قرار وزاري رقم (388) لسنة 2025

بشأن تنظيم تسجيل وتداول المستحضرات الصحية

وزير الصحة:

- بعد الاطلاع على أحكام المرسومين بقانون ونظام الخدمة المدنية وتعديلاتهما.
- وعلى أحكام القانون رقم 28 لسنة 1996 في شأن تنظيم مهنه 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 14 لسنه 2022 بشأن إعادة تنظيم تسجيل وتداول المستحضرات الصحية.
- وعلى القرار الوزاري رقم 53 لسنه 2021 بشأن إعادة تنظيم تسجيل وتداول المكملات الغذائية.
- 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 بشأن تنظيم إجراءات الافراج والتداول للمنتجات المستوردة الخاضعة لرقابة إدارة تسجيل ورقابة الادوية والمنتجات الطبية.
- ورغبة من الوزارة في إعادة تنظيم تسجيل وتداول المستحضرات الصحية بما يضمن سلامة تداولها.
- وبناء على مقتضيات العمل وما عرضه علينا السيد/ وكيل الوزارة.

قرر

مادة أولى

يقصد بالمصطلحات التالية المعنى المبين قرين كل من:

الوكيل المحلي: هي الشركة المحلية الممثلة للشركة صاحبة حق التسويق للمستحضرات الصحية والمرخص لها في دولة بيعها الكويت، ومسؤولة عن جميع الإجراءات القانونية المتعلقة بالمستحضر الصحي من بيع أو سحب أو إتلاف أو متابعة الأعراض الجانبية وخلافه داخل دولة الكويت.

المكتب العلمي: هو المركز الصيدلي الذي يقوم بتمثيل الشركة صاحبة حق التسويق في دولة الكويت ومسئول عن المعلومات والإجراءات العلمية والفنية والتسويقية للمستحضرات الصحية.

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

الشركة المصنعة: هي المنشأة التي يتم فيها تصنيع المستحضر الصحي وفقاً لأسس التصنيع الجيد، أو مطابقة المعايير الدولية للجودة (ISO).

الشركة صاحبة حق التسويق: هي الشركة التي تحمل ترخيص المستحضر الصحي وتتولى تسويقه سواء كانت الشركة المصنعة أو المتعهدة بالتسويق، وتكون مسؤولة مسؤولية كاملة عن جودة المستحضر الصحي ومأمونيته وفعاليته ومتابعته بعد التسويق وجميع الإجراءات القانونية المتعلقة بالمستحضر الصحي من بيع، أو سحب، أو إتلاف، أو متابعة الأعراض الجانبية وخلافه في جميع الدول التي يسوق فيها المستحضر.

بلد المنشأ: هي بلد الشركة المصنعة أو صاحبة حق التسويق الذي تصدر سلطاته الرقابية شهادة المستحضر الصحي.

شهادة حرية التداول المستحضر الصحي: شهادة صادرة من السلطة الرقابية المختصة بالدولة صاحبة حق التسويق أو الدولة التي يتم فيها التصنيع كاملاً أو جزء من تصنيع المستحضر الصحي.

السلطات الرقابية المرجعية: تشمل السلطات الرقابية العالمية الصارمة مثل: إدارة الغذاء والدواء الأمريكية (US FDA)، الإتحاد الأوروبي (EU)، 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).

المستحضر الصحي: مستحضر مصنع في شكل صيدلاني يستخدم بهدف الحفاظ على الصحة أو تعزيزها عن طريق تعديل الوظائف الفسيولوجية في جسم الإنسان من خلال تأثيرات دوائية أو مناعية أو أيضية ، ويحتوي على مكونات غير دوائية.

تصنف المستحضرات الصحية إلى الفئات التالية:

1. المكملات الغذائية.
2. المكملات الصحية الداعمة.
3. منتجات العناية الصحية الموضعية.
4. منتجات صحة الجهاز الهضمي.
5. مطهرات ومعقمات الجلد والمستحضرات المضادة للميكروبات.
6. العلاجات البديلة.
7. منتجات صحة الأنف والبلعوم.
8. منتجات صحية متنوعة.

مادة ثانية

تخضع للتسجيل جميع المستحضرات الصحية المراد تسويقها في دولة الكويت وفقاً لهذا القرار.

مادة ثالثة

يشترط لتسجيل المستحضرات الصحية تقديم الممثل المعتمد للشركة صاحبة حق التسويق طلب تسجيل موجه إلى إدارة تسجيل ورقابة الأدوية والمنتجات الطبية طبقاً للشروط والمتطلبات التالية:

5. المتطلبات الخاصة بالوكيل المحلي:

1.1 ترخيص مزاولة نشاط استيراد الأدوية والمستلزمات الطبية أو ما يعادله صادر من وزارة التجارة والصناعة.

1.2 ترخيص الشركة لإستيراد الأدوية والمستلزمات الطبية صادر من وزارة الصحة.

1.3 ترخيص مستودع صادر من وزارة الصحة.

1.4 تفويض توقيع ممثلي الشركة صادر من غرفة التجارة والصناعة.

1.5 صور عن البطاقة المدنية لممثلي الشركة.

6. 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 لممثلي الشركة.

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

3.1 خطاب الوكالة يوضح العلاقة التجارية بين الوكيل المحلي والشركة صاحبة حق التسويق، أو الموزع المعتمد إن وجد من تأكيد الشركة المالكة لحقوق التسويق على العلاقة بينها وبين الموزع المعتمد[1].

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

3.3 شهادة ترخيص الشركة المصنعة صادرة من السلطات الصحية أو الرقابية في بلد المنشأ[1].

3.4 شهادة تطبيق أسس التصنيع الجيد للشركة المصنعة صادرة من السلطات الصحية أو الرقابية في بلد المنشأ أو شهادة مطابقة المعايير الدولية للجودة (ISO) ذات الصلة بتصنيع المنتج[1].

3.5 تقديم ملف تسجيل لمستحضر صحي واحد أو أكثر.

3.6 طرق التواصل مع الشركة يشمل أرقام الهواتف والبريد الإلكتروني أو طرق تواصل أخرى.

● [1]يتوجب تقديم أصول هذه الشهادات وتصديقها كما هو موضح في المادة الرابعة من هذا القرار.

* ملاحظة: يحق لإدارة تسجيل ورقابة الأدوية والمنتجات الطبية القيام بزيارة الشركة المصنعة للتأكد من تطبيق أسس التصنيع الجيد متى ما ارتأت ذلك، وفقاً للشروط والضوابط المعتمدة.

8. المتطلبات الخاصة بتسجيل المستحضرات الصحية:

4.1 يشترط أن يكون المستحضر الصحي المقدم للتسجيل مسجل ومسوق في بلد المنشأ، وفي حال عدم تسويقه يتم توضيح الأسباب، ومن ثم تدرس من قبل إدارة تسجيل ورقابة الأدوية والمنتجات الطبية للموافقة أو رفض طلب التسجيل.

4.2 يتضمن ملحق القرار باللغة الإنجليزية كامل المتطلبات والشروط التي يجب توافرها في ملف تسجيل المستحضر الصحي.

مادة رابعة

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

4. 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.

5. يتوجب تصديق شهادة الوكالة بين الوكيل المحلي والشركة صاحبة حق التسويق للمستحضرات الصحية 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 خامسة

الاشتراطات التنظيمية للمستحضرات الصحية:

1. عدم إحتوائه على أي مواد فعالة غير معلن عنها على عبوة المستحضر.

2. عدم إحتوائه على مواد لها خصائص دوائية مثبتة في علاج بعض الامراض وتصنف كدواء طبي.

3. عدم إحتوائه على أي من المواد أو الأعشاب المخدرة أو السامة المحظور تداولها وفقاً للقرارات الوزارية المنظمة لذلك والمدرجة في مواد القانون رقم 159 لسنة 2025 في شأن مكافحة المخدرات والمؤثرات العقلية وتنظيم استعمالها والإتجار فيها.

4. عدم إحتوائه على أي مادة تؤثر بالسلب على صحة الإنسان.

5. عدم إحتوائه على أي مكونات ومشتقات من الخنزير.

6. عدم إحتوائه على معدلات مستقبلات الأندروجين الإنتقائية Selective Androgen Receptors Modulators (SARMs)).

مادة سادسة

يحق لإدارة تسجيل ورقابة الأدوية والمنتجات الطبية طلب أي مستندات أو دراسات إضافية أو طلب عينات لإجراء تحاليل مخبرية في إدارة فحص الأدوية والمنتجات الطبية أثناء أو بعد عملية التسجيل وعلى الشركة الإلتزام بذلك.

مادة سابعة

يجب على الشركة صاحبة حق التسويق/ الشركة المصنعة إخطار إدارة تسجيل ورقابة الأدوية والمنتجات الطبية بأي تغيير أو تعديل يطرأ على المنتج على ألا يتم تطبيق هذا التغيير داخل دولة الكويت إلا بعد الحصول على موافقة الإدارة على ذلك، وإلا سيتم اتخاذ الإجراءات القانونية اللازمة.

مادة ثامنة

صلاحية شهادة تسجيل المستحضر الصحي خمس سنوات من تاريخ الإصدار.

مادة تاسعة

للمستحضرات المصنعة محلياً أو حق تسويقها مملوك لصالح شركة محلية فإن إصدار شهادات المستحضر الصحي وشهادة تسجيل الشركة المصنعة أو صاحبة حق التسويق وشهادة أسس التصنيع الجيد وغيرها من الشهادات المتعلقة بالمستحضر الصحي من إختصاص إدارة تسجيل ورقابة الأدوية والمنتجات الطبية.

مادة عاشرة

يجب إعادة تجديد تسجيل المستحضر الصحي والشركة المصنعة، على أن يقدم طالب التجديد المستندات المطلوبة من قبل الإدارة قبل ستة أشهر من إنتهاء مدة صلاحية شهادة التسجيل.

مادة حادية عشر

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

4. شهادة الوكالة صادرة من الشركة صاحبة حق التسويق (أو الموزع المعتمد مع تقديم الشركة صاحبة حق التسويق ما يثبت وجود علاقة تجارية سارية مع

الموزع المعتمد) بتعيين وكيل محلي جديد لها مرخص من قبل وزارة التجارة و وزارة الصحة[1].

5. شهادة إلغاء الوكالة الممنوحة للوكيل السابق من الشركة صاحبة حق التسويق (أو الموزع المعتمد مع تقديم الشركة صاحبة حق التسويق ما يثبت وجود علاقة تجارية سارية مع الموزع المعتمد) موضحاً بها تاريخ إلغاء الوكالة[1]

6. قائمة بالمستحضرات الخاضعة لنقل الوكالة صادرة من الشركة صاحبة حق التسويق موضحاً فيها الاسم التجاري للمستحضر، التركيز، الشكل الصيدلاني، والشركة المصنعة.

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

مادة ثانية عشر

يجب على مقدم طلب التسجيل (الممثل المعتمد) إبلاغ إدارة تسجيل ورقابة الأدوية والمنتجات الطبية بوزارة الصحة في حالة صدور أي تحذير من أي من الجهات الرقابية الدولية بشأن سلامة ومأمونية استخدام المستحضر الصحي.

مادة ثالثة عشر

يحق لإدارة تسجيل ورقابة الأدوية والمنتجات الطبية تعليق تسجيل أي مستحضر صحي أو شركة مالكة لحق التسويق/ الشركة المصنعة إذا ثبت للإدارة ما يلي:

8. إذا صدر قرار بتعليق أو حظر المستحضر أو الشركة من قبل السلطات الرقابية في بلد المنشأ.

9. إذا ثبت عدم فعالية ومأمونية استخدام المستحضر الصحي.

10. إذا ثبت التلاعب في المستندات المقدمة لإدارة تسجيل ورقابة الأدوية والمنتجات الطبية.

11. إذا ثبت مخالفة الشركة لنظم ولوائح إدارة تسجيل ورقابة الأدوية والمنتجات الطبية.

12. إذا ثبت عدم استمرار الشركة باتباع أسس التصنيع الجيد أو أسس مطابقة معايير الدولية للجودة ISO)).

13. تكرار عدم إجتياز المستحضر للتحليل لدى مختبرات إدارة فحص الأدوية والمنتجات الطبية بحد اقصى 5 مرات.

14. في حال عدم إبلاغ الوكيل المحلي لإدارة تسجيل ورقابة الأدوية والمنتجات الطبية عن صدور أي تحذيرات تتعلق بالمستحضر الصحي أو الشركة من الهيئة الصحية المعتمدة.

مادة رابعة عشر

يحق لإدارة تسجيل ورقابة الأدوية والمنتجات الطبية إلغاء تسجيل أي مستحضر صحي أو شركة مالكة لحق التسويق/ الشركة المصنعة وذلك إذا ثبت للإدارة ما يلي:

1. إذا تم إلغاء تسجيل المستحضر أو الشركة في بلد المنشأ.

2. عدم مطابقة المستحضر للمواصفات الفنية المعتمدة بملف التسجيل لدى الإدارة.

3. بناءً على طلب الشركة صاحبة حق التسويق مع ذكر الأسباب.

4. إذا ثبت عدم فعالية وأمان استخدام المستحضر الصحي.

5. عدم تجديد التسجيل في الفترة المحددة.

6. إذا ثبت التزوير في المستندات المقدمة لإدارة تسجيل ورقابة الأدوية والمنتجات الطبية.

7. إذا مضت سنتين من دون استيراد المستحضر الصحي إلى دولة الكويت.

8. عدم تقديم الشركة المبررات والمستندات الداعمة لإلغاء تعليق المستحضر خلال ست شهور من التعليق.

9. إذا ثبت احتواء المنتج على مادة فعالة غير معلن عنها.

10. تكرار عدم اجتياز المستحضر للتحليل لدى مختبرات إدارة تسجيل ورقابة الأدوية والمنتجات الطبية.

مادة خامسة عشر

يحق لإدارة تسجيل ورقابة الأدوية والمنتجات الطبية رفض تسجيل أي مستحضر أو شركة دوائية مع ذكر الأسباب التي أدت إلى رفض طلب التسجيل.

مادة سادسة عشر

يحق للوكيل المحلي الإعتراض على قرار الإدارة في رفض التسجيل أو تعليق التسجيل أو إلغائه خلال مدة أقصاها 90 يوماً من تاريخ صدور القرار، وعليه يعتبر القرار نهائياً بعد تقديم الرد بناءً على دراسة الاعتراض.

مادة سابعة عشر: يحق لإدارة تسجيل ورقابة الأدوية والمنتجات الطبية في حال عدم التزام الشركة بتوريد المستحضر الصحي أو عدم الإلتزام بالشروط والضوابط المذكورة في هذا القرار إلغاء المستحضر الصحي أو الموافقة على تعيين وكيل محلي آخر في دولة الكويت.

مادة ثامنة عشر

يخضع الإفراج عن المستحضرات الصحية والسماح بتداولها للقرارات الوزارية المنظمة لذلك.

مادة تاسعة عشر

لا يتم الإعلان عن المستحضرات الصحية إلا بعد الحصول على الموافقات الخاصة من الإدارة المعنية في وزارة الصحة.

مادة عشرون

تسجيل المستحضرات الصحية يخضع للرسوم المقررة في القرار الوزاري المنظم لأسعار وأجور الخدمات الصحية.

مادة حادية وعشرون

يُبلغ هذا القرار من يلزم لتنفيذه، ويعمل به اعتباراً من تاريخه ويلغى كل قرار أو نص يتعارض مع أحكام هذا القرار وينشر في الجريدة الرسمية.

وزير الصحة

د. أحمد عبد الوهاب العوضي

صدر في: 10 رجب 1447هـ

الموافق : 30 ديسمبر 2025م

STATE OF KUWAIT
MINISTRY OF HEALTH
Medicines & Medical Products Registration& Regulatory Administration
MINISTERIAL DECREE FOR REGISTRATION OF HEALTH PRODUCTS
ملحق القرار الوزاري رقم (388) لسنة 2025 بشأن تسجيل وتداول المستحضرات الصحية
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authority issues the certificate of Pharmaceutical Product (CPP) or Free Sale Certificate (FSC).
Contract Manufacturer: A manufacturing entity that produces products or components for another company predesigned specification by contract for the purpose of partial or full manufacturing.
Distributor: A company in the supply chain, other than the manufacturer, marketing authorization holder, or the agent who makes a health product available within the defined geographic region.
Good Manufacturing Practice (GMP): A system of quality assurance that ensures medicinal products are consistently produced and controlled according to quality standards appropriate for their intended use, as required by the marketing authorization and relevant regulatory guidelines. GMP compliance is mandatory for all manufacturers of medicinal products and is verified through regular inspections by competent authorities.
Gulf Health Council (GHC): The Gulf Health Council (GHC) is a specialized health organization established under the umbrella of the Gulf Cooperation Council (GCC). It operates as a regional regulatory and coordination body for health-related initiatives among member states, which include Saudi Arabia, Kuwait, the United Arab Emirates, Qatar, Bahrain, and Oman.
Label: Any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed or impressed on, or attached to the container of health product.
Local Manufacturer: A manufacturer which is licensed by relevant authorities in Kuwait & the Ministry of Health for manufacturing of health products in state of Kuwait.
Marketing Authorization Holder (License Holder): A marketing Authorization Holder (MAH) is a legal entity that holds the marketing authorization for a health product, granting its right to place the product in the market and assume full responsibility for its safety, quality, and efficiency thought its lifecycle.
Manufacturer: is responsible for the operations involved in the manufacturing, quality control, batch release, and packaging of a health product.
Ministry of Health (MOH) – Kuwait: The Ministry of Health is the central governmental authority responsible for regulating,

INTRODUCTION

1.1. Objectives

Based on the updated International Health Authorities & GCC recommendations, this guideline offers comprehensive description of various categories of health products, along with revised definitions and classification rules.
Additionally, it provides detailed instructions for the required documents for registration and other regulatory processes that control regulation of health products in Medicine & Medical Products Registration & Regulatory Administration.

1.2. Background

Medicine & Medical Products Registration & Regulatory Administration will apply an updated scientific approach on health products regulations taking into consideration the product's category, quality, safety and efficacy.

1.3. Scope

This guideline updated the health products definitions, set up new standards for classification of all categories with clear description of steps and related requirements for regulation of health products.

1.4. Related guidelines

- Pharmaceutical Products Registration Guidelines
- Herbal Products Registration Guidelines
- Cosmetic Products Registration Guidelines

2. TERMS AND DEFINITIONS:

Authorized Representative in Kuwait: Also referred to as 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 for all matters related to registration importation, pricing, post-marketing surveillance, and communication of health products.
Claim: Any message or representation, including pictorial, graphic or symbolic representation, in any form, which states, suggests or implies that a product has particular characteristics & indication.
Country of Origin: The country of the manufacturing company or marketing authorization holder, where the regulatory

3.4. General Principles and Specific Rules for Claims:
Claims submitted to the Medicine & Medical Products Registration & Regulatory Administration should follow a strict set of general principles and specific rules based on the product sought to be claimed

3.4.1. General Principles

3.4.1.1. Truthfulness
Claims should state the truth about the product. There should be no overstatement, ambiguity, or deception.

3.4.1.2. Evidential Support
All claims should be supported by evidence relevant to the claims, which should come from approved resources. This includes references such as scientific organizations, well established regulatory authorities. The evidence of the product might be based on its ingredients or the overall finished productor as requested by Medicine & Medical Products Registration & Regulatory Administration.

3.4.1.3. Language
Claims should be written in English (and Arabic if available). Moreover, claims should not be confusing, and in alliance with Medicine & Medical Products Registration & Regulatory Administration rules and regulation of required labelling information.
Claims on the label must have the same meaning in all languages.

3.4.1.4. Legal Compliance
Claims must comply with all laws within the GCC members states, and do not conflict with Islamic values or habits of society.

3.4.2. Specific Rules for Claims:
All health products should have certain requirement for their claims depending on the nature of the product.

3.4.2.1. Unacceptable claims can be:
- Claims that refer to specific percentage or amount of weight loss.
- Claims that refer to recommendations by individual doctors or health professionals.
- Claims that suggest that health could be affected by not consuming this dietary supplements.
- Claims implying that a regular or balanced diet foods cannot supply adequate amounts of nutrients.
- Claims, which cannot be proven by scientific evidence.
- Meaningless claims, including incomplete comparatives and superlatives.
- Claims cannot state that a product does not have any side effects. Therefore, a term such as "100% safe" is not permitted. The fact that a product is natural should not suggest that is 100% safe.

4. CATEGORIES AND TYPES OF HEALTH PRODUCTS:
Health products can be one of the following types of products as indicated in the diagram and table below.

planning, and overseeing healthcare services in the State of Kuwait.
Stringent Regulatory Authority (SRA): SRAs include USFDA, EMA, Health Canada, MHRA, PMDA, Swiss medic, TGA.

3. HEALTH PRODUCTS DEFINITIONS & CHARACTARISTICS

3.1. Definition:
Health product can be defined as a finished labelled product in pharmaceutical dosage form, that contains low risk ingredients and has indications such as health maintenance, health enhancement and/or modifying physiological functions by exerting pharmacological, immunological or metabolic actions.

3.2. Ingredients
Health product can include one or more of the following natural ingredients:
1. Vitamins
2. Synthetic duplicate of Vitamins
3. Minerals
4. Amino acids
5. Essential Fatty Acids
6. Plant and plants materials
7. Probiotics
8. Extracts
9. Isolates
10. Algae
11. Fungi
12. Animal material (with certain specifications and special requirements)
13. Human origin materials (can be accepted in topical preparation under certain conditions and special requirements)
14. Health products should be completely free from the following types of ingredients:
- Medicinal Ingredients: Health Products must not contain any active pharmaceutical ingredients (APIs) or exceed the established concentration thresholds that would reclassify the product as a therapeutic drug.
- Ingredient Declaration: Formulations must be free from any undeclared medicinal or biologically active substances.
- Controlled Substances: Inclusion of any prohibited narcotics or toxic substances as defined by applicable Ministerial Decrees or regulatory circulars is strictly forbidden.
- SARMS: The inclusion or marketing of Selective Androgen Receptor Modulators (SARMS) is prohibited.
- Safety Profile: Ingredients must not pose a known risk of adverse physiological effects under intended conditions of use.

3.3. Accepted Health Products claims
Health product claims can be divided into two risk levels:

3.3.1. Low Level Claims:
- Health maintenance, including nutritional supplement vitamin or mineral supplement.
- Health enhancement

3.3.2. Medium Level Claims:
- Helps in the reduction of risk or diseases or disorder
- Assist in management of a named symptom/ diseases or disorder
- Relief of symptoms of a named diseases or disorder

[UL]) or less than the (Lower Limit [LL]). Both Upper and Lower limit of vitamins and minerals will be calculated based on the daily dose mentioned in the product label. The derivatives of vitamins and minerals salts are subjected to the rules mentioned above as per Annex I

- The word (Multivitamins) is allowed to be printed on the product if it contains three (elements) of vitamins.
- The word (Multimineral) is allowed to be printed on the product if it contains three (elements) of minerals.
- The words (Multivitamins/Multimineral) are allowed to be printed on the product if it contains three (elements) of vitamins and three (elements) of minerals.

4.2. Supportive Health Supplements

Are specially designed food supplements which contain one or more of the ingredients in a concentration exceeds the maximum upper limits as mentioned in Annex I of low toxicity ingredients to achieve a medical indication.

On the other hand, products with therapeutic medical claims AND/OR ingredients above the max dosage values for vitamins and minerals, reaching a therapeutic limit will be classified as Pharmaceutical Medicines.

4.3. Herbal Supplements:

Some herbal products can be classified as health products if:

- They contain medicinal herbs that are not in its natural form and have gone through any manufacturing process.
- A synergetic blend of botanical extracts mixed with naturally derived active ingredients– including vitamins, minerals and bee products as primary active ingredients and the functional drivers of the medical indication.
- Aromatic and medicated herbal oils that contain one or more of oils that are extracted from medicated plants that have non nutritional claims and used internally.

4.4. Workout Supplements/Athletic Supports:

A group of food supplements intended for sports persons who exercise to achieve specific nutritional or functional support. To be classified as health products they should:

1. Formulated in a pharmaceutical dosage form (e.g. capsules, tablets, etc.) that aren't typical of foods
2. Must carry directions for use
3. Requires a recommended dose
4. The labels include product facts table which includes the active ingredients, uses, warnings and directions for use.
5. Composed of one or more of the following ingredients groups:

- Whey proteins/proteins
- Amino Acids (Essential amino acids /non-essential amino acids)
- Carbohydrates
- Non medicinal, legal ergogenic agents (non-caffeinated ergogenic agents / caffeine)
- Vitamins and Minerals
- Complementary ingredients

For all the aforementioned categories, in parts (4.1, 4.2, 4.3., 4.4.) the acceptable pharmaceutical dosage forms include, but are not limited to capsules, pastilles, gummies, tablets, pills and other similar forms, oral dispensing films/sheets/strips, sachets of

Health Products	
1. Food Supplements	- Vitamins/Minerals/Amino Acids - Herbal Supplements - Oral Fixed Oils e.g., Fish Oil - Mushrooms - Cognitive Function Supplements - Joint Health Supplements - Cardiovascular Support Supplements - Male/Female Health Supplements - Weight Management Supplements - Gastrointestinal Health Supplements - Urinary Tract health Supplements - Respiratory Health Supplements - Antioxidants & Immunity Support Supplements - Melatonin/DHEA (Dehydroepiandrosterone) Supplements - Workout & Athletic Supplements
2. Supportive Health Supplements	Food supplements with one or more ingredients in concentration exceed the maximum upper limits. (as stated in Annex I)
3. Topical Healthcare Products (THCP)	- Skin Care Products - Oral Care Products - Hair/Nail Care Products - Intimate Care Products - Body Care Products
4. Gastro-Intestinal Health Products	- Non-Medicinal Laxatives - Hemorrhoids Relief/Health Products - Charcoal
5. Antiseptics/Biocidal Products	- First-Aid Antiseptic - Medicated Skin Cleansers/Sanitizers - Surgical applicators/wipes
6. Alternative Therapies	- Aromatherapy - Homeopathy - Others
7.Nasopharyngeal Health Products	- Nasal Care Health Products - Mouth &Throat Care Health Products - Ear Care Health Products - Medicated Vapors/Balms
8.Miscellaneous Health Products	- Insect repellents that are in direct contact with human skin - Oral Rehydration Salts (ORS) - Pharmacopeial preparations - Counter irritants

N.B.: Products that act by physical or mechanical means can be classified as medical devices as per Medicine & Medical Products Registration & Regulatory Administration evaluation.

4.1. Food Supplement:

Are defined as concentrated sources of nutrients or other substances with a nutritional or physiological effect intended to supplement the diet and contains one or more of vitamins/ minerals/ amino acids/ essential oils, natural substances of plant or animal origin, probiotics, prebiotics, enzymes, substances with nutritional or physiological function or contains any combination of any of these.

The product is subjected to be a food supplement if:

- It contains one or more from either vitamins or minerals or both, and this/those elements do not exceed the (Upper Limit

4.5.3.2. Oral Care Products

Oral care products are classified as THCP if the primary intended purpose is a symptomatic/adjuvant therapies by significantly modifying the physiological function in the following diseases or disorders:

- Mouth ulcers, sore gums, periodontal conditions such as gingivitis, dry mouth (xerostomia) or any references to gums and teeth diseases.
- Mouthwashes and dental gels with primary "antimicrobial, antibacterial or antiviral claims intended for the treatment or prevention of infections, inflammation or other oral cavity diseases.
- Products which, according to their presentation, are defined to be used to detect plaque on teeth.

4.5.3.3. Hair/Nail Care Products

Hair/Nail care products are classified as THCP if the primary intended purpose is a symptomatic/adjuvant therapies by significantly modifying the physiological function in the following diseases or disorders:

- Products which are indicated for hair & eyelash/eyebrow re-grow.
- products claiming to treat or prevent alopecia.
- Anti- dandruff products which contain non-medicinal ingredients with anti-fungal activity or other significant physiological effects.
- Products indicated for treatment or prevention of head lice infestation irrespective of their composition.
- Nail care products which according to their overall characteristics are indicated for fungal nail infections (with non-medicinal ingredients/concentrations)
- Product intended exclusively or mainly for the prevention of nail biting.

4.5.3.4. Body Care Products:

Body care products are classified as THCP if the primary intended purpose is a symptomatic/adjuvant therapies by significantly modifying the physiological function in the following diseases or disorders:

- Product which reduces cellulite with a significant modification of the body's physiological function by exerting pharmacological, immunological or metabolic actions.
- Products to relieve tired swollen and heavy legs by significantly modifying the physiological function.
- Topical breast augmentation products achieving their objective through the action of hormones or hormone-like substances (e.g. phytoestrogens).They therefore significantly "restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action.
- Antiperspirants intended for excessive sweating, hyperhidrosis or any references to perspiration from hormonal/endocrine changes/malfunction.
- A product which is only aimed to help the act of massage by acting on muscles through a significant modification of the body's physiological function.

4.5.3.5. Intimate Care Products

powder or granules, ampoules of liquids, drop-dispensing bottles, and other forms designed to be taken in measured units.

Note: The inclusion or marketing of selective androgen receptor modulators (SARMs) is prohibited.

4.5. Topical Healthcare Products (THCP)

4.5.1. Definition

Topical preparations combine both cosmetic and pharmaceutical properties, in which the primary intended purpose is not the cosmetic functions. They contain nonmedicinal ingredients (cosmeceutical ingredients) in non-medicinal concentration and are indicated for:

1. Health maintenance, health enhancement and/or modifying physiological functions by exerting pharmacological, immunological or metabolic actions.
2. Claim to significantly change an underlying physiological process to achieve a different appearance.
3. Assist in management, or relief of, symptoms of a named diseases or disorder by non-cosmetic function.

The field of application of cosmetics:

- The skin (epidermis)
- The hair system
- The nails
- The lips
- The genital organs
- The teeth and mucous membrane of the oral cavity

4.5.2. Dosage Forms

Acceptable dosage forms include but are not limited: creams, ointments, balms, gels, lotions, soap, shampoos, mouth washes, toothpaste, washes, topical spray, serum or wipes.

4.5.3. Sub-Categories

4.5.3.1. Skin Care Products:

Skin Care products are classified as THCP if the primary intended purpose is a symptomatic/adjuvant therapies by significantly modifying the physiological function in the following skin diseases or disorders:

- Rashes, hives, rosacea, atopic dermatitis, psoriasis, pruritus, melisma, post inflammatory hyperpigmentation, insect bites, burns, sun burns, cuts, scrapes, cradle scalps, therapeutic emollient for medical conditions, pain, inflammation, or refer to any other skin disease or disorder.
- Products for diaper rash treatment.
- Products intended to simulate wound healing, scars, warts, corns, etc.
- Products that are presented, either explicitly or implicitly, for use in the prevention or treatment of acne (e.g. Acne vulgaris) or other inflammatory lesions of the skin (such as papules and pustules)
- Primary and secondary sunscreens with medical claims such as reduction of skin cancer or solar keratosis or refer to altering in a physiological function or exerting pharmacological, immunological or metabolic actions.
- Skin-whitening lotions that contain ingredients such as hydroquinone (not more than 2%) or other non-medicinal, known to inhibit the physiological process of melanin production.

Intimate care products are classified as THCP if the primary intended purpose is a symptomatic/adjuvant therapies by significantly modifying the physiological function in the following diseases or disorders:

- Products for internal vaginal use
- Male genital desensitizers (for delay claims)
- Male/Female Lubricants
- Products which, according to their presentation, are intended to stimulate sexual activity with scientifically represented sexual claims that do not conflict with moral principal of society.
- Intimate care products with a germicidal claim.
- Intimate care products that contain substances with direct physiological effects such as povidone-iodine.

4.5.3.6. Mesoceuticals

Products used with invasive devices/ techniques to enable superficial penetration of the product in the epidermis, or which delivered through iontophoresis or similar mechanisms with medical indication or reference to significantly modifying physiological functions by exerting pharmacological, immunological or metabolic actions.

Please refer to Annex III in EU Cosmetic Regulation EC 1223/2009 for prohibited & Annex IV-VI for colors, preservatives, UV filters in EU Cosmetic Regulation EC 1223/2009 and its updates.

4.6. Gastro-Intestinal Health Products

- Charcoal
- Non-Medicinal Laxatives
- Haemorrhoids relief health products: products that can temporarily soothe pain and reduce swelling. It contains natural active ingredients in which the primary mode of action is not by physical or mechanical means. Dosage form can be creams, ointments, gel, or suppository.

4.7. Antiseptics/Biocidal Products:

These products are defined as preparations for external use intended for local application on human body to eradicate microbial contamination by antiviral, antibacterial or antiseptic activity and its repeated use does not cause a change or damage to the body tissue.

- First-Aid Antiseptic: Used to help prevent infection in minor wounds, cuts and scratches.
- Medicated Skin Cleansers/Sanitizers: intended as personal hand hygiene.
- Surgical applicators and wipes that act as skin disinfectant before surgery.

Accepted dosage form can be wipes, sponges, brush, soap solutions, gels, foam, ointment spray, applicators, etc.

4.8. Alternative Therapies

Other types of health products categorised in accordance with internationally recognised monographs or the standards of relevant regulatory authorities.

4.8.1. Aromatherapy

Aromatherapy is the therapeutic use of plant derived aromatic essential oils to promote physical and psychological wellbeing. It is sometimes used in combination with massage and other therapeutic techniques as part of a holistic treatment approach.

Aromatherapy is classified as health products if they have a medical claim or refer to any disease /disorder.

4.8.2. Homeopathy

Homeopathy is a complementary alternative medical practice based on the use of highly diluted substances, which practitioners claim can cause the body to heal itself.

Homeopathic therapies or their stocks/mother tinctures are prepared from natural or synthetic sources that are referenced in pharmacopeial monographs or other recognized documents from international authorities.

4.9. Nasopharyngeal Health Products

Pharmaceutical preparations that contain natural active ingredients and achieve its primary intended purpose by pharmacological, immunological, and/or metabolic means and not by the physical or mechanical means.

4.9.1. Nasal Care Health Products

Spray, drops, wash, gel or strips that can provide relief from nasal congestion, soothing for dry irritated nose, cleansing etc.

4.9.2. Mouth &Throat Care Health Products

Mouth, throat spray and lozenges indicated for temporary relief of sore throat, lubricate or soothe irritated tissues of the throat.

Throat lozenges which consist only of volatile oils, ascorbic acid (or its salts) and at least menthol with acceptable medical claim.

4.9.3. Ear Care Health Products

Soothing ear drops, cleaning, dissolving ear wax or helping to reduce ear pain.

4.9.4. Medicated Vapours/Balms

Topical products for inhalation which provide soothing vapours that helps to relieve mild nasal congestion, headache and cough associated with common cold.

4.10. Miscellaneous Health Products

4.10.1. Insect Repellents:

Products that are in direct contact with human skin which contains (non-medicinal) ingredients for the purpose of insect repellent.

4.10.2. Oral Rehydration Salts (ORS):

Oral Rehydration Solution (ORS) is a fluid used to enhance the absorption of fluid and electrolytes in the intestines, commonly used to treat dehydration and improve hydration in patients.

4.10.3. Pharmacopeial Preparations:

Pharmacopeial Grade Finished Products (FGFP): Products which are manufactured according to the requirements of the main Pharmacopeia used in the pharmaceutical industry, like the European Pharmacopeia (Ph. Eur.), the United States Pharmacopeia (USP) and the British Pharmacopoeia (BP), etc. These products are strictly controlled according to the methods and specifications defined in these Pharmacopoeias, have medical claims, instructions for use and all other required label information.

Raw Materials for Pharmaceutical Preparation (RMFPP): Raw materials which are used for pharmaceutical preparations in pharmacy or health institute.

4.10.4. Counter irritants:

Topical patches, creams, ointments and gels containing counter irritant ingredient as an externally applied substance that causes

irritation or mild inflammation of the skin for the temporary relieve of pain in muscles or joints by reducing inflammation in deeper adjacent structure.

5. PRODUCTS CLASSIFICATION & RE-CLASSIFICATION

Products which are not categorized in this document, should be submitted for assessment by the classification committee in the Medicine & Medical Products Registration & Regulatory Administration to identify its category or classification. The committee will take decision based on this guideline as well as the international practices and scientific references.

Registered products can be re-classified according to the updated guidelines or committee decisions. In such cases, Medicine & Medical Products Registration & Regulatory Administration will enable a transition state for valid registration certificate to keep the continues supply, avoid sudden changes in the market and protecting business. Local agents and their principal companies will be given a grace period (the time of validity of the registration certificate) to re-register their products in the new section or department. Local agents are responsible for completing this process before the expiry of their registration to avoid stopping of their shipments or else if requested by Medicine & Medical Products Registration & Regulatory Administration.

6. HEALTH PRODUCTS LICENSING AND REGULATIONS PROCEDURE

6.1. Types Of A Health Product's Applications:

- Application for new registration.
- Application for variation during valid registration
- Application for agency transfer
- Application of registration renewal
- Others

Authorized representative should prepare an application including all required documents according to the type of application that meet these guidelines requirement, except for the local manufacturing sites application where the differences in their application are clarified in (Annex II).

6.2. Document Legalization and Certification

Legalization of Certificates issued by regulatory 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.

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

Other Official Documents such as the Letter of Appointment, 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.

6.3. Electronic Certificates and Verification

Valid electronic certificates are acceptable provided that an approved electronic verification tool is available for the authentication and verification of the electronic certificates. In such case paper legalisation is not required.

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

6.4. Assessment & Queries

Each application is assessed by Health Products Regulatory Affairs in accordance with Medicine & Medical Products Registration & Regulatory Administration standard operating procedures.

Where queries arise, a request for further information will be issued to the applicant to respond to such queries. The resolution of queries will be managed by the Health Products Regulatory Affairs and the absence of any response within the defined period will result in rejection of the application and will require resubmission.

6.5. Responsibilities of MAH and Authorized Representative

MAHs must be represented by a local Health Products company, referred to as the Authorised Representative (Local Agent or scientific office or their local approved affiliates.)

Authorized representative is responsible for submitting the necessary documents, as specified in this guideline to complete the registration process for the health product.

6.6. Authorized Representative Registration

If the authorised representative is a new local pharmaceutical company, the following must be submitted:

- Valid license issued by the Ministry of Commerce in which the company activity includes the sale of medicines.
- Valid agency license issued by MOH (Pharmaceutical Inspection & Licensing Administration).
- Valid store license issued by MOH (Pharmaceutical Inspection & Licensing Administration).
- Copy of authorized signatories from public authority of manpower.
- Copy of authorized personal legalized from Kuwait chamber of commerce
- Any other documents set by the administration in accordance with other MD's or memos issued.

6.7. Licensing

6.7.1. Validity of Certificate

Registration & renewal certificate valid for 5 years, or other letter will be issued after approval from Medicine & Medical Products Registration & Regulatory Administration.

6.7.2. Place of Sale

Medicine & Medical Products Registration & Regulatory Administration shall designate the authorized distribution channels and points of sale for each health product, subject to an evaluation of its category, active ingredients, target demographic, and the clinical risk profile associated with the medical indication.

7. DOCUMENTATIONS AND REQUIREMENTS

7.1. Documents Required for New Registration:

7.1.1. Administrative Documents

7.1.1.0. Covering letter

The applicant shall include a signed and stamped covering letter for each submission on a letterhead from the local agent. The

content of the cover letter should clearly represent the type of application, the name of the product and list the submitted file documents.

7.1.1.1. Application Form

Application form should be filled under the complete responsibility of the Marketing Authorization Holder to ensure that all information complies to the submitted file documents.

7.1.1.2. Comprehensive Table of Content

The table of content for the entire submission should list all documents included in the same order as mentioned in the application form.

7.1.1.3. Valid Store License

Should be issued from MOH (Pharmaceutical Inspection & Licensing Administration.)

7.1.1.4. Valid Agent License

Should be issued from MOH (Pharmaceutical Inspection & Licensing Administration.)

7.1.1.5. Valid Authorization Letter /Letter of Appointment (LOA)

A valid Authorization Letter issued from the MAH appointing the local agent. The letter should be original and legalized by the Chamber of Commerce & Kuwait embassy in the country of origin.

7.1.2. Manufacturing Documents

7.1.2.1. Valid Manufacturing License

Should be issued from the regulatory authority in the country of origin.

N.B. In case the manufacture is approved or licensed in other relevant document (GMP or FSC), the manufacturing license certificate is not mandatory.

7.1.2.2. Valid Good Manufacturing Practice (GMP) Certificate

GMP Certificate issued from the regulatory authority in the country of origin or ISO Certificate from approved accredited Notified Body for relevant scope of products for all manufacturing sites. The certificate must be legalized by the Kuwait embassy in the country of origin.

7.1.2.3. Relationship Letter

In case that MAH is different from the manufacturer, a declaration letter issued from the brand owner showing the relationship between the two companies (MAH & manufacturer) is required.

In case the distributer is included in the supply chain, an authorization letter issued from the MAH should be provided with clarification for the rules of each party.

7.1.3. Product Documents:

7.1.3.1 Certificate of Pharmaceutical Product (CPP) or Free Sales Certificate (FSC)

The CPP in accordance with WHO guidelines or FSC for the product(s) issued from the regulatory authority in the country of origin and legalized by Kuwait embassy.

• It should contain the product(s) name (Trade name), name of the manufacturer/ MAH with their addresses.

• It should declare that the product is freely sold/marketed in the country of origin, otherwise a reasonable justification should be submitted and assessed by Medicine & Medical Products Registration & Regulatory Administration.

• If the trade name of the product intended for registration in Kuwait is different from that in the country of origin, the difference should be explained clearly with confirmation of similarity in the composition and other specifications.

7.1.3.2. Certificate of Composition (COC)

Detailed Certificate of Composition for active and in-active ingredients with their quantities per dose /serving. Names of all excipients, colouring agents, diluents and perfumes should be mentioned.

The information in the COC should be corresponding and matching to the product's label and finished product sample.

7.1.3.3. Finished Product Specifications (FPS)

FPS with method of analysis (if applicable) including all parameters and their limits & reference.

7.1.3.4. Certificate of analysis of the Finished Product (COA)

Certificates of analysis for more than one batch of the finished product should be submitted from the supplier including all tests mentioned in the FPS, limits and result.

7.1.3.5. Certificate of suitability for TSE /BSE

TSE/BSE free Certificate confirming the safety of ingredients from animal origin (Whenever applicable)

7.1.3.6. Halal Certificate

Should be issued by authorized organizations (whenever applicable)

7.1.3.7. Certificate of Compliance (Free from Certificates)

Declaration issued from MAH letterhead, declaring that the products do not contain hormones, heavy metals, antibiotics, steroidal products, pork derivatives.

7.1.3.8. Control of Excipients

Declaration letter issued from MAH showing that the preservatives, colorants, diluents and perfumes present in the formula are permitted by the international health authorities.

The colors permitted for use are limited to those listed in the EU "List of permitted food colors" and the US FDA "Inactive ingredient guide" and GSO updated guidelines.

For THCP carcinogenic, mutagenic and toxic to reproduction (CMR) substances free certificate according to EU Cosmetic regulation Board should be submitted.

7.1.3.9. For products containing herbal ingredient(s)

• Summary of the profile of the plant used including botanical name, genus, species, plant part used, weather cultivated or wild, harvesting practices and treatment to obtain raw material.

• Raw materials specifications and certificate of analysis including tests for heavy metals and pesticides.

• Description of physiological functions of the herbal ingredients / supplements to the intended user.

• Data to demonstrate the safety of each herbal ingredient in human beings e.g. through scientific studies & references.

7.1.3.10. For Workout & Athletic Supplements

• Declaration letter issued from MAH confirming that the products) are completely free from Any of Selective Androgen Receptors Modulators (SARMS).

• Calculation for the total amount of Caffeine released from all stimulant ingredients, It should not exceed 200 mg per single dose.

7.1.3.11. For THCP including human origin substance

Source of the substance should be provided, with description of the standard for eligibility of doners, tissue collection, purification, production, quality control data, particularly those relating to microbial limits (including viruses) and the absence of hormonal substances.

7.1.3.12. Stability Summary and Conclusions for shelf life:

The manufacturer should define the period 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.

7.1.3.13. Complete Stability Studies (Whenever requested)

The studies should include testing of those attributes of the finished product specification that are susceptible to change during storage and are likely to influence quality, safety, and efficacy. The study divided into two parts

• Long Term Stability Study over the complete shelf life of the product at 30 °C ±2 & 65%

• Accelerated Stability Study at 40 °C +2 & 75% ±5% RH over a period of 6 months

7.1.3.14. List of Countries

List of countries where the product is registered & marketed supported by photocopies of registration certificates (if available).

7.1.3.15. Post Market Surveillance (PMS) Control

Provide a declaration that states the following: We "the name of the authorized representative / Marketing authorization holder" declares that if one of the products included for registration ever featured any recall, post market notice or adverse event, or has been withdrawn or suspended in the country of origin, we will inform Medicine & Medical Products Registration & Regulatory Administration for any PMS Recall and Alert.

7.1.3.16. Evidence to Support the Safety and Efficacy

Depending on the nature and status of the health product, sources of acceptable evidence may include but not limited to:

• Clinical Studies: Evidence from clinical studies that provide information about the efficacy and safety of the health product.

• Regulatory documents e.g., references from international authority, assessment report, approved herbal monograph etc.

• Bibliographic evidence, e.g., pharmacopoeia

• List of traditionally used herbs currently in use in Stringent Regulatory Authorities.

7.1.4. Labelling Information

This section contains the Labelling, Patient Information Leaflet (PIL) in English (and /or Arabic if available) Artworks. This should be submitted as stamped and signed coloured hard copy in addition to the soft copy.

Labelling information should be in English (and/or Arabic if available) with the following requirements:

• Trade name.
• Composition *
• Claim /indication
• Name and address of the MAH
• Name and address of the Manufacturer (if applicable)
• Pack size.
• Dosage form.
• Dosage & Administrations
• Storage condition.
• Strength.
• Batch details: Batch number, manufacturing date (if applicable), expiry date.
• Statement "consult your health care provider if you have any medical condition or are under any medication." (If applicable)
• Warning for pregnancy and lactation (if applicable).
• Warning for alcohol content. (If applicable).
• Side effect (if applicable)
• Contraindications (if applicable)
• Drug interactions (if applicable)
• Number and date of revision of the pack inserts (if applicable)

*Active ingredients should be expressed qualitatively and quantitatively per dosage unit. Excipients known to have a recognized action or effect should be expressed qualitatively. In THCP, the qualitative formula should be expressed.

7.1.5. Finished Product Sample and analysis:

Samples for registration (and analysis whenever requested) with related documents

• Samples of the product.
• Certificate of analysis with the same batch number of the submitted sample.
• Reference standard for the active ingredients and related substances along with their certificate of analysis (if applicable)
• Product composition certificate.
• Complete method of analysis & finished product specification

7.1.6. Any Additional documents might be required.

Medicine & Medical Products Registration & Regulatory Administration reserves the right to request any additional information, data or studies not specifically described in this document or samples during or even after the process of registration to assess adequately the safety, efficacy and quality of health products.

7.2. Documents required for registration of Raw Materials For Pharmaceutical Preparations (RMFPP)

• Covering letter requesting registration
• Filled registration application
• Valid Store license issued from MOH (Pharmaceutical Inspection & Licensing Administration).
• Valid Agent license issued from MOH (Pharmaceutical Inspection & Licensing Administration).
• Valid Authorization letter issued from MAH to local agent.
• Valid CPP or FSC issued from the regulatory authority in country of origin.
• Valid GMP Certificate issued from the regulatory authority in the country of origin or ISO Certificate includes related scope of products for the manufacturer.
• Detailed Certificate of Composition /specification

• Certificate of Analysis
• Safety data sheet
• Artwork/label

7.3. Documents Required for Application for Variation During Valid Registration

Any change in a registered product during the valid registration period, should be submitted to Medicine & Medical Products Registration & Regulatory Administration prior to implantation in Kuwait market. For any type of variation, set of required documents must be provided as described below:

7.3.1. Types of Variation

7.3.1.1. Major Variation:

Changes to Health Products must be considered to fundamentally alter the basic nature of the product; therefore, cannot be accepted as a change. For such changes an application for new registration should be submitted.

Such changes include:

• Addition of new active ingredient(s).
• Removal of any existing active ingredient.
• Change in the label claim of active ingredient (Considerable change in quantity which exceeds the specified overage %)
• Change in dosage form
• Complete change in the indication combined by artwork modifications

7.3.1.2. Minor Variation:

This type of variation in registered Health Products will be applied by submitting variation application by Authorized Representative in Kuwait & all supportive documents related to each case of variation as described below:

Change		Documents Required reflecting updated information
A. Administrative Changes		
1.	Replacement, addition of new manufacturing site / change in the name of manufacturing site (with change in site location)	• Valid legalized GMP/ISO Certificate • Valid legalized CPP/FSC (if applicable) • Certificate of Analysis (COA) • from the new Manufacturer • Updated Artwork
2.	MAH name change	• Valid original legalized Authorization Letter • Valid original legalized CPP/FSC (if applicable) • Updated Artwork
3.	MAH change in address (country (with change in site location)	• Valid Authorization Letter • Valid CPP/FSC (if applicable) • GMP/Relevant ISO (in case it is a manufacturer)

B. Finished product changes		
1.	Change in trade name of finished product	• Original legalized CPP/FSC • Updated Artwork
2.	Change in/addition of Pack size	• Updated Artwork
3.	Artwork (label / outer pack design, /color, information etc.)	• Updated Artwork • Comparison between old/ new artwork
4.	Storage condition	• Stability study covering new storage conditions with justification for the change (if applicable) • Updated Artwork
5.	Shelf-life extension	• Stability study covering new shelf life with justification for the change. • Updated Artwork (if applicable)
6.	Reduction of shelf life	• New shelf-life declaration and justification for the change • Updated Artwork
7.	Change in excipients (adding, removing or considerable changes in existing amounts)	• Comparison between current and new quantitative composition • Updated Certificate of composition for both active and inactive ingredients quantitatively • Certificate of Analysis (COA) • Updated Artwork • Confirmation for no change in the active ingredients
8.	Changes in Finished product specification FPS	• Comparison table between old and new FPS
9.	Method of analysis	• Comparison table between old and new FPS
10.	Primary packaging material	• Stability study data on the new packaging, packing type • Justification for the change • Updated Artwork

C. Safety updates		
1.	Leaflet (PIL) update	• New leaflet • Comparison table between current and proposed leaflet
2.	Indication	• Comparison table between current and proposed indication • Studies and source of information • Updated Artworks
3.	Addition of Safety information (warnings, side effects, contraindication, drug interactions, age groups etc.)	• Comparison table between current and proposed indication • Safety Studies and source of information • Updated Artworks
4.	Removal of approved Safety information (warnings, side effects, contraindication, drug interactions, age groups etc.)	• Safety Studies and source of information • Approval from the regulatory authority in the country of origin (whenever applicable) • List of countries which approve this change • Updated Artworks

7.3.1.3. Notification Variations

Notification can be applied by submitting variation application with supportive documents.

The notification variation is related to the following types of variation (but not limited):

• Change in the address of the manufacturing site (without actual change in the site location)
• Change in the address of the MAH (without actual change in the site location.
• Change in manufacturing process, batch size or simple changes in Finished products specifications FPS.
• Change in primary packaging (without any change in the main components material – variation only in the material specification e.g. thickness or dimension)
• Change in composition of secondary packaging material
• Change in Outer carton/pack dimensions
• Replacement or deletion of measuring administration devices

• Revised wording of the leaflet/Artwork, redesign, dimension or logo change without actual change in the approved information.
• Addition or removal of one or more language to the product's label/PIL.
• Any changes in source of Active Ingredient or excipients.

7.4. Documents Required for Transfer of Agency

1. Covering letter requesting transfer of agency of a product/products
2. Filled Agency transfer Application
3. Valid Store license for the new agent issued from MOH (Pharmaceutical Inspection & Licensing Administration).
4. Valid Agency license for the new agent issued from MOH (Pharmaceutical Inspection & Licensing Administration).
5. Copy of product's valid registration certificate.
6. A valid Letter of appointment for new local agent issued from the MAH (or regional distributer in case the legal relation is already mentioned in the original letter of appointment and its validity is recently confirmed from the MAH). The LOA should be original and legalized by the Chamber of Commerce & Kuwait embassy in the country of origin.
7. Termination letter for the previous local agent in Kuwait issued from the MAH (or regional distributer in case the legal relation is already mentioned in the original letter of appointment and its validity is recently confirmed from the MAH) 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.

7.4.1. Terms And Conditions of Agency Transfer

• Medicine & Medical Products Registration & Regulatory Administration will not be responsible for any illegal practices or legal disputes and conflicts that can exist between the MAH & the previous local agent or between the old and new local agents.
• Medicine & Medical Products Registration & Regulatory Administration will not be included or legally interrupted in the details or conditions of agreements, authorization or termination letters.
• The agency transfer will be assessed based on valid legalized documents which should be trustworthy.
• If the Registration is expired, the new local agent should apply for new registration including all previously mentioned requirements in part 7.1 and an original termination letter to the previous agent issued from the MAH (or regional distributer in case the legal relation is already mentioned in the original letter of appointment and its validity is recently confirmed from the MAH) and legalized by the Chamber of Commerce & Kuwait embassy in the country of origin.

7.5. Documents Required for Registration's Renewal

Applicants are required to renew the health product registration every five years of its registration/renewal date. The applicant should submit the renewal application within six months prior to expiry of the existing health product registration. It is the responsibility of the applicant to adhere to these timelines.

Renewal of registration requirements:

1. Covering letter requesting registration's renewal
2. Filled renewal application
3. Valid Store license issued by MOH (Pharmaceutical Inspection & Licensing Administration).
4. Valid Agent license issued by MOH (Pharmaceutical Inspection & Licensing Administration).
5. Copy of product's registration certificate issued by Medicine & Medical Products Registration & Regulatory Administration
6. Valid Authorization letter issued from MAH for continuing the agency to local agent.
7. Original CPP or FSC issued from the regulatory authority in country of origin and legalized by Kuwait Embassy including all mentioned details (as described before in section 7.1.3.1.)
8. GMP Certificate issued from the regulatory authority in the country of origin or ISO Certificate issued from approved accredited notified body includes for relevant scope of products for all manufacturing sites. The certificate must be legalized by the Kuwait embassy in the country of origin.
9. Detailed Certificate of Composition for active and in-active ingredients with their quantities per dose /serving. Names of colouring agents, diluents and perfumes should be clarified. The information in the COC should be in contrast with the product's label and sample.
10. Confirmation letter from the company stating that there are no changes on the product other than what have been approved previously by Medicine & Medical Products Registration & Regulatory Administration.
11. Finished product's artworks for labelling, Patient Information Leaflet (PIL). This should be submitted as stamped and signed coloured hard copy in addition to the soft copy.
12. Finished product sample
13. Any Medicine & Medical Products Registration & Regulatory Administration approved variations made to the product(s)

N.B. If any unapproved variation had been detected upon reviewing the application, the agent will be notified to apply for such variation before renewal of registration.

7.6. Product's Suspension Circumstances

Medicine & Medical Products Registration & Regulatory Administration reserves the right to suspend the registration of any registered health product in the following circumstances:

• If the product, the MAH, or the manufacturer is suspended in country of origin.
• Evidence of noncompliance safety or efficacy of the device.
• If the company does not comply with the current GMP /ISO standards.
• If the product does not comply with the specification issued by the manufacturer.
• If discrepancy in the documents were observed.
• Noncompliance to Medicine & Medical Products Registration & Regulatory Administration laws and regulations.
• Warning issued for a specific product or manufacturer by FDA, EMA, WHO, GCC or reference agencies.

7.7. Registration Cancellation Circumstances

- A product is liable to cancellation if undeclared medicinal ingredient had been detected during periodic analysis.
- If it fails to comply with this guidance.
- If two years passed without importing the registered product.
- If the product is banned or withdrawn in the country of origin or in any country due to safety, quality issue or lack of efficacy, or if it's proved to cause toxicity or have serious adverse effects.
- Falsified or manipulated documents are submitted to Medicine & Medical Products Registration & Regulatory Administration.

Medicine & Medical Products Registration & Regulatory Administration reserves the right to cancel the registration of any registered health product in the following circumstances:

- If the product does not comply with the specification issued and approved by Medicine & Medical Products Registration & Regulatory Administration.
- As per the instruction from the MAH to cancel with justification.
- Warning issued for a specific product or manufacturing site by any International Health Authorities or reference agencies.
- If the local agent failed to renew the product registration and/or the MAH failed to fulfil the requirements for renewal of registration.

ANNEX I .8

Life Stage Group		Biotin (µg /day)			Vitamin B9 /Folate/ Folic acid (µg /day)			Vitamin B2/Riboflavin (mg/day)			Vitamin B1/Thiamine (mg/day)			VitaminB12 (mg/day)		
		Min	RDA	Max	Min	RDA	Max	Min	RDA	Max	Min	RDA	Max	Min	RDA	Max
Infants	0-12 months	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Children	1-3 years	10	8	500	15	150	300	0.6	6	10	0.04	0.5	100	0.05	0.5	30
	4-8 years	10	12	500	15	200	400	0.6	8	15	0.04	0.6	100	0.05	0.8	40
Adolescents	9-13 years	10	20	500	15	300	600	0.6	12	20	0.04	0.9	100	0.05	1.0	60
	14-18 years	10	25	500	30	400	800	1.0	16 (M) 14 (F)	30	0.07	1.2 (M) 1.0 (F)	100	0.10	1.3 (M) 1.2 (F)	80
Adults	≥ 19 years	1.8	30	500	30	400	1,000	1.0	16 (M) 14 (F)	900	0.07	1.2 (M) 1.1 (F)	100	0.10	1.8	100
Pregnancy	19-50 years	-	30	-	-	600	-	-	18	-	-	1.4	-	-	1.9	-
Breastfeeding	19-50 years	-	35	-	-	500	-	-	17	-	-	1.4	-	-	2.0	-

Life Stage Group		Calcium (mg /day)			Chromium (µg /day)			Cobalt (µg /day)			Copper (µg /day)			Iodine (µg /day)		
		Min	RDA	Max	Min	RDA	Max	Min	RDA	Max	Min	RDA	Max	Min	RDA	Max
Infants	0-12 months	-	200	-	-	-	-	-	-	-	-	-	-	-	-	-
Children	1-3 years	65	700	1,500	-	-	-	0.004	0.04	44	35	340	700	6	90	133
	4-8 years	65	1,000	1,500	-	-	-	0.004	0.05	44	35	440	2,500	6	90	200
Adolescents	9-13 years	65	1,300	1,500	-	-	-	0.004	0.08	44	35	700	4,000	6	120	400
	14-18 years	65	1,300	1,500	-	-	-	0.006	0.10	44	65	880	6,500	14	150	600
Adults	≥ 19 years	65	1,100	1,500	2.2	30 (M) 20 (F)	500	0.006	0.10	44	65	900	8,000	14	150	600
Pregnancy	19-50 years	-	1,000	-	-	30	-	-	0.11	-	-	1,000	-	-	220	-
Breastfeeding	19-50 years	-	1,000	-	-	45	-	-	0.12	-	-	1,300	-	-	290	-

Life Stage Group		Vitamin B5/Pantothenic acid (mg /day)			Vitamin B6/ Riboflavin (mg /day)			Vitamin B12/Cobamamide (µg /day)			Vitamin C/Ascorbic Acid (mg/day)			Vitamin D (µg/day)		
		Max	RDA	Max	Min	RDA	Max	Min	RDA	Max	Min	RDA	Max	Min	RDA	Max
Infants	0-12 months	-	-	-	-	-	-	-	-	-	-	-	-	0.5	10	25
Children	1-3 years	0.2	2	500	0.04	0.5	100	0.09	0.9	1,000	2.2	15	400	0.8	15	25
	4-8 years	0.2	3	500	0.04	0.6	100	0.09	1.2	1,000	2.2	25	650	0.8	15	25
Adolescents	9-13 years	0.2	4	500	0.04	0.9	100	0.09	1.8	1,000	2.2	45	1,200	0.8	15	25
	14-18 years	0.4	5	500	0.08	1.3 (M) 1.0 (F)	100	0.14	2.4	1,000	6.0	75 (M) 65 (F)	1,800	1.0	15	25
Adults	≥ 19 years	0.4	5	500	0.08	1.3 (M) 1.1 (F)	100	0.14	2.4	1,000	6.0	90 (M) 75 (F)	2,000	1.0	17	25
Pregnancy	19-50 years	-	6	-	-	1.4	-	-	2.6	-	-	85	-	-	15	-
Breastfeeding	19-50 years	-	7	-	-	1.6	-	-	2.8	-	-	120	-	-	15	-

Life Stage Group		Vitamin K (µg /day)			Vitamin A as retinal (µg /day)			Vitamin E as D-alpha tocopherol (mg /day)		
		Min	RDA	Max	Min	RDA	Max	Min	RDA	Max
Infants	0-12 months	-	-	-	30	400	600	-	-	-
Children	1-3 years	3	30	30	30	300	600	0.6	6	200
	4-8 years	3	55	55	30	400	900	0.6	7	300
Adolescents	9-13 years	3	60	60	30	600	1,700	0.6	11	600
	14-18 years	6	75	75	65	900 (M) 700 (F)	2,800	1.0	15	800
Adults	≥ 19 years	6	120 (M) 90 (F)	120	65	900 (M) 700 (F)	3,000	1.0	15	1,000
Pregnancy	19-50 years	-	90	-	-	770	-	-	15	-
Breastfeeding	19-50 years	-	90	-	-	1,300	-	-	19	-

Life Stage Group		Iron (mg/day)			Magnesium (mg /day)			Manganese (mg /day)			Molybdenum (µg/day)			Phosphorus (mg/day)		
		Min	RDA	Max	Min	RDA	Max	Min	RDA	Max	Min	RDA	Max	Min	RDA	Max
Infants	0-12 months	0.6	11 (<6M)	40	-	-	-	-	-	-	-	-	-	-	-	-
Children	1-3 years	0.6	7	40	12	80	65	-	-	-	-	-	-	62	460	2,000
	4-8 years	0.6	10	40	12	130	110	-	-	-	-	-	-	62	500	2,000
Adolescents	9-13 years	0.6	8	40	12	240	350	-	-	-	-	-	-	62	1,250	2,000
	14-18 years	1.4	11 (M) 15 (F)	45	20	410 (M) 360 (F)	350	-	-	-	-	-	-	62	1,250	2,000
Adults	≥ 19 years	1.4	8 (M) 13 (F)	45	20	420 (M) 320 (F)	500	0.13	2.3 (M) 1.8 (F)	9	2.5	45	2,000	62	700	2,000
Pregnancy	19-50 years	-	27	-	-	355	-	-	2.0	-	-	50	-	-	700	-
Breastfeeding	19-50 years	-	9	-	-	315	-	-	2.6	-	-	50	-	-	700	-

Life Stage Group		Selenium (µg /day)			Silicon (mg/day)			Zinc (mg /day)		
		Min	RDA	Max	Min	RDA	Max	Min	RDA	Max
Infants	0-12 months	-	-	-	-	-	-	0.2	2	2
Children	1-3 years	-	-	-	-	-	-	0.4	3	7
	4-8 years	-	-	-	-	-	-	0.4	5	12
Adolescents	9-13 years	-	-	-	-	-	-	0.4	8	23
	14-18 years	-	-	-	-	-	-	0.7	11 (M) 9 (F)	34
Adults	≥ 19 years	3.5	55	300	>0	-	84	0.7	11 (M) 8 (F)	58
Pregnancy	19-50 years	-	60	-	-	-	-	-	11	-
Breastfeeding	19-50 years	-	70	-	-	-	-	-	12	-

Free Sale Certificate FSC	Is not required during registration process but can be requested by the local company after issuing health product's registration or renewal certificate.	Valid Original CPP/FSC issued from the regulatory authority in the country of origin.	Valid Original CPP/FSC issued from the regulatory authority in the country of origin and legalized by Kuwait embassy in the country of origin.

10 REFERENCES

- Food And Drug Administration (FDA), USA
- Health Canada, Canada
- National Institute of Health, USA
- European Union Data Base, EU
- Therapeutics Goods Administration (TGA), Australia
- WHO Guidelines, Essential Medicines and Health Products Information Portal
- The Gulf Health Council (GHC) & GCC authorities Guidelines
- GCC Standardization Organization (GSO 1943/2016)
- Natural Health Products, listing of monographs – Health Canada
- European Union Monograph and list entries
- Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products
- Cosmetic ingredients Hotlist – Health Canada
- National Institute of Health–Dietary Supplements Fact sheet
- Regulation (EC) No 1223/2009 of the European Parliament and of the Council – Legislation.gov.uk
- Therapeutic Good Administration TGA – Australia
- GSO 2528:2024–Cosmetic products – Technical Regulation of Cosmetic and Personal Care Products Claim
- GSO 1943:2024–Cosmetic Products – Safety Requirements of Cosmetics and Personal Care Products.

9. ANNEX II

Differences in some Required Documents Between Local, GCC and International Manufacturing Companies/Marketing Authorization Holder (MAH)Document	Local Manufacturing Company	GCC manufacturing Company	International Manufacturing Company
Authorization/ Appointment Letter (The contract between the agent and the MAH)	No t required	Valid Original Legalized by the chamber of commerce/ Kuwait embassy in the country of origin.	Valid Original Legalized by the chamber of commerce and Kuwait embassy in the country of origin.
Manufacturing license ML (For any manufacturing site)	Valid Manufacturing License for Kuwait local manufacturing company issued from Medicine & Medical Products Registration & Regulatory Administration.	Valid Manufacturing License for GCC manufacturing company issued from the regulatory authority in the country of origin	Valid Manufacturing License for the international manufacturing company issued from the regulatory authority in the country of origin
Good Manufacturing Practice GMP /ISO (For any manufacturing site)	Valid Original Good Manufacturing Practice certificate for the Kuwait local manufacturing company issued from Medicine & Medical Products Registration & Regulatory Administration after Inspection for the manufacturer to ensure the implementation of Good Manufacturing Practice (GMP).	Valid Original Good Manufacturing Practice or ISO certificate related to the product's scope for the GCC manufacturing company issued from the regulatory authority in the country of origin.	Valid Original Good Manufacturing Practice certificate for the international manufacturing company issued from the regulatory authority in the country of origin and legalized by Kuwait embassy in the country of origin.