قرار وزاري رقم (344) لسنة 2025
بشأن تنظيم تسجيل مواد ومستحضرات التجميل

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 2001 ولائحتيهما التنفيذية.

– وعلى القرار الوزاري رقم 200 لسنة 1997 في شأن تنظيم إجراءات الرقابة على تصنيع واستيراد وتداول مواد التجميل ذات الصفة الطبية.

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

– ورغبة من الوزارة في تحديث تنظيم تسجيل وتداول مواد ومستحضرات التجميل وتداولها.

– وبناءً على مقتضيات مصلحة العمل وما عرضه علينا السيد/ وكيل الوزارة.

– قرر –

مادة أولى

يقصد بالمصطلحات التالية المعنى المبين قرين كلا من:

• الممثل المعتمد للشركة/ الوكيل المحلي: هي جهة قانونية محلية تمثل الشركة صاحبة حق التسويق للمستحضرات التجميلية والمرخص لها بيع مستحضرات التجميلية في دولة الكويت ومسؤولة عن جميع الإجراءات القانونية المتعلقة بالمستحضر التجميلي من تسجيل وبيع وتسويق ومتابعة داخل دولة الكويت.

• المستحضر التجميلي: مواد يتم استخدامها على الأجزاء الخارجية لجسم الإنسان، جلد الانسان، الأسنان أو الشعر بهدف تنظيفها، تعطيرها، تغير مظهرها، حمايتها، الحفاظ على حالتها، أو إزالة الروائح.

• العطور: تركيبات كحولية أو غير كحولية من مواد طبيعية أو مصنعة تستخدم لتعطير الجسم.

• الادعاءات التجميلية: هي أي ادعاء مكتوب أو مرئي أو صوتي أو بأي وسيلة أخرى يهدف إلى الترويج المباشر أو غير المباشر أو تسويق المستحضر التجميلي.

• الادعاء التجميلي الأساسي: هو الادعاء الذي يتناول بوضوح الوظيفة الرئيسية للمنتج ويُفهم منهم الغرض الأساسي للمستهلك

• الادعاء التجميلي الثانوي: الادعاءات التي تصف وظائف أخرى للمستحضر التجميلي بالإضافة إلى الادعاء الأساسي.

• الادعاءات غير المقبولة: الادعاءات التي لا تتوافق مع تعريف مستحضرات التجميل أو المعايير الأساسية للموافقة عليها، مثل الادعاءات العلاجية أو تلك التي تؤثر بشكل كبير على وظائف الجسم.

• الشركة المصنعة: هي المنشأة التي يتم فيها تصنيع المستحضر التجميلي.

• الشركة مالكة حق التسويق: هي الشركة التي تحمل ترخيص المستحضر وتتولى تسويقه سواء كانت الشركة المصنعة أو المتعهدة بالتسويق، وتتحمل المسئولية الكاملة عن جودة المستحضر التجميلي وأمونيته وفعاليته ومتابعته بعد التسويق وجميع الإجراءات القانونية المتعلقة بالمستحضر التجميلي من

بيع، وتسويق ومتابعة داخل دولة الكويت.

• المصنع المتعاقد: جهة تصنيعية تقوم بإنتاج المستحضرات أو مكوناتها لصالح شركة أخرى وفقاً لمواصفات مُحددة مسبقاً.

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

مادة ثانية

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

مادة ثالثة

تصنف المستحضرات التجميلية كالآتي:

• منتجات العناية بالبشرة.
• منتجات العناية بالشعر.
• منتجات العناية بصحة الفم.
• مساحيق التجميل والمكياج.
• العطور.
• مزيلات العرق ومضادات التعرق.
• منتجات الحماية من الشمس.
• منتجات النظافة الشخصية.
• منتجات العناية بالأطفال.
• المناديل المبللة والمنتجات التي لا تتطلب الشطف No Rinse Products

مادة رابعة

التصديقات والمستندات:

1- يعتمد التحقق الإلكتروني Electronic Verification للشهادات إن وجد دون الحاجة إلى التصديق الورقي من الجهات المعنية.

2- 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.

3- يتوجب تصديق شهادة الوكالة بين الوكيل المحلي والشركة صاحبة حق التسويق للمستحضرات التجميلية 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

يشترط لتسجيل المستحضر التجميلي التالي:

1. المتطلبات الخاصة بالوكيل المحلي:

1.1 ترخيص مزاولة النشاط التجاري صادر من وزارة التجارة والصناعة.

1.2 ترخيص الشركة لاستيراد مستحضرات التجميل صادر من وزارة الصحة.

1.3 ترخيص مستودع صادر من وزارة الصحة.

1.4 اعتماد توقيع ممثلي الشركة من الهيئة العامة للقوى العاملة.

1.5 صور من البطاقة المدنية لصاحب الشركة والمفوض بالتوقيع.

2. المتطلبات الخاصة بالشركة صاحبة حق التسويق:

2.1 خطاب الوكالة يوضح العلاقة التجارية بين الوكيل المحلي والشركة صاحبة حق التسويق مصدق من سفارة دولة الكويت في بلد المنشأ وغرفة التجارة والصناعة في بلد المنشأ.

2.2 شهادة ترخيص الشركة صادرة من السلطات المختصة في بلد المنشأ مصدقة كما هو موضح في المادة الرابعة.

2.3 شهادة تطبيق أسس التصنيع الجيد او شهادة مطابقة المواصفات الأيزو رقم (22716) للمصنع صادرة من السلطات المختصة في بلد المنشأ ومصدقه وفقا للألية المذكورة في المادة الرابعة.

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

3.1 شهادة ترخيص الشركة المصنعة صادرة من السلطات المختصة في بلد المنشأ مصدقة وفقا للألية المذكورة في المادة الرابعة.

3.2 شهادة تطبيق أسس التصنيع الجيد للشركة المصنعة صادرة من السلطات المختصة في بلد المنشأ مصدقة وفقا للألية المذكورة في المادة الرابعة.

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

4. المتطلبات الخاصة بتسجيل المستحضرات التجميلية:

يتضمن ملحق القرار باللغة الإنجليزية (ملحق رقم 1) المرفق بهذا القرار تفصيل كامل للمتطلبات التي يجب توافرها في ملف التسجيل المقدم الى إدارة تسجيل ورقابة الأدوية والمنتجات الطبية.

مادة سادسة: يجب على مقدم طلب التسجيل (الوكيل المحلي) تقديم كتاب تعهد من الشركة صاحبة حق التسويق يتضمن إبلاغ إدارة تسجيل ورقابة الأدوية والمنتجات الطبية بوازرة الصحة في حالة صدور أي تحذير من أي من الجهات الرقابية الدولية بشأن سلامة وأمونية استخدام المستحضر التجميلي.

مادة سابعة

يحق لإدارة تسجيل ومراقبة الأدوية الطبية والنباتية طلب أي مستندات أو دراسات إضافية أو إجراء اختبارات لدى مختبرات الإدارة وعلى الشركة الالتزام بذلك.

مادة ثامنة

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

مادة تاسعة

صلاحية شهادة تسجيل المستحضر التجميلي هي خمس سنوات.

مادة عاشرة

للمستحضرات المصنعة محلياً أو حق تسويقها مملوك لصالح شركة محلية، فإن إصدار شهادات التداول الحر وترخيص التصنيع للشركة المصنعة أو صاحبة حق التسويق وشهادة أسس التصنيع الجيد وغيرها من الشهادات المتعلقة بالتسجيل تكون من اختصاص إدارة تسجيل ورقابة الأدوية والمنتجات الطبية.

مادة حادية عشر

يجب إعادة تجديد تسجيل المستحضر التجميلي قبل ستة أشهر من إنتهاء مدة صلاحية شهادة التسجيل.

مادة ثانية 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 لها مصدقة من سفارة دولة الكويت في بلد المنشأ وغرفة التجارة والصناعة في بلد المنشأ وقد يكون صادراً من الموزع الإقليمي في حال تم توضيح العلاقة القانونية بوضوح في الخطاب الأصلي.
2. شهادة إلغاء الوكالة الممنوحة للوكيل السابق من الشركة صاحبة حق التسويق أو الموزع الإقليمي المعتمد في خطاب الوكالة المقدم للإدارة في ملف تسجيل المستحضر، موضحاً بها تاريخ إلغاء الوكالة مصدقة من سفارة دولة الكويت في بلد المنشأ وغرفة التجارة والصناعة في بلد المنشأ.
3. قائمة بالمستحضرات الخاضعة لنقل الوكالة صادر من الشركة صاحبة حق التسويق موضح فيها الاسم التجاري للمستحضر، التركيز، الشكل الصيدلاني، الشركة المصنعة.

مادة ثالثة عشر

يحق لإدارة تسجيل ورقابة الأدوية والمنتجات الطبية تعليق تسجيل أي مستحضر تجميلي وذلك إذا ثبت للإدارة ما يلي:

1. إذا صدر قرار بتعليق أو حظر المستحضر من قبل السلطات الرقابية في بلد المنشأ.
2. إذا ثبت عدم فعالية ومأمونية استخدام المستحضر التجميلي.
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 المستحضر للتحليل لدى إدارة فحص الأدوية والمنتجات الطبية.
7. في حال عدم إبلاغ الوكيل المحلي إدارة تسجيل ورقابة الأدوية والمنتجات الطبية عن صدور أي تحذيرات تخص المستحضر التجميلي من الهيئات الصحية المعتمدة.

مادة رابعة عشر

يحق لإدارة تسجيل ورقابة الأدوية والمنتجات الطبية إلغاء تسجيل أي مستحضر تجميلي أو شركة صاحبة حق التسويق أو شركة مصنعة وذلك إذا ثبت للإدارة ما يلي:

1. إذا تم إلغاء تسجيل المستحضر أو الشركة في بلد المنشأ.
2. عدم مطابقة المستحضر التجميلي للمواصفات الفنية المعتمدة بملف التسجيل لدى الإدارة.
3. بناءً على طلب الشركة المصنعة مع ذكر الأسباب.
4. إذا طرأت أضرار جسيمة جراء استخدام المستحضر التجميلي.
5. عدم تجديد التسجيل في الفترة المحددة.
6. إذا ثبت التزوير في المستندات المقدمة لإدارة تسجيل ورقابة الأدوية والمنتجات الطبية.
7. عدم تقديم الشركة المبررات والمستندات الداعمة لإلغاء تعليق المستحضر أو الشركة الواردة خلال ستة أشهر من التعليق.

مادة خامسة عشر

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

مادة سادسة عشر

يحق للوكيل المحلي الاعتراض على قرار الإدارة في حال رفض تسجيل مستحضر تجميلي أو تعليق التسجيل أو إلغاؤه خلال مدة أقصاها 90 يوم من تاريخ صدور القرار، وعليه يعتبر القرار نهائي بعد تقديم الرد بناءً على دراسة الاعتراض.

مادة سابعة عشر

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

مادة ثامنة عشر

الموافقة على إفراج وتداول المستحضرات التجميلية يخضع للقرار الوزاري المنظم لذلك.

مادة تاسعة عشر

يخضع الإعلان عن مستحضرات التجميل لشروط وضوابط ولوائح تنظيم عملية الإعلانات الطبية في وزارة الصحة.

مادة عشرون

تمنح فترة سماح لمدة ستة أشهر من تاريخ صدور هذا القرار لإتمام اصطفاء وتوفيق أوضاع الشركات الموردة والمستودعات التابعة لها من إدارة التفتيش والترخيص الصيدلاني.

مادة حادية وعشرون

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

د. أحمد عبد الوهاب العوضي

وزير الصحة

صدر في 2 رجب 1447هـ

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aiming to directly or indirectly promote, sell or market the product

3.4 Primary Cosmetic Claim

Claims that are clearly and prominently mentioned or convey the idea to the consumer and describe the main function of the product

3.5 Secondary Cosmetic Claim

Claims that describe the other functions of the product in addition to the primary claim

3.6 Unacceptable Claims

Claims that do not comply with the definition of a cosmetic product and the basic criteria for a cosmetic product approval, including claims to treat a medical condition or a significant change in body physiological functions

3.7 Authorized representative in Kuwait

A Legal Entity established in the state of Kuwait, officially appointed by the marketing authorization holder (MAH) to act on their behalf before Medicine and Medical Products Registration and Regulatory Administration in all matters related to the registration, post market surveillance, marketing and communication of cosmetic products

3.8 Marketing Authorization Holder

A Marketing authorization holder (MAH) is a legal entity that has been granted the official authorization to market or sell a specific cosmetic product within the defined geographic region. MAH is responsible for ensuring the safety, quality, and compliance with all relevant regulations throughout the product lifecycle from premarket to post market surveillance.

3.9 Manufacturer

A Manufacturing site that produces a designed cosmetic product.

3.10 Contract Manufacturer

A manufacturing entity that produces products or components for another company predesigned specifications.

3.11 Country of Origin

Refers to Marketing authorization holder country or country where the finished product is manufactured.

4. GENERAL CATEGORIES OF PRODUCTS

4.1 Skin care products

4.2 Hair care products

4.3 Oral hygiene products

4.4 Makeup and Decorative cosmetics

4.5 Perfumes and Colognes

4.6 Deodorants and Anti- Perspirants

4.7 Sun Protection products

4.8 Personal hygiene products

4.9 Nail Care products

4.10 Wet wipes and No rinse products

5. COSMETIC PRODUCT CLAIMS

All Cosmetic claims shall meet the general and specific requirements referred in these guidelines, as per GSO guidelines (GSO2528:2024) and EU Cosmetic regulation (EC) No 1223/2009) and their updates, and to meet to the following criteria.

5.1 Legal Compliance

5.1.1 Claims must comply with all applicable laws in the State of Kuwait and must not contradict Islamic values or societal norms.

5.1.2 Claims must be evaluated from the perspective of the average consumer, taking into account linguistic, social, and cultural contexts.

5.2 Truthfulness

5.2.1 Product presentation and individual claims must not be

1. INTRODUCTION

1.1 Objectives

This Guideline establishes the regulatory framework for the registration of cosmetics and personal care products in the state of Kuwait. It aims to ensure product safety, quality and compliance with international and regional standards, particularly those set by the (GSO), European Union (EU), and GCC member states.

1.2 Responsible Authority

The responsible authority is the Medicine and Medical Products Registration and Regulatory Administration, Ministry of Health, State of Kuwait

1.3. Scope

These Guidelines shall apply to all cosmetic and personal care products intended to be marketed or distributed in the State of Kuwait, including but not limited to the product categories mentioned in this ministerial decree.

2.ABBREVIATIONS

BSE	Bovine Spongiform Encephalopathy
EU	European Union Cosmetic Regulation
FSC	Free Sale Certificate
GCC	Gulf Cooperation Council
GMP	Good Manufacturing Practice
GSO	Gulf Standardization Organization
INCI	International Nomenclature of Cosmetic Ingredients
M.D	Ministerial Decree
MAH	Marketing Authorization Holder
TSE	Transmissible Spongiform Encephalopathy
COA	Certificate of Analysis
WHO	World Health Organization

3. TERMS AND DEFINITIONS

3.1 Cosmetic preparations

Cosmetic preparations are any substance or preparations intended to be placed in contact with the various external part of the human body (Skin, hair system , nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity , with a view exclusively or mainly to clean , perfume , change their appearance and/or correcting body odors , and/or protecting them or keeping them in good condition.

3.2 Fragrances

Alcoholic or non-alcoholic preparations natural or synthetic substances used for perfuming the body or cosmetic products.

3.3 Cosmetic Product Claims

Any Statement whether written, audio, visual or otherwise

misleading or based on false information.

5.2.2 All claims must be factually accurate.

5.2.3 If a product claims to contain a specific ingredient, that ingredient must be intentionally included.

5.2.4 Claims about an ingredient's properties must not suggest that the entire product possesses those properties unless substantiated.

5.3 Evidential support

5.3.1 Claims for cosmetic products, whether explicit or implicit, shall be supported by adequate and verifiable evidence released by the manufacturer, this requires the possibility of linking between references studies used as evidence and product used by the claim, and it should use scientific methods to prove a well-designed and followed (true, reliable and rechargeable experience), and respects the ethical considerations.

5.3.2 The level of evidence or substantiation shall be consistent with the type of claim being made, in particular for claims where lack of efficacy may cause a safety problem.

(Note: for example, sunscreen products which claim a certain sun protection Factor (SPF) must have been tested according to the relevant international standards).

5.3.3 Assessment of the acceptability of a claim shall be based on the weight of evidence of all studies, data and information available depending on the nature of the claim and the prevailing general knowledge of the consumers.

5.3.4 The product must comply with the technical requirements of a claim according to globally recognized standard/ best practice for the final product.

5.4 Honesty

It should not be overstated in view of the performance of the product. The

following are some examples:

5.4.1 The amendment to the images before and after use to illustrate the effect of the product.

5.4.2 Claims of no 'preservatives' in perfume products as they contain a high amount of alcohol that does not require adding preservatives.

5.4.3 Claims shall not attribute to the product concerned specific (i.e. unique)

characteristics if similar products possess the same characteristics.

5.4.4 Presentations of a products performance shall not go beyond the available

supporting evidence.

5.4.5 If the action of a product is linked to specific conditions, such as use in association with other products, this shall be clearly stated.

5.5 Fairness

Claims for cosmetic products shall be objective and shall not denigrate the

competing products or legally permitted ingredients unless it serves a valid consumer benefit or appeal.

5.6 Informed decision making

5.6.1 Claims must be clear, accurate, and easily understood by the average consumer.

5.6.2 Marketing professionals must consider the comprehension levels of all consumer segments and ensure that information is relevant, transparent, and accessible.

6. PRODUCTS CLASSIFICATION & RECLASSIFICATION

• The base for classification depends on claims, ingredients and the ingredient limits given by EU standards and GSO Standards.

For new product types that are not covered under existing claims or categories, the applicant may submit the product for evaluation by the Classification Committee at the Medicine and Medical Products Registration and Regulatory Administration. The Committee will assess the product in accordance with these guidelines, international regulations, and relevant scientific references.

• Previously registered products may be subject to reclassification based on updated guidelines or decisions made by the classification committee. In such cases, Medicine and Medical Products Registration and Regulatory Administration will allow a transitional period during which the current registration certificate remains valid. This is intended to ensure uninterrupted product availability, minimize disruption to the market, and support business continuity.

• Local agents, authorised representatives and their principal companies will be granted a grace period as specified by memo issued by Medicine and Medical Products Registration and Regulatory Administration to avoid importation delays or shipment rejections. During this time, they are required to re-register their products under the new category or department.

7. COSMETIC PRODUCTS REGISTRATION PROCEDURE

• Authorized Representative applying for registration, renewal variation, transfer of agency, and other procedures shall follow the rules and requirements mentioned in this M.D.

• The registration of products will be done as per claims, percentages/ types of ingredients and other documents given in these guidelines and EU Standards.

• The applicant must submit:

1. Valid import license issued by the Kuwait Ministry of Commerce, authorizing the import of cosmetic preparations.

2. Valid store license issued by the Drug Inspection Administration, Ministry of Health, Kuwait.

3. Valid agent license issued by the Ministry of Health, Kuwait

4. Copy of the authorized signature certificate issued by the Kuwait Chamber of Commerce and Industry.

5. Copy of the Civil ID of the company owner or the authorised signatory.

7.1 Application for New Registration

7.1.1 Cover letter addressed to Medicine and Medical Products Registration and Regulatory Administration stating the product name, intended use, manufacturer, country of origin, and an enclosed list of documents, along with the application form.

7.1.2 Valid legalized letter of appointment from the marketing authorization holder, regional distributor in case the legal relation is clearly mentioned, appointing a local agent in Kuwait, legalized by Kuwait embassy in the country of origin and chamber of commerce in country of origin.

7.1.3 Valid legalized Free Sale Certificate issued or attested by the relevant authority in the country of origin confirming that the product is classified and freely sold as a cosmetic under the same name, formula, and intended use, including details of the manufacturer and/or marketing authorization holder and applicable regulatory framework legalized by Kuwait embassy in the country of origin (electronic issued certificates with electronic verification tool are acceptable without legalization).

7.1.4 Valid Good Manufacturing Practice (GMP) certificate or ISO 22716, certificate issued by the relevant authority in the country of origin, (electronic issued certificates with electronic verification tool are acceptable).

7.1.5 Detailed quantitative Certificate of Composition for both

active and inactive ingredients, issued by the manufacturer or marketing authorization holder.

7.1.6 Certificate for the source of biological ingredients, free from pathogenic or infections and microbes, (BSE /TSE free certificate for ingredients from animal origin), if applicable.

7.1.7 Certificate for the source of biological ingredients and Certificate confirming the absence of detectable pathogenic viruses or infectious agents, and the non-metabolic or endocrine activity of biological extracts, enzymes, or proteins (If applicable)

7.1.8 Certificate confirming product safety and the absence of hormones, corticosteroids, Carcinogenic Mutagenic Reprotoxic (CMR) and prohibited substances or additives (including banned colorants and preservatives).

7.1.9 List of countries where the product is registered and marketed.

7.1.10 Study demonstrating the efficacy and safety of products with medicated features. (Upon request)

7.1.11 Certificate describing the product's specifications (e.g., colour, Odor, texture, pH, alcohol content, heavy metal content). (Upon request)

7.1.12 Finished product sample with full labelling (in English or Arabic), including product name, intended use, warnings/precautions, batch number, expiry date, and manufacturer or license holder details, along with final artwork.

7.2 Application for renewal of registration

Renewal of registered products shall be submitted with the following documents six months prior to expiration of registration:

7.2.1 Valid legalized Free Sale Certificate issued or attested by a relevant authority in the country of origin confirming that the product is classified and freely sold as a cosmetic under the same name, formula, and intended use, including details of the manufacturer and/or marketing authorization holder and applicable regulatory framework legalized by Kuwait embassy (electronic issued certificates with electronic verification tool are acceptable without legalization).

7.2.2 Detailed quantitative Certificate of Composition for both active and inactive ingredients, issued by the manufacturer or marketing authorization holder.

7.2.3 Valid Good Manufacturing Practice (GMP) or International Organization for Standardization (ISO: 22716) certificate issued from relevant authority in country of origin. (electronic issued certificates with electronic verification tool are acceptable).

7.2.4 Updated official letter confirming there is still ongoing relationship between the MAH and the local agent in Kuwait.

7.3 Application for registration of locally manufactured products in Kuwait

The applicant shall submit the following documents:

7.3.1 Valid Copy of GMP certificate issued by Medicine and Medical Products Registration and Regulatory Administration.

7.3.2 Full product details including name, composition (active/inactive with concentrations), and intended use.

7.3.3 Certificate of analysis complying with the quality specification (e.g., color, smell, pH, alcohol content, heavy metal content) and contamination – free certificate issued from MOH certified laboratory or the approved manufacturer laboratory.

7.3.4 Shelf-life declaration (upon request.)

7.3.5 Scientific evidence supporting the product's safety and efficacy (upon request).

7.3.6 Certificate confirming the safety and efficacy of cosmetic products with medicated features.

7.3.7 BSE/TSE Free for ingredients from animal origin, and pathogen-free certification for products with biological additives (if applicable).

Note:

• Application shall only be accepted and processed if it is complete, the administration may during the evaluation of the product request for additional information or clarification or samples from the applicant.

• The manufacturing shall start only after the consent of the Medicine and Medical Products Registration and Regulatory Administration has been granted.

7.4 Application for Free Sale Certificate for local manufacturer (export Purpose):

The applicant shall submit the following documents:

7.4.1 A cover letter addressed to Medicine and Medical Products Registration and Regulatory Administration, stating the products name and country of exportation.

7.4.2 Valid certificate of registration issued by Medicine and Medical Products Registration and Regulatory Administration for locally manufactured products.

7.4.3 Valid copy of GMP certificate issued by Medicine and Medical Products Registration and Regulatory Administration

• The sale of products in Kuwait or export of cosmetic preparation shall start only after the manufacturer receives Good Manufacturing Practice (GMP) certificate issued by the administration and products are registered.

• The export of cosmetic preparation shall start only after the manufacturer receives Good Manufacturing Practice (GMP) certificate issued by the administration.

7.5 Customized cosmetic preparations that are manufactured/ prepared to be sold in the State of Kuwait only:

Applicants must submit the following documents:

7.5.1 Valid legalized letter of appointment from the marketing authorization holder, regional distributor in case the legal relation is clearly mentioned, appointing a local agent in Kuwait, legalized by Kuwait embassy in the country of origin and chamber of commerce in country of origin.

7.5.2 Legalized certificate from the competent authority in the country of origin confirming classification as a cosmetic product freely sold under the same name or other name, ingredients, and intended use in the country of origin.

7.5.3 If a Free Sale Certificate cannot be provided, a justification letter must be submitted explaining the reason, accompanied by an authorized declaration.

7.5.4 Valid Good Manufacturing Practice (GMP) certificate or ISO 22716, certificate issued by the relevant authority in the country of origin, (electronic issued certificates with electronic verification tool are acceptable).

7.5.5 Full product details including name, full composition with concentrations, and intended use.

7.5.6 Product label showing name and product information.

7.5.7 Certificate confirming product safety and the absence of hormones, corticosteroids, Carcinogenic Mutagenic Reprotoxic (CMR) and prohibited substances or additives (including banned colorants and preservatives).

7.5.8 Certificate from the country of origin confirming biological ingredient safety (BSE/TSE Free and pathogen-free), if applicable.

7.5.9 Studies demonstrating the efficacy and safety of products with medicated features. (Upon request)

Note:

The applicant is responsible for the product and documentation provided. Applications will be processed only if complete. Medicine and Medical Products Registration and Regulatory Administration may request additional information or samples, and the application will be held until all requirements are met.

8. LABELING REQUIREMENTS

The label shall conform with the below mentioned specifications in force in the state of Kuwait and must be written in Arabic and /or English.

Requirements for labeling for cosmetic preparation should be as follow:

8.1 The label must include:

- Product name
- Net quantity (volume or weight)
- Manufacturer's name/ MAH name
- Country of origin
- Full list of ingredients
- Directions for use and intended use
- Batch number
- Date of manufacture and expiry (if applicable)

8.2 The expiry or minimum durability date must be clearly indicated in month/year or day/month/year format. Additional usage conditions may be required to ensure product stability.

8.3 Indication of the date of minimum durability shall not be mandatory for cosmetic products with a minimum durability of more than 30 months. For such products, there shall be an indication of the period of time after opening for which the product is safe and can be used without any harm to the consumer. This information shall be indicated, except where the concept of durability after opening is not relevant, by the symbol Period after opening (PAO).

8.4 The declaration of time period after opening as stated in point no.8.2 is not
relevant in the following cases:

a) Products presented in containers where there is no need of physical opening and
there is no possibility of contact between the product in the container with the
external environment (e.g. sealed pressurized containers)

b) Single-application products.

c) Products with a low microbiological contamination risk such as those with
pH≥10.0, pH≤3.5, high alcohol content (e.g. perfumes, eau de cologne, ...)

8.5 Specific precautions to be observed during the use of cosmetic products must be indicated on the product labels.

8.6 Special warnings shall be printed on the label both in Arabic and/or in English.

eg: tanning products that does not contain sunscreen ingredients must have the warning 'Does not contain any sunscreen agent must use any sunscreen product before sun exposure".

8.8 All this information shall be printed in an indelible and irremovable manner.

8.9 Where it is not feasible to print all required information on the package, the data must be included on an enclosed leaflet, or attached label.

8.10 Preparations that are used for hair dying, hair highlighters, hair straighteners, depilatories shall contain all label information including direction of use, sensitivity test, precautions, warning if any in both Arabic and/or English.

8.11 The INCI names of ingredients shall appear on the ingredient list of the label and shall contain aroma and the solvents used, colorants (Colorants other than intended to color the hair shall be listed with Color Index (CI no.) in order after other cosmetic ingredients.

8.12 Fragrance components must be declared as "parfum" or "aroma," and any allergens listed under Annex III of EU Regulation 1223/2009 and GSO 1943 must also be identified.

8.13 Nano materials used in cosmetic preparations shall be indicated by the suffix 'nano' after the INCI name of the ingredient.

8.14 The product function must be clearly stated on both the primary and secondary packaging, unless it is obvious from presentation, naming, function claims, or visual symbols.

9. LABORATORY ANALYSIS

In Cases where a laboratory analysis is requested by Medicine and Medical Products Registration and Regulatory Administration, authorized representative must submit samples and method of analysis if necessary.

10. LICENSE

Registration approval certificate will be granted for a period of 5 years upon fulfillment of all the requirements

11. IMPORTATION AND CLEARENCE PROCEDURE

Release of goods are carried out as per the ministerial regulation governing release of all products

12. ADVERTISEMENT

Advertisement for any registered cosmetic product follows the rules and regulations governing advertisement of medical products in Kuwait.

13. PACKAGING AND CLAIMS

- Packaging must preserve product integrity and ensure consumer safety.
- All claims must be truthful, evidence-based, and non-misleading, in accordance with these guidelines; GSO standards, and EU regulations.

14. PROHIBITTED AND RESTRICTED SUBSTANCES

Ingredients used for the cosmetic preparations must be in compliance with:

➢ Gulf Technical Regulation (GSO-1943) and their Annexes on banned/ restricted / prohibited substances and its updates.

➢ Annexes II for prohibited, III for restricted, IV-VI for colors, preservatives, UV filters in EU cosmetic Regulation EC 1223/2009 and its updates

And must be free from:

➢ Materials which are poisonous or deleterious substances which may render the content harmful or injurious to health including CMR declared substances.

➢ Decayed, spoiled or decomposed materials

➢ Materials that have been prepared processed or filled by improper method, which expose the materials to contamination

➢ Cosmetic materials are considered misleading if the external label
bears incorrect information or does not confirm with the specification of the ministerial decree.

15. POST MARKET SURVEILLANCE

➢ Registered products are subjected to market inspection, random sampling, and laboratory analysis.

➢ Adverse reactions or consumer complaints should be reported to Kuwait pharmacovigilance Center.

16. FEES

Applicable fees specified in the ministerial decree regulating fees for ministry of health control services should be paid.

17. APPLICATION FOR AGENCY TRANSFER

The applicant must submit the following document:

17.1 Valid legalized letter of appointment for new local agent, from the Marketing Authorization Holder or regional distributor in case the legal relation is clearly mentioned in the original issued letter of appointment.

17.2 Valid Legalized termination letter of the old local agent and Marketing Authorization Holder or regional distributor in case the legal relation is clearly mentioned in the original issued letter of appointment, including termination date.

18. APPLICATION FOR VARIATION DURING VALID REGISTRATION

- Any Changes in the registered product during the valid registration period, should be submitted to Medicine and Medical Products Registration and Regulatory Administration prior to the implementation by the manufacturer/ MAH For any type of variation set of required documents should be submitted.
- Variation guidelines will be followed as per memo issued by Medicine and Medical Products Registration and Regulatory Administration.

19. REGISTRATION SUSPENSION CIRCUMSTANCES:

A cosmetic product registration may be Suspended based on Medicine and Medical Products Registration and Regulatory Administration evaluation under the following conditions:

- Notification from international regulatory authorities on warnings about the product or its manufacturing site
- Proven toxicity or serious adverse effects
- Submission of falsified documents or inconsistencies between submitted and verified data.
- Non-compliance with specifications approved by Medicine and Medical Products Registration and Regulatory Administration
- Detection of undeclared medicinal ingredients during analysis
- Non-compliance with GMP or ISO standards.
- Ban or suspension of the product in the country of origin or any other country due to safety, quality, or efficacy concerns

20. REGISTRATION CANCELLATION CIRCUMSTANCES:

A cosmetic product registration may be cancelled based on Medicine and Medical Products Registration and Regulatory Administration evaluation under the following conditions:

- Non-compliance with specifications approved by Medicine and Medical Products Registration and Regulatory Administration
- Voluntary cancellation request from the Marketing Authorization Holder, with justification
- Notification from international regulatory authorities regarding warnings about the product or its manufacturing site
- Failure by the authorised representative to renew registration or failure by the MAH to meet renewal requirements.
- Detection of undeclared medicinal ingredients during analysis
- Non-conformity with these guidelines
- Ban or cancellation of the product in the country of origin or any other country due to safety, quality, or efficacy concerns.
- Proven toxicity or serious adverse effects
- Submission of falsified documents or inconsistencies between submitted and verified data.

21. LEGALIZATION OF DOCUMENTS

The following documents must be duly legalized:

- Free Sale Certificate, issued or attested by the health authority or governmental body responsible for cosmetic regulation. This Certificate should be legalized by Kuwait embassy in the country of origin. In Cases Where a Kuwait embassy is not available, legalization by any other GCC embassy present in the country of origin will be accepted to fulfil the registration requirements in Kuwait.
- Valid GMP or ISO 22716 Certificate, should be attested by Kuwait embassy in the country of origin. In Cases Where a Kuwait embassy is not available, legalization by any other GCC embassy present in the country of origin will be accepted to fulfil the registration requirements in Kuwait.
- Letter of Appointment should be legalised by Kuwait embassy and chamber of commerce in the country of origin.
- Certificates issued from GCC authorities, are exempted from legalization.
- Electronic verification methods are also acceptable if applicable as proof of authenticity without need of paper legalization.

Table showing the legalization requirements of registration documents:

Document	Local Manufacturing Company	GCC manufacturing Company	International Manufacturing Company
Authorization/ Appointment Letter	Confirmation letter stating that the local manufacturing company is the authorized representative/agent	Valid Original letter Legalized by the chamber of commerce and Kuwait embassy in the Country of origin.	Valid Original Legalized by the chamber of commerce and Kuwait embassy in the Country of origin.
Good Manufacturing Practice (GMP)/ISO 22716 (For any manufacturing site)	Valid Good Manufacturing Practice certificate for the Kuwait local manufacturing company issued from Medicine and Medical Products	Valid Good Manufacturing Practice or ISO certificate related to the product's scope for the GCC	Valid Original Good Manufacturing Practice certificate for the international manufacturing

	Registration and Regulatory Administration after Inspection for the manufacturer to ensure the implementation of Good Manufacturing Practice (GMP).	manufacturing company issued from the regulatory authority in the Country of Origin.	company issued from the regulatory authority in the Country of origin/ ISO 22716 legalized by Kuwait embassy in the Country of origin.
Free Sale Certificate FSC	To be issued upon request of the manufacturing company by Medicine and Medical Products Registration and Regulatory Administration for exportation purpose	Valid Original FSC issued from health authority or concerned governmental authority for cosmetics in the country of origin	Valid Original FSC issued from health authority or concerned governmental authority for cosmetics in the country of origin and legalized by Kuwait embassy in the Certificate of origin

REFERENCES

- GCC Standardization Organization (GSO 1943/2016) for Safety Requirements of Cosmetics and Personal Care Products and their annexes
- GSO 2528 Gulf Technical regulation for Cosmetic and personal care products claims
- EU Regulation (EC No. 1223/2009 on Cosmetic Products)
- Food and Drug Administration (FDA), USA
- GCC Unified Cosmetic Regulations
- WHO Guidelines on Regulatory Oversight of Cosmetics (as supportive Reference)
- Cosmetic ingredient Review–CIR
- Cosmetic ingredient Hot List/ Canada