Newsletter

REGULATORY BRAINBOX

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Medical Devices Regulatory Consultancy

OCTOBER NEWSLETTER

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OMC MEDICAL
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REGULATORY SERVICES

Our mission is to support our clients in launching their products in various markets.

Who we are?

OMC Medical is primarily based in the UK with offices around the globe offering regulatory support to medical device manufacturers and distributors

- ✓ EU MDR and IVDR compliance
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MEDICAL DEVICES

COSMETICS

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EU Releases New MDCG Documents | October 2024

The EU has released new MDCG documents, updating guidance on medical device regulations to clarify compliance requirements and best practices for manufacturers.

Title	Overview
MDCG 2021-25 rev.1 - Application of MDR requirements to "legacy devices" and to devices placed on the market prior to 26 May 2021 - October 2024 ***MDCG 2021-25 rev.1***	The document explains that legacy devices with valid certificates under previous directives must adhere to specific MDR requirements, including post-market surveillance, vigilance, and registration. It outlines transitional provisions to ensure these devices meet essential safety and performance standards as they shift towards full MDR compliance. The revision also offers updated guidance to help manufacturers manage regulatory challenges, ensuring continued market access for legacy devices during the transition.
Corrective and preventive action (CAPA) plan assessment: guidance and templates for conformity assessment bodies, notified bodies, designating authorities, and joint assessment teams ***Annex I: Template CAPA plan and assessment thereon - MDCG 2024-12 Annex I Form*** ***Annex II: Template JAT review of the CAPA and the DA's opinion - MDCG 2024-12 Annex II Form***	This guidance and templates provides structured tools for conformity assessment bodies, notified bodies, designating authorities (DAs), and joint assessment teams (JATs) to evaluate and document CAPA plans effectively. The guidance includes two key annexes: • Annex I: A template for drafting and assessing a CAPA plan, ensuring it addresses identified issues and outlines corrective actions comprehensively. • Annex II: A template for the JAT's review of the CAPA plan, along with the DA's formal opinion, facilitating a consistent and transparent assessment process. These templates support regulatory bodies in standardizing CAPA evaluations, improving conformity, and ensuring continuous improvement in device safety and compliance.

Guidance on qualification of in vitro diagnostic medical devices ***MDCG 2024-11***	This guidance document clarifies the qualification and classification of in vitro diagnostic (IVD) medical devices under the EU In Vitro Diagnostic Regulation (IVDR). It explains criteria to determine if a product qualifies as an IVD, aiding manufacturers in ensuring regulatory compliance. Key areas include the IVD definition, examples of qualifying products, and scenarios where a product may or may not be considered an IVD. This support helps manufacturers assess devices and navigate classification effectively.

UNITED KINGDOM (UK)

New Guidance for Reporting Issues with Insulin Pumps and Continuous Glucose Monitoring (CGM) Devices | 24 October 2024

The UK Medicines and Healthcare products Regulatory Agency (MHRA) has issued guidance to improve the reporting of suspected adverse events and safety concerns associated with insulin pumps and continuous glucose monitors (CGMs) via its Yellow Card scheme. This guidance is intended to help both users and healthcare professionals streamline the reporting process, ultimately aiding in the early detection of issues that could pose serious risks.

Users of diabetes management devices are encouraged to report any suspected device malfunctions promptly and to switch to alternative diabetes management methods if issues arise. The guidance also includes detailed instructions to assist patients in submitting comprehensive incident reports, which are essential for effective investigations.

Additionally, clinics are advised to display a QR-coded poster from the MHRA linking to the reporting guidance, and healthcare professionals are encouraged to collaborate with local Medical Device Safety Officers (MDSOs) for further support. This initiative seeks to improve the volume and quality of information received by MHRA, addressing challenges previously posed by insufficient reporting details.

UK Introduces Groundbreaking Regulatory Framework for Innovative Medicines at Point of Care | 21 October 2024

The UK has introduced a pioneering regulatory framework aimed at enabling the manufacture of highly personalized medicines, such as cell and gene therapies, at or near the point of patient care. Established through a Statutory Instrument presented to Parliament on 21 October, this framework supports the on-site or portable production of medicines with short shelf lives, allowing hospitals and care facilities to rapidly produce and administer these treatments.

This flexibility is especially beneficial for patients in critical need, reducing the burden of travel and ensuring timely, safe access to advanced therapies.

Additionally, by supporting medicine production closer to patients, the regulation will foster the growth of "hospital at home" services, including virtual wards, which can ease healthcare facility pressures and enhance community and home-based care. This strategic move places the UK at the forefront of healthcare innovation, offering more efficient and personalized treatments.

UNITED STATES OF AMERICA (USA)

FDA's Emergency Use Authorization: Expanding Ventilator Access in Public Health Emergencies | 16 October 2024

The FDA issued an Emergency Use Authorization (EUA) on March 24, 2020, to address the shortage of ventilators during the COVID-19 pandemic. This umbrella EUA permits the emergency use of certain ventilators, modified anesthesia gas machines, positive pressure devices adapted for ventilator use, ventilator tubing connectors, and accessories, provided they meet FDA safety, performance, and labeling standards.

This authorization is limited to the use of ventilators and related accessories for patient care in healthcare settings.

FDA Issues Correction to Final Rule on Medical Device Quality System Regulation Amendments | 15 October 2024

The U.S. Food and Drug Administration (FDA) has issued a correction to a final rule that was published in the Federal Register on February 2, 2024. This final rule amended the device current good manufacturing practice (CGMP) requirements of the Quality System (QS) regulation, aiming to harmonize and modernize the standards for medical device manufacturing practices.

The correction addresses an editorial oversight that resulted in the omission of a definition in the codified section of the final rule. While the error was purely editorial and does not alter the substance of the regulation, the FDA's correction ensures the document's accuracy and clarity, reflecting the Agency's commitment to maintaining precise and comprehensive regulatory standards.

This adjustment is part of the FDA's ongoing efforts to enhance regulatory frameworks and align them with international standards, supporting the safety and effectiveness of medical devices on the market.

FDA Introduces Safety and Performance-Based Pathway for Medical Devices | 11 October 2024

The FDA has introduced a new Safety and Performance-Based Pathway to streamline the approval of certain low to moderate-risk medical devices. This pathway allows manufacturers to demonstrate safety and effectiveness through performance-based assessments instead of traditional clinical trials, using existing data and real-world evidence to expedite submissions.

The initiative is expected to benefit devices such as diagnostic tools, monitoring equipment, and therapeutic devices, supporting faster access to innovative technologies while prioritizing patient safety. Detailed guidance on this pathway will be provided to outline specific requirements for manufacturers.

Algeria Conducts First-Ever Bioequivalence Study, Advancing Pharmaceutical Sector | 28 October 2024

Algeria has reached a major milestone in its pharmaceutical industry with the completion of its first bioequivalence study, marking progress toward producing high-quality generic drugs that meet international standards. The study, done in partnership with local and international experts, confirmed the therapeutic equivalence of a locally made generic drug to its branded version.

This achievement underscores Algeria's commitment to strengthening its pharmaceutical infrastructure, supporting local innovation, and providing accessible, affordable medicines.

It also enhances regulatory confidence and may attract further investment, impacting both Algeria’s healthcare system and the broader African market.

Health Minister Welcomes UNAIDS Representative in Algeria | 24 October 2024

On October 28, 2024, Algeria's Minister of Health, received a representative from UNAIDS, the Joint United Nations Programme on HIV/AIDS, in Algiers. The meeting focused on strengthening the partnership between Algeria and UNAIDS to enhance the country's response to HIV/AIDS.

During discussions, both parties highlighted Algeria's progress in HIV prevention, treatment, and care, while also addressing the need for increased awareness and outreach. The UNAIDS representative praised Algeria’s efforts in combating the epidemic and pledged continued support to further the country's strategic goals in achieving the 2030 target of ending AIDS as a public health threat.

This visit marks another step in Algeria’s commitment to global health initiatives and reaffirms its collaboration with international organizations to combat HIV/AIDS.

ARGENTINA

ANMAT Clarifies Provincial Governments' Authority to Import Medicines Independently | 04 October 2024

Argentina's National Administration of Drugs, Food, and Medical Technology (ANMAT) recently clarified that provincial governments can import medicines independently, without needing ANMAT or Ministry of Health approval, provided they oversee quality, safety, and efficacy standards.

Only provincial health departments may import without additional authorization, though customs rules still apply. Imported medicines must be used exclusively within the importing province, and compliance with all regulatory standards is mandatory.

While Law 16.463 and Decree 9763/64 allow provinces to request ANMAT's support in drug control, most have opted to manage public health decisions independently. ANMAT remains available to collaborate with provinces to uphold drug standards.

AUSTRALIA

3G Network Shutdown Set to Impact Medical Devices and Personal Alarms| 11 October 2024

Australia's upcoming 3G network shutdown could disrupt older medical and personal safety devices reliant on 3G connectivity, impacting functions like emergency calls and data transmission.

Devices potentially affected include cardiac monitors, pacemakers, glucose transmitters, CPAP machines, wearable health monitors, and personal safety pendants.

The TGA recommends that users contact suppliers to check device compatibility and consider replacements if critical functions depend on 3G.

Manufacturers are encouraged to proactively inform customers about risks, especially those in rural areas. Additional guidance is available from Telstra and AMTA.

BRAZIL

Anvisa Streamlines Medicine Classification Process with New Codes| 25 October 2024

Anvisa has introduced changes to the petition process for determining prescription requirements for medicines, effective October 29.

The update, guided by Collegiate Board Resolution (RDC) 882/2023, introduces new subject codes to classify medicines more accurately as over-the-counter (OTC) or prescription-only. This affects various categories, including generic, innovative, phytotherapeutic, and biological medicines.

The restructuring decentralizes responsibilities, allowing technical areas to handle specific protocols, which is expected to expedite evaluations. Companies with pending requests filed before October 29 need not take any action, as these will be reassigned automatically to the appropriate code for streamlined processing.

ANVISA Updates Health Service Regulations with Format Adjustments in Line with New Decree | 14 October 2024

In September, Anvisa released five Collegiate Board Resolutions (RDCs) concerning health services, following the review and consolidation of regulatory acts mandated by Decree 12,002 (April 22, 2024). These updates were solely for formatting purposes, as specified by the decree's guidelines. Below are the published standards, along with a brief overview of this review and consolidation effort:

Published standard	Summary	Replaced (revoked) standard
COLLEGIATE BOARD RESOLUTION - RDC 916, OF SEPTEMBER 19, 2024	Offers best practices for the use of parenteral solutions (SP) in healthcare services.	Resolution of the Board of Directors - RDC 45, of March 12, 2003; and Resolution of the Board of Directors – RDC 9, March 3, 2009

Published standard	Summary	Replaced (revoked) standard
COLLEGIATE BOARD RESOLUTION - RDC 917, OF SEPTEMBER 19, 2024	Supports the operation of services that deliver home care.	Resolution of the Board of Directors - RDC 11, of January 26, 2006
COLLEGIATE BOARD RESOLUTION - RDC 918, OF SEPTEMBER 19, 2024	Provides for the operation of Human Milk Banks.	Resolution of the Board of Directors - RDC 171, of September 4, 2006
COLLEGIATE BOARD RESOLUTION - RDC 919, SEPTEMBER 19, 2024	It ensures the planning, programming, preparation, evaluation, and approval of Water Treatment and Distribution Systems for Hemodialysis within the National Health Surveillance System.	Resolution of the Board of Directors - RDC 33, of June 3, 2008
COLLEGIATE BOARD RESOLUTION - RDC 920, OF SEPTEMBER 19, 2024	Supports the Operation of Obstetric and Neonatal Care Services.	Resolution of the Board of Directors - RDC 36, of June 3, 2008

The updates to these regulations were purely structural, aligning the text with current legislative standards on formatting and organization (e.g., chapters, articles). No substantive changes were made to the regulations themselves. This consolidation aligns with Anvisa's ongoing effort, initiated in 2019, to review all agency standards to improve coherence and eliminate outdated language.

Anvisa Launches New Integrated Registry System to Streamline Access and Improve Efficiency| 09 October 2024

Anvisa has launched a new integrated registry system that consolidates four previously separate registries, aiming to enhance efficiency and access for users. The updated platform, aligned with federal administration best practices, enables profile management, batch assignments, audits, and streamlined search capabilities for organizations and employees.

Organizations can register by validating their link through Gov.Br, allowing legal representatives to manage profiles and assign registration managers who can add employees with Gov.Br accounts. The Solicita System is the first integrated module, with future integrations planned. Anvisa's modernization addresses past issues with outdated systems, promising a more reliable user experience.

Costa Rica and PAHO Collaborate to Strengthen Medical Regulatory Systems | 16 October 2024

Authorities from Costa Rica's Ministry of Health and the Pan American Health Organization (PAHO) have launched a three-day workshop aimed at restructuring Costa Rica's Directorate for the Regulation of Products of Sanitary Interest (DRPIS). This initiative forms part of a broader policy to strengthen national regulatory frameworks for medicines and medical devices across the Americas.

Since 2023, Costa Rica has sought to enhance DRPIS, leading to a proposed reorganization that will split the current Standardization and Control Unit into two separate units: the Standardization Unit and the Surveillance and Control Unit. This change will help address regulatory functions that DRPIS previously did not manage.

The workshop will cover DRPIS's roles and outline next steps for ongoing regulatory improvements.

New Reporting Application for Medicinal Products Set to Launch | 21 October 2024

The State Institute for the Control of Medicines (SÚKL) is set to launch a new application designed to facilitate compliance with reporting obligations under the Medicinal Products Act. This application aims to streamline notifications related to the introduction, interruption, renewal, or termination of medicinal product marketing by registration holders.

Users will access the application through existing authentication certificates, allowing them to view, edit, or cancel their submitted reports while also providing a history of changes.

One notable feature is the requirement for holders to submit a Recovery Plan for products designated as "limited availability," detailing corrective measures taken. Additionally, the application will allow reporting exclusively for the user's own products and enable bulk submissions for multiple products.

A testing environment is currently available, with the official launch expected by the end of 2024. After this date, only authorized individuals will be able to submit reports, as SÚKL will no longer enter reports on behalf of holders.

Pharmacy Operators Warned About Mail-Order Dispensing Regulations | 21 October 2024

The State Institute for the Control of Medicines has alerted pharmacy operators about their responsibilities when dispensing medicinal products via mail using self-service boxes. Pharmacies are accountable for the quality of products delivered, even if third-party equipment is used, as per Act No. 378/2007 Coll. They must also document compliance with transport conditions outlined in Decree No. 84/2008 Coll., ensuring proper handling based on product specifications.

The Institute recommends using validated self-service boxes with regulated temperature and humidity to maintain storage conditions. Non-compliance can result in penalties of up to CZK 2,000,000.

Egyptian Drug Authority Strengthens Collaboration with Medical Professionals | 22 October 2024

In a significant move to enhance the quality of healthcare services in Egypt, the Chairman of the Egyptian Drug Authority (EDA) convened with the Head of the Egyptian Doctors Syndicate and representatives from the Egyptian Pharmacists Syndicate.

The meeting aimed to foster cooperation among key stakeholders in the health sector to ensure the provision of safe and effective medications for Egyptian patients.

This gathering highlights the EDA's commitment to sustainable collaboration between doctors and pharmacists, which is vital for improving healthcare standards. Attendees emphasized the necessity of partnerships among various entities to guarantee that medicines are delivered to patients with the utmost safety and quality. Such initiatives are expected to bolster public confidence in the Egyptian health system and enhance the overall quality of life for citizens.

Egypt Boosts Local Pharmaceutical Industry Amid Global Challenges | 22 October 2024

The Egyptian Drug Authority and the Arab African Company met to enhance the local pharmaceutical industry and achieve self-sufficiency in medical supplies amid global healthcare challenges. They discussed the Authority's technical support for localizing the production of pharmaceutical raw materials, aiming to reduce costs for the state and consumers. The Authority emphasized its commitment to creating an attractive investment environment for the health sector.

The Arab African Company highlighted its progress in localizing medical supplies, with a shared goal of improving healthcare quality and contributing to national security and economic stability.

New Payment Requirement for Medical Device Companies in Italy | 01 October 2024

Starting this year, companies in the medical device sector in Italy must pay an annual fee of 0.75% of their turnover from the sale of medical devices, large equipment, and in vitro diagnostic medical devices to the National Health Service (NHS). This payment is due between November 1 and December 31 each year and can be made online through the Ministry's Online Payments platform, integrated with PagoPA.

The funds collected will be directed to the Medical Devices Governance Fund, which supports the governance of medical devices in the country. A significant portion of this funding—one third—will be allocated to the National Agency for Regional Health Services (Agenas) to support the national program for the evaluation of medical devices (HTA).

The Ministry of Health formalized the payment criteria and the management of the governance fund with a decree issued on December 29, 2023.

South Africa and Australia Enhance Collaboration in Health Product Regulation | 07 October 2024

The South African Health Products Regulatory Authority (SAHPRA) and the Australian Therapeutic Goods Administration (TGA) have signed a Memorandum of Understanding (MoU) to enhance their collaboration in health product regulation.

This agreement aims to improve the assessment and monitoring of medical products and therapeutic goods, focusing on efficacy, safety, and quality post-registration. Key initiatives include data sharing and strengthening pharmacovigilance programs. The partnership seeks to leverage each regulator's strengths, ultimately improving therapeutic outcomes for their respective populations.

New Guidelines and Protocols for Medical Device Regulation | 09 October 2024

The Tanzania Medicines and Medical Devices Authority (TMDA) would like to inform its valued stakeholders that it has developed three (3) new guidelines and six (6) protocols for the regulation of medical devices and in-vitro diagnostic devices, as outlined below:

- Guidelines on Good Review Practices for Regulation of Medical Devices, March, 2024;
- Compendium of Guidelines for Marketing Authorization of Medical Devices, Diagnostics and Laboratory Equipment, June, 2024;
- Guidelines for Conducting Performance Evaluation of In-Vitro Diagnostic Devices Submitted for Marketing Authorization, June, 2024;
- Protocol for Performance Laboratory Evaluation of Malaria Plasmodium Falciparum (PF) and MA PF/PAN Antigen Rapid Diagnostic Tests, First Edition, April, 2024;
- Protocol for Performance Laboratory Evaluation of Combined HIV and Syphilis Serology Assays, First Edition, April, 2024;
- Protocol for Performance Laboratory Evaluation of HIV Serology Assays, First Edition, April, 2024;
- Protocol for Performance Laboratory Evaluation of Hepatitis C Serology Assays, First Edition, April, 2024;
- Protocol for Laboratory Performance Evaluation of Hepatitis B Surface Antigen, First Edition April 2024;
- Protocol for Laboratory Performance Evaluation of SARS-CoV-2 Antigen Assays, First Edition April 2024;

TMDA to Release Medical Device and IVDD Assessment Reports | 04 October 2024

The Tanzania Medicines and Medical Devices Authority (TMDA) will begin publishing assessment reports (PARs) for registered medical devices and in-vitro diagnostic devices (IVDDs) that meet specific criteria. This initiative aims to enhance transparency and provide public access to information regarding the safety, quality, and performance of these products.

Eligible devices include those for treating or diagnosing infectious diseases like HIV and malaria, reproductive health products, and those used in public health emergencies. Reports will be published twice a year, and Marketing Authorization Holders will be notified prior to publication to protect any confidential information.

CDSCO Releases New Version of Medical Device Adverse Event Reporting Form | 08 October 2024

CDSCO has launched Medical Device Adverse Event Reporting Form Version 1.2 to improve the reporting process for adverse events associated with medical devices. Key updates include a streamlined process, expanded data fields, and a user-friendly design. The organization urges healthcare providers and consumers to utilize the new form, which is now available on the CDSCO website, to enhance patient safety and monitoring.

Report Highlights Safe Expansion of Over-the-Counter Drug Sales | 03 October 2024

A recent report from a working group appointed by the Ministry of Social Affairs and Health calls for safe and responsible expansion of over-the-counter (OTC) drug sales beyond pharmacies. The Finnish Medicines Agency (Fimea) supports this initiative, emphasizing that any changes must not compromise medication safety or effective treatment.

The report highlights the importance of careful preparation for providing medication counselling in various sales channels. Currently, only university-educated pharmacists can offer this counselling, which is essential for helping consumers self-manage their health.

To facilitate the sale of OTC drugs outside pharmacies, the report recommends requiring pharmaceutical companies to submit applications to Fimea for assessment. Additionally, Fimea should oversee these new retail outlets to ensure consistent supervision and safety.

Pricing strategies for OTC drugs are still under consideration, with options for complete deregulation or adherence to existing pricing limits. The overarching goal remains to expand access to medications while preventing inappropriate use.

SWITZERLAND

Swissmedic Releases Updated Documents on Human Tissue Notifications and Export Certificates for Medical Devices | October 2024

Two new regulatory documents have been released to provide updated guidance for the medical device and tissue product industries. These documents are critical for companies involved in the handling of devitalised human tissue and the export of medical devices. Below is a summary of the updates:

Document	Overview
BW630_30_008e_MB Notifications for Devitalised Human Tissue	This document outlines the updated procedures and requirements for notifications related to devitalised human tissue used in medical applications. The revisions aim to streamline the regulatory framework, ensuring clear compliance guidelines for companies working with these sensitive biological materials. The updates emphasize documentation, handling protocols, and reporting mechanisms to ensure the safe use of devitalised tissue in medical treatments.
BW690_00_001defi_FO Orders for Export Certificates for Medical Devices	This updated form addresses the procedures for obtaining export certificates for medical devices. The document provides detailed guidance on how manufacturers can request certificates needed for exporting medical devices to international markets. The form has been revised to include additional fields that reflect recent regulatory changes and improve the clarity of the process, making it easier for manufacturers to meet export requirements.

Both documents are essential for stakeholders involved in the development, sale, and distribution of medical devices and human tissue products. These updates align with the latest international standards and regulatory demands, aiming to improve transparency and safety in the global healthcare market.

SFDA Joins International Efforts to Harmonize Medical Device Regulations | 08 October 2024

The Saudi Food and Drug Authority (SFDA) has joined the International Medical Device Regulators Forum (IMDRF) to enhance alignment with global medical device standards. This move supports SFDA's commitment to international regulatory collaboration as part of its Fourth Strategy.

Through its membership, SFDA will contribute to IMDRF initiatives, including knowledge sharing, promoting regulatory convergence, and engaging in technical committees. The SFDA is also focused on creating guidelines for emerging technologies like AI, robotics, and digital health.

This partnership underscores the SFDA's commitment to advancing public health and safety in Saudi Arabia and globally.

INDONESIA

Indonesia Updates Implementation Regulation of Halal Product Assurance | 26 October 2024

Indonesia published and put into effect Government Regulation (GR) No. 42 of 2024 Concerning the Implementation of Halal Product Assurance on October 17, 2024. The following are the main changes:

- Defining the documents needed to appoint the halal supervisor;
- Modifying the deadlines for certain halal certification procedures;
- Elucidating the responsibilities of businesses holding halal certificates ;
- Defining the conditions for renewing a halal certificate from BPJPH;
- Establishing an exemption for halal labelling;
- Adjusting the timeline for renewing foreign halal certificate registration;
- Modifying the duration for renewing a foreign halal certificate registration; and
- Clarifying the requirements for halal certificate renewal.

Following the publication of Government Regulation (GR) No. 42 of 2024 Concerning Implementation of Halal Product Assurance 1, Indonesia's BPJPH declared on October 18, 2024, that the first stage of required halal certification would be formally enforced. All food and beverage products that enter, circulate, or are traded within Indonesia are subject to this rule. The implementation of required halal certification for imported food items has been delayed until 2026. On October 18, 2026, halal certification for cosmetics will become mandatory.

INDIA

India Reviewed Proposal for Mandating INCI Names on Cosmetic Labels | 23 October 2024

A proposal that required the addition of International Nomenclature of Cosmetic Ingredients (INCI) names in the ingredient statement on cosmetic product labels was evaluated by India's Drugs Consultative Committee (DCC) during its most recent meeting, which took place on June 19, 2024.

The plan sought to increase label transparency and improve ingredient identification.

Following careful consideration, the DCC determined that space limitations would make it impractical to include INCI names on cosmetic labels. Rather, the committee suggested that the cosmetics industry stick to the current ingredient labelling guidelines set forth by the Bureau of Indian Standards (BIS).

Current Cosmetic Labeling Requirements:

Significant product details, including the product name, manufacturer information, expiration date, batch number, and manufacturing license number, must be shown on both the inner and external labels in accordance with the Cosmetics Rules 2020 (the "2020 Rules"). The product's net contents must also be disclosed on its external label. The inner label of a cosmetic product must include information on the potential hazardous substances, warnings, and clear instructions for safe usage. The import registration certificate number must appear on the label of imported cosmetics. The phrase "INGREDIENTS" should appear before the entire list of ingredients. Ingredients with concentrations greater than 1% should be presented in decreasing weight or volume order, followed by those with lower concentrations.

Additionally, as stated in the Ninth Schedule of the 2020 Rules, cosmetics must adhere to any labelling requirements that may be included in the applicable Indian standard established by the BIS. Standards for 37 cosmetic goods, such as skin powders, shampoos, hair oils, nail paint, and lipstick, are currently included in the Schedule.

Thailand Approved Eight TIS Standards for Cosmetics | 23 October 2024

The approval of eight new voluntary Thai Industrial Standards Institute (TIS) cosmetics standards was published by Thailand's Ministry of Industry in the Official Gazette on October 1, 2024. These guidelines address a number of topics that are essential to the safety and quality of cosmetics, such as analytical techniques, microbiological testing, the assessment of sun protection, and natural and organic cosmetic ingredients.

All eight of the criteria became operative on October 2, 2024. TISI has not yet released the complete wording of these guidelines; companies interested in more detailed information are encouraged to speak with the Institute directly.

Details of the eight approved standards are as follows:

Standards	Introduction
TIS 3794-2567 (2024) Cosmetics - Microbiology - General Instructions for Microbiological Examination	This is a general guideline for appropriate microbiological testing and risk analysis of some cosmetic products (e.g., low water activity products, aqueous alcohol products, and high pH products) to ensure their quality and safety. Given the variety of cosmetic products, this guideline may not be applicable to certain types of products (e.g., some products that are water-insoluble).
TIS 3795-2567 (2024) Cosmetics - Microbiology - Microbiological Limits	This guideline applies to all types of cosmetic products for the assessment of microbiological quality. Products deemed to have low microbiological risk, as per ISO 29621, are exempt from microbiological testing requirements.
TIS 3796-2567 (2024) Cosmetics - Microbiology - Detection of Specified and Non-Specified Microorganisms	This standard provides methods for detecting and identifying microorganisms in cosmetic products that can grow at moderate temperatures. While specific microorganisms like **Pseudomonas aeruginosa**, **Escherichia coli**, **Staphylococcus aureus**, and **Candida albicans** are commonly included, the list may vary by country. To ensure product quality and consumer safety, stakeholders should conduct a microbiological risk assessment. Low-risk products, such as those with low water activity, alcohol-based formulations, or high pH, may be exempt from testing. Alternative methods, like automated systems, may be used if proven equivalent or suitable.

Standards	Introduction
TIS 3797-2567 (2024) Cosmetics - Analytical Methods - Nitrosamines: Detection and Determination of N-Nitrosodiethanolamine (NDELA) in Cosmetics by HPLC, Post-Column Photolysis and Derivatization	This standard outlines a method for detecting and measuring N-nitrosodiethanolamine (NDELA) in cosmetics and cosmetic raw materials using high-performance liquid chromatography (HPLC), post-column photolysis, and derivatization. It excludes the analysis of non-NDELA nitrosamines, non-cosmetic products or raw materials, and compounds with oxidative dyes. For potential NDELA contamination or formation in products, ISO 15819 is recommended as an alternative testing method.
TIS 3798-2567 (2024) Cosmetics - Analytical Methods - Validation Criteria for Analytical Results Using Chromatographic Techniques	This standard establishes criteria for verifying analytical results obtained from cosmetic product analysis. It also specifies the analytical methods that laboratories can use to analyze samples through chromatography techniques.
TIS 3799-2567 (2024) Cosmetics - Analytical Methods - Nitrosamines: Detection and Determination of N-Nitrosodiethanolamine (NDELA) in Cosmetics by HPLC-MS-MS	This standard outlines the method for detecting an determining N-nitrosodiethanolamine (NDELA) in cosmetics and cosmetic raw materials. It can neither be applied to the detection or quantification of non-NDELA nitrosamines, nor be used for non-cosmetic products or raw materials.
TIS 3800-2567 (2024) Cosmetics - Sun Protection Test Methods - Water Immersion Procedure for Determining Water Resistance	This standard outlines a procedure for assessing the water resistance of sunscreen products via immersion testing. It applies to sunscreens that protect against UV radiation through UV-absorbing, reflecting, or scattering ingredients, including water-removable additives. This testing should be used alongside SPF determinations as specified in ISO 24444.

Standards	Introduction
TIS 3801 Volume 1-2567 (2024) Guidelines on Technical Definitions and Criteria for Natural and Organic Cosmetic Ingredients and Products - Part 1: Definitions for Ingredients	This standard outlines guidelines for defining natural and organic ingredients in cosmetics but does not address product claims, safety, social or economic factors, packaging, or legal requirements. It also recognizes that some non-natural ingredients may be necessary in formulating natural and organic cosmetics.

Anvisa's Cosmetics Technical Chamber Launches Platform for Knowledge Sharing | 25 October 2024

The Cosmetics Technical Chamber (Catec) has launched a new website to facilitate the sharing of technical knowledge related to personal hygiene products, perfumes, and cosmetics, supporting regulatory and safety matters in the industry.

Regulated by Ordinance 199 (March 24, 2022), the website provides access to Catec's structure, activity reports, and approved recommendations. Coordinated by Anvisa's General Management of Cosmetics and Disinfectants, Catec organizes meetings to discuss specific topics, increasing social participation in Anvisa's regulatory decisions.

The chamber includes 14 experts from academia, research institutions, professional associations, and public hospitals, serving three-year terms to ensure safe access to personal care products.

SINGAPORE

Health Authority Warns of Unsafe Products | 03 October 2024

The Health Sciences Authority (HSA) has issued an advisory about health products identified by international regulators in September 2024 as containing dangerous, prohibited ingredients. This warning aims to inform the public about potential health risks associated with these products, which may impact local consumers.

Annex A provides a list of the affected products, while Annex B details the possible side effects of the harmful ingredients. The HSA advises individuals who have consumed these products to seek medical attention if they feel unwell. Additionally, consumers are encouraged to avoid purchasing these products abroad and to exercise caution when buying health products online, especially from unfamiliar sources.

The HSA also warns against trusting products that make exaggerated claims of safety or effectiveness. For managing health conditions, individuals should consult a healthcare professional. The authority underscores the importance of being vigilant in health product purchases to safeguard public health.

List of ISO standards updated in October 2024:

- ISO 8536-13:2024 - Infusion equipment for medical use — Part 13: Graduated flow regulators for single use with fluid contact
- IEC 80601-2- 49:2018/Amd 1:2024 Medical electrical equipment — Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment — Amendment 1
- ISO 14630:2024 - Non-active surgical implants — General requirements
- ISO 7199:2024 - Cardiovascular implants and artificial organs — Blood-gas exchangers (oxygenators)
- ISO 80369-2:2024 - Small-bore connectors for liquids and gases in healthcare applications — Part 2: Connectors for respiratory applications
- ISO/TS 22583:2024 - Requirements and recommendations for supervisors and operators of point-of-care testing (POCT) equipment