيل ورقابة الأدوية والمنتجات الطبية رفض تسجيل أي منتج أو شركة المصنعة أو شركة صاحبة حق التسويق مع ذكر الأسباب التي أدت إلى ذلك.

مادة ثالثة وعشرون

يحق للممثل المعتمد التظلم على قرار الإدارة في رفض أو تعليق التسجيل أو إلغاء التسجيل خلال مدة أقصاها 90 يوم من تاريخ العلم بصدور القرار، وعليه يعتبر القرار نافذاً بعد دراسة التظلم.

مادة رابعة وعشرون

يخضع تسجيل الأدوية النباتية والمستحضرات العشبية والشركات المصنعة للرسم المقررة في القرار الوزاري المنظم لأعمال وأجور الخدمات الصحية.

مادة خامسة وعشرون

يحق لإدارة تسجيل ورقابة الأدوية والمنتجات الطبية في حال عدم التزام الشركة بتوريد الأدوية النباتية والمستحضرات العشبية أو عدم الالتزام بالشروط والضوابط المذكورة في هذا القرار إلغاء التسجيل أو الموافقة على تعيين وكيل محلي آخر في دولة الكويت.

مادة سادسة وعشرون

يخضع الإفراج عن الأدوية النباتية والمستحضرات العشبية وتداولها وفقاً للقرار الوزاري الخاص بذلك.

مادة سابعة وعشرون

لا يتم الإعلان عن الأدوية النباتية والمستحضرات العشبية إلا بعد الحصول على الموافقات اللازمة من الإدارة المعنية في وزارة الصحة.

مادة ثامنة 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.

وزير الصحة

د. أحمد عبد الوهاب العوضي

صدر في: 10 رجب 1447 هـ

الموافق: 30 ديسمبر 2025م

| |
|--|
| 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 ethanol containing 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 ethanol containing 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. |

| |
|---|
| 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 Succubra, (Red Cinchona), C. Calisaya (Calisaya bark), Cinchona Micrantha |
| Restrictions: |
| Internal use: max. dose 250 mg max. daily dose 750 mg. |
| Pharmacy only. |
| 12- Colchicum Autumnale, Colchicum corn |
| Restrictions: |
| Internal use: max. dose 100 mg, max. daily dose 300 mg. |
| Pharmacy only. |
| 13-Cascara sagarda or Rhamnus purshiana 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 |
| 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 ethanol containing 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 |

| |
|--|
| 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 alkalis (lye) and strong acids, or petroleum distillates such as kerosene, 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. |
| Can only be sold in pharmacy |
| 8- Poison Hemlock (Conium Maculatum) |
| Restrictions: |
| For external use only: max. 7.0 %. |
| 9- Piper Methysticum (Kava Kava) |
| Restrictions: |
| For external use only. |

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|---|
| 22-Red yeast rice (Poisonous dye Sudan Red G) |
| 23-Red squill or V Maritima or squill bulb |
| 24-South American arrow Poison or Curare, Strychnous Castelnai, 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 |
| 30-Areca Catchu |

| |
|--|
| الجدول رقم (2) المكونات العشبية الخاضعة لقواعد محددة (مثل الإحصائيات، دواعي الاستعمال، والحدود القصوى للقبولة، وغيرها) |
| 1-Aconitum spp. (Aconite, Monkshood): all Aconitum species including: Aconitum napellus, Aconitum stoerkianum, Aconitum uncinatum var japonicum, Aconitum deinoerhizum, Aconitum balfourii, Aconitum chasmanthum, Aconitum spicatum, Aconitum lycoctonum |
| Restrictions: |
| External use only: 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). |
| Can only be sold in a pharmacy |
| 5-Gelsemium sempervirens, Yellow Jessamine, Gelsemium |
| Restrictions: |
| Internal use: maximum dose 25 mg, maximum daily dose 75 mg. |
| can only be sold in a pharmacy |

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ABBREVIATIONS

| | |
|-------|---|
| BP | British Pharmacopoeia |
| BSE | Bovine Spongiform Encephalopathy |
| CPP | Certificate of Pharmaceutical Product |
| EMA | European Medicines Agency |
| FSC | Free Sale Certificate |
| GCC | Gulf Cooperation Council |
| GMP | Good Manufacturing Practice |
| HM | Herbal medicine |
| HNS | Herbal natural supplement |
| M.D | Ministerial Decree |
| MAH | Marketing Authorization Holder |
| MHRA | Medicines and Healthcare products Regulatory Agency |
| PIL | Product Information Leaflet |
| RH | Relative Humidity |
| TCM | Traditional Chinese Medicine |
| TDM | Traditional Herbal Medicine |
| TSE | Transmissible Spongiform Encephalopathy |
| USFDA | United States Food and Drug Administration |
| USP | United States Pharmacopoeia |
| COA | Certificate of Analysis |
| WHO | World Health Organization |

GLOSSARY OF TERMS

Adverse effect: any unfavorable 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 effect and which does not necessarily have a causal relationship with this treatment.

Authorized representative: also referred to as the Local Agent or scientific office or local approved affiliates, is a legal entity established in the State of Kuwait, officially appointed by the Marketing Authorization Holder (MAH) to act on their behalf before the Medicine and Medical Products Registration and Regulatory Administration in all matters related to the registration, importation, pricing, post-marketing surveillance, and communication of medicinal products

1.5 Electronic Certificates and Verification 162

1. Valid Electronic certificates are acceptable provided that an approved verification tool is available for the authentication and verification of the electronic certificates. 162

2. For Electronic certificates legalisation is not required. 162

3. Electronic legalization is acceptable provide that an approved verification tool is available for the authenticity of legalisation. 162

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1.2 Marketing Authorization Holder (MAH) registration requirements 161

1. Legalized letter of appointment from the MAH stating that the local agent or the scientific office is the authorized representative in the State of Kuwait. 161

2. Original legalized manufacturing license from the country of origin for such manufacturing site issued by the health authority or the concerned authorized authority in the country of origin. 161

3. Original legalized Good Manufacturing Practice (GMP) certificate \ relevant International Organization for Standardization such as (ISO) 22716 or 2200 from the country of origin. 161

4. Site master file (for herbal products only) which contain the following: 161

1.3 Manufacturing site registration requirements (If the manufacturer is different than the MAH) 162

1. A letter issued from the MAH explaining the relationship between the MAH and the manufacturer. 162

2. GMP certificate of the manufacturer / ISO. 162

3. Manufacturing license of the manufacturer. 162

1.4 Document Legalization and Certification 162

1. Legalization of Certificates issued by Health Authorities such as the CPP, GMP Certificate, Manufacturing License, and any other certificates issued by the Health Authority in the country of origin must be Original, legalized by the Embassy or Consulate of the State of Kuwait in the country of origin. 162

2. In cases where this is not possible, legalization may be done by an authorized GCC Embassy or Consulate in the country of origin. 162

3. Other Official Documents such as the Letter of Appointment, Pricing Certificate, and similar administrative documents must be legalized by the Embassy or Consulate of the State of Kuwait in the country of origin (or an authorized GCC Embassy/Consulate if not available), and The Chamber of Commerce in the country of origin. 162

• Not to be used for more than 1 week.
Not suitable during pregnancy.

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

Restrictions:

Internal use: max. dose 100 mg, max. daily dose 300 mg.

Pharmacy only

ملاحظة: بالإضافة الأعشاب والنباتات المدرجة أعلاه في الجدولين (1) و(2)، يحظر لوزرة الصحة حظر أو تقييد أي عشبة أو نبات إذا ثبت أنه ضار بالاستخدام البشري بأي شكل من الأشكال، أو في حال صدور أي تحذير بشأن استخدامه من قبل المنظمات الصحية أو الجهات التنظيمية العالمية أو أي دراسات علمية مثبتة.

STATE OF KUWAIT
MINISTRY OF HEALTH
Medicines & Medical Products
Registration & Regulatory
Administration

MINISTERIAL DECREE FOR
REGISTRATION OF
HERBAL MEDICINES AND HERBAL
PRODUCTS

ملحق القرار الوزاري رقم (389) لسنة 2025 بشأن تسجيل وتداول الأدوية النباتية والمستحضرات العشبية

M.D. (389 / 2025)

Version 1.0

December 2025

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1.1 Authorized Representative Requirements

AUTHORIZATION HOLDER (MAH) AND MANUFACTURING COMPANY REGISTRATION REQUIREMENTS

1.1 Authorized Representative Requirements

1. Copy of valid license from the Ministry of Commerce in which the company activity includes the sale of medicines.
2. Copy of valid store license issued from the Pharmaceutical Inspection and licensing Administration.
3. Copy of valid agency license issued from Pharmaceutical Inspection and licensing Administration
4. Copy of authorized personal signatures.

1.2 MARKETING AUTHORIZATION HOLDER (MAH) REGISTRATION REQUIREMENTS

- 1 Legalized letter of appointment from the MAH stating that the local agent or the scientific office is the authorized representative in the State of Kuwait.
- 2 Original legalized manufacturing license from the country of origin for each manufacturing site issued by the health authority or the concerned authorized authority in the country of origin.
- 3 Original legalized Good Manufacturing Practice (GMP) certificate \ relevant International Organization for Standardization such as (ISO) 22716 or 2200 from the country of origin.
- 4 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 unit and quality management.
 - 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.

herbal preparations and various mind and body practices, such as acupuncture and tai chi, to treat or prevent health problems.

INTRODUCTION

In compliance with the Pharmacy Law of the State of Kuwait, pharmaceutical products, including herbal products and herbal teas, may not be marketed locally unless they are registered with the Medicines and Medical Products Registration and Regulatory Administration. This Ministerial Decree (M.D.) is issued to clarify the regulatory framework and requirements established by the Medicines and Medical Products Registration and Regulatory Administration. All herbal products and herbal teas must be represented by a locally registered entity, referred to as the Authorized Representative. The Authorized Representative shall be responsible for submitting all documentation required under this Ministerial Decree in order to complete the registration of the herbal product or herbal tea, as well as the registration of its manufacturing company.

This Ministerial Decree is structured into four sections:

- Section I defines the registration requirements for Authorized Representatives, local agents, Marketing Authorization Holders (MAHs), and manufacturing companies.
- Section II sets out the definitions, classifications, and registration requirements applicable to herbal products.
- Section III defines herbal teas and outlines their registration requirements.
- Section IV establishes the requirements governing variations, transfer of agency, and cancellation of registered herbal products and herbal teas.

This Ministerial Decree shall be applied in a manner that is transparent, consistent, and effective.

Where necessary, the Administration may issue official memos specifying additional or product-specific requirements that must be fulfilled by the Authorized Representative or agent

1. SECTION I. LOCAL AGENT, MARKETING

Country of origin: The country where the product is manufactured or the country of the product marketing authorization holder (MAH). Finished product: a medicinal product, which has undergone all stages of production, including packaging in its final container.

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.

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

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.

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.).

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.

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

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

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 or mineral components.

Certificate of Pharmaceutical Product (CPP): is an internationally recognized 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 Organization (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.

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.

Compatibility study: Herbal product compatibility refers to the documented evaluation of interactions between a herbal medicinal product and its reconstitution diluent(s), container-closure system, or dosage/administration device(s) to ensure that such interactions do not adversely affect the product's quality, safety, stability, or performance throughout its shelf life and in-use period

(e.g. Traditional Chinese Medicine, Ayurvedic Medicine, etc.). The traditional herbal registration is to provide a simplified registration option for herbal products. Therefore, no clinical tests and trials on efficacy are required as long as sufficient safety and efficacy data 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 or a claim 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.

2.2.3 Herbal Natural Supplements

This refers to a supplement of one or more herbs or a herbal preparation derived from herbal plants (or plant parts), presented in a dosage form such as capsules, tablets or liquids that is not intended to diagnose, treat, cure or prevent disease and it can be used to maintain normal overall health.

2.3. REQUIREMENTS FOR THE REGISTRATION OF A HERBAL PRODUCT

2.3.1 Administrative registration requirements

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 regulatory 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 The FSC/CPP should include the following:

• Herbal Natural Supplements (HNS)

• Herbal Tea with medical claims



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.

1. A Herbal Medicine must be limited to 5 herbal active ingredients, in case more than 5 active herbs a compatibility study is needed.

2. A herbal product cannot be sterile or be administered by injection.

3. 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.

4. The presence of vitamins or minerals in the herbal product will not prevent the product from being eligible for registration under the Herbal category, provided that the action of vitamins or minerals is supplementary to that of the herbal active ingredients regarding the specified claimed indication.

5. Herbal products containing Honey presented in pharmaceutical dosage form is eligible for registration under the herbal section.

6. Raw medicinal herbs and extracts used in pharmaceutical manufacturing or scientific research does not require registration and is granted approval by the release department.

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

2. For Electronic certificates legalisation is not required.

3. Electronic legalization is acceptable provide that an approved verification tool is available for the authenticity of legalisation.

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

2. SECTION II: HERBAL PRODUCTS

2.1 SCOPE 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 consist 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.

2.2 CLASSIFICATION OF HERBAL PRODUCTS

• Herbal Medicines (HMS)

• Traditional Herbal Medicines (THMs)

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)

1. A letter issued from the MAH explaining the relationship between the MAH and the manufacturer.

2. GMP certificate of the manufacturer / ISO.

3. Manufacturing license of the manufacturer.

1.4 DOCUMENT LEGALIZATION AND CERTIFICATION

1. Legalization of Certificates issued by Health Authorities such as the CPP, GMP Certificate, Manufacturing License, and any other certificates issued by the Health Authority in the country of origin must be Original, legalized by the Embassy or Consulate of the State of Kuwait in the country of origin.

2. In cases where this is not possible, legalization may be done by an authorized GCC Embassy or Consulate in the country of origin.

3. Other Official Documents such as the Letter of Appointment, Pricing Certificate, and similar administrative documents must be legalized by the Embassy or Consulate of the State of Kuwait in the country of origin (or an authorized GCC Embassy/Consulate if not available), and The Chamber of Commerce in the country of origin.

1.5 ELECTRONIC CERTIFICATES AND VERIFICATION

1. Valid Electronic certificates are acceptable provided that an approved verification tool is available for the authentication and verification of the electronic certificates.

- c) Identification of the active ingredients of the finished products
d) Assay in full details of the active ingredients (as the parameters stated by references)
e) Impurities
f) Microbiological tests
➤ 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 (as the parameters stated by references)
d) Impurities
e) Viscosity
f) PH
g) Water content
h) Uniformity of dosage unit
i) Microbiological tests
j) Particle size
9. For products containing substances extracted from an animal source, certificate of suitability for Transmissible Spongiform Encephalopathy (TSE)/Bovine Spongiform Encephalopathy (BSE) should be submitted.
10. 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).

8. Finished Product Specifications must include following parameters and their limits:

- Description
 - Weight content
 - Weight variation
 - Solubility in water
 - Identification of the active ingredients of the finished products
 - Assay of the active ingredients
 - Microbiological tests and impurities should be mentioned
 - ❖ N B In case the herbal active is mention in a referenced pharmacopeia the applicant are expected to follow pharmacopeial specifications. Otherwise, the same specifications mentioned above should be submitted from a non-pharmacopeial approved references for herbal product with their limits and validation.
9. Certificate of analysis of finished product of at least one batch that should be the same batch number as the sample submitted. The certificate should include all following parameters with the limits and results:
- In case of solid dosage forms: -
- a) Description
 - b) Weight content / Weight variation
 - c) Identification of the active ingredients of the finished products
 - d) Assay in full details of the active ingredients (as the parameters stated by references)
 - e) Impurities
 - f) Microbiological tests
 - g) Dissolution
- In case of liquid dosage forms: -
- a) Description
 - b) Desintegration
 - c) Identification of the active ingredients of the finished products
 - d) Assay in full details of the active ingredients (as the parameters stated by references)
 - e) Impurities
 - f) Microbiological tests
- In case of suppositories: -
- a) Description
 - b) Disintegration

- 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
- 1. Free from certificate an evidence that the product is free from any 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 batches (preferably commercial or pilot scale). The studies must include all the tests that are mentioned in the finished product specification including:
 - Long-term stability studies as per ICH guidelines over the 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. In use stability studies
- In used stability study (post container opening) if applicable
- 7. Stability Summary and Conclusions for shelf life for :
The manufacturer should define the period of time during which, after being packaged for sale, the product will maintain its purity and physical characteristics and its medicinal ingredients will maintain their quantity per dosage unit and their potency. Therefore, the MAH is responsible for the determined shelf life based on scientific data.

- 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 as per pricing decree regulation.
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

medical/therapeutic indication explaining its purpose.

3.2 REQUIREMENTS FOR THE REGISTRATION OF A HERBAL TEA

3.2.1 Regional administrative registration requirements for a herbal tea

1. Covering letter: The applicant shall include a covering letter with each submission, titled 'Registration of a Herbal tea' including:

- the herbal tea trade name
- concentration
- MAH
- manufacturing company (if different than MAH)
- a complete list of documents submitted for registration

2. Original FSC issued from the Ministry of Health or from the concerned authorized 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

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

2. Application Form: Either the standard application form or the electronic application form available through the registration portal is acceptable.

3. Letter from Marketing Authorization Holder: Confirming continuation of Agent authorization in Kuwait.

4. Valid Certificate of Pharmaceutical Product (CPP).

5. Original Legalized Price Certificate: As per pricing department requirements.

6. Summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL), and labeling, with approved revision date.

7. Proof of ongoing/ post approval stability studies.

8. Confirmation of al API & Finished Product Manufacturer(s): Including Primary, Secondary, and Batch Release sites of Kuwait with corresponding valid Kuwait manufacturing site registration certificate(s).

9. Confirmation of primary packaging material: Intended for Kuwait.

10. Updated clinical overview: Including a summary of safety data and abenefit-risk evaluation, confirming that the product's benefit-risk balance remains favourable.

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

3. 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

- 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.

➤ Non-Pharmacopeial evidence for THMS

Applicants who submit 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.

1. Covering letter: The applicant shall include a covering letter with each submission, titled 'Request for Renewal of Registration' including:

- Trade name, Generic name, Strength, Dosage form
- Manufacturer, Marketing Authorization Holder (MAH)

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 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.

➤ 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.

• If the Medicine and Medical products registration and Regulatory 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

Medicine and Medical products Registration and Regulatory 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 Medicine and Medical products Registration and Regulatory 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 LIST OF BANNED AND RESTRICTED HERBS

Manufacturers and Authorized representatives must ensure any herbal products/ herbal teas they

system

• Valid Store license issued from Pharmaceutical Inspection & Licensing Administration for the new agent.

• Valid Agency license issued from Pharmaceutical Inspection & Licensing Administration for the new agent.

• Copy of product's valid registration certificate.

• A valid Letter of appointment (LOA) for new local agent issued from the MAH or regional distributor in case the legal relation is already mentioned in the original letter of appointment. The LOA should be original and legalized by the Chamber of Commerce or the Ministry & Kuwait embassy in the country of origin.

• Termination letter for the previous local agent in Kuwait issued from the MAH or regional distributor in case the legal relation is already mentioned in the original letter of appointment, with confirmation that this termination is legally compatible to the previous signed agreement and including termination date. The termination letter should be original and legalized by the Chamber of Commerce & Kuwait embassy in the country of origin.

4.3 HERBAL PRODUCT/ HERBAL TEA SUSPENSION

Medicine and Medical products Registration and Regulatory 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.
- Non compliance to Medicine and Medical products Registration and Regulatory Administration laws and regulations.

country of origin.

• 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.

4. 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

- Covering letter requesting transfer of agency of a product/products
- Application form printed out from the MOH

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 and microbiology) mentioned in the finished product specifications, including the limits and results (if applicable).

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 Pharmacopoeia (Eur. Ph.), British Pharmacopoeia (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).

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 shall include a covering letter with each submission, titled 'Request for Renewal of Registration' including:
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:

- The date and registration number in the

(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.

Can only be sold in pharmacy

8- Poison Hemlock (Conium Maculatum)

Restrictions:
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.

Pharmacy only.

12- Colchicum Autumnale, Colchicum corn
Restrictions:
Internal use: max. dose 100 mg, max. daily dose 300 mg.

Pharmacy only.

13- Cascara sagarda or Rhamnus 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

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).

Can only be sold in a pharmacy

5- Gelsemium sempervirens, Yellow Jessamine, Gelsemium

Restrictions:

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

can only be sold in a pharmacy

6- Ipecac, Caphaelus Ipecacuanha, 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.'

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. Hausknechtii, M. Vernalis, M. neglecta, M. praecox

15- Metopium Toxicum (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- Phytigima, Calabar Bean or Ordeal Bean, Phytostigma Venenosum

22- Red yeast rice (Poisonous dye Sudan Red G)

23- Red squill or V. Maritima or squil bulb

24- South American arrow Poison or Curare, Strychnous Castelnai, S. Toxicifera, 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

30- Areca Catchu

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

1- Aconitum spp. (Aconite, Monkshood): all Aconitum species including: Aconitum napellus, Aconitum stoeckianum, Aconitum uncinatum var japonicum, Aconitum deionrhizum, Aconitum balfourii, Aconitum chasmanthum, Aconitum spicatum, Aconitum lycoctonum

Restrictions:

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 banned herbs that 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.

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

1- Aristolochia species
♦ Aristolochia Clematis
♦ Aristolochia Contorta
♦ Aristolochia Debelis
♦ Aristolochia Fang-chi
♦ Aristolochia Manshuriensis
♦ Aristolochia Serpentina

2- Amygdalin

3- Cantharides, Cantharis Vesicatoria, dried insect

4- Curare or South American arrow poison, Strychnos Castelnai, S. Toxicifera, S. Cervauxii

5- Cicuta Spp. (Water Hemlock), C. Maculata

6- Chinaberry tree, Melia Azedarach, White Cedar

7- Canada Moon seed, Menispermum canadense

8- Colocynthis, Citrullus Colocynthis

9- English Holly Ilex Aquifolium

10- Euphorbia species; Asthmaplant, Chamaesyce hirta, Euphorbia, Euphorbe, Euphorbia hirta, Euphorbia capitulata, Euphorbia pilulifera, Euphorbium Officinatum, Pillbearing Spurge, Snakeweed.

11- Jequirity (Abrus Precatorius)

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
4. Note Sn/Sc/6002 (12 Feb 2014)'
5. Mhra, Traditional Herbal Medicines Registration Scheme: Key Requirements.
6. Medicines & Health Products Regulatory Agency, Banned And Restricted Herbal Ingredients Published 18th Of December 2014
7. Saudi Food And Drug Authority 'Guidance For Products
8. Classification'
9. Saudi Food And Drug Authority 'Data Requirements For Herbal &
10. Health Products Submission'
11. Sultanate Of Oman Ministry Of Health Directorate
12. General Of Pharmaceutical Affairs And Drug Control Muscat Circular No. 28/2008 (01-03-1429) (07-4-2008).
13. Health Sciences Authority Regulatory Guidance Revised
14. August 2017 (Health Supplements Guidelines).
15. 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.
16. World Health Organization, Swiatowa Organizacja Zdrowia. Who Guidelines On Good Agricultural And Collection Practices [Gacp] For Medicinal Plants. World Health Organization; 2003 Dec 16.

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- Hyoscyamus Muticus (Egyptian Henbane), Hyoscyamus Niger (Black Henbane), Hyoscyamus Albus

Restrictions:

Internal use: max. dose 100 mg, max. daily dose 300 mg.
 Pharmacy only

Note: 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 or stated in an established scientific reference.

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)'

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

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 ethanol containing 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 ethanol containing 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 ethanol containing finished products: 24 mg;