Newsletter

REGULATORY BRAINBOX

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Medical Devices Regulatory Consultancy

JUNE NEWSLETTER

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OMC MEDICAL
Regulatory Services

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
- ✓ Global language translation
- ✓ Global product registrations and Maintenance
- ✓ Product/Process compliance
- ✓ Labelling and Unique Device Identification
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EUROPEAN UNION (EU)

Guidelines for Orphan Medical Devices under MDR: Enhancing Clinical Evaluation and Access | 25 June 2024

The Medical Device Coordination Group (MDCG) has issued guidelines to assist manufacturers and notified bodies in clinically evaluating orphan medical devices. These devices are intended for rare diseases with limited diagnostic and therapeutic options, crucial for addressing unmet medical needs. The guideline defines criteria under the Medical Devices Regulation 2017/745 (MDR) for qualifying as "orphan devices".

It aims to streamline compliance with MDR clinical evidence requirements, facilitating faster patient access to these critical devices. Manufacturers and notified bodies can also consult EMA expert panels for guidance on orphan device status and necessary clinical data.

Updated Guidelines on Benefit-Risk Assessment of Phthalates in Medical Devices | 18 June 2024

The updated guidelines aim to assess the risk of phthalates in medical devices, focusing on carcinogenic, mutagenic, toxic to reproduction (CMR), or endocrine-disrupting (ED) phthalates. They provide a comprehensive framework for evaluating the presence of these phthalates, ensuring patient safety and regulatory compliance.

Key elements include detailed criteria for assessing potential risks, acceptable exposure levels, and strategies for mitigating identified risks. The guidelines also outline documentation and reporting requirements for manufacturers to demonstrate compliance. The aim is to protect patients from harmful substances while ensuring the availability of essential medical devices.

MHRA releases guidance on Designation, Re-assessment, and Notification of Conformity Assessment and Notified Bodies | 17 June 2024

The MDCG 2022-13 Rev.1 document offers comprehensive guidance on the designating, re-assessing, and notifying of conformity assessment bodies and notified bodies within the regulatory framework. It aims to ensure these bodies meet strict requirements to maintain their designation and operate effectively under the Medical Devices Regulation (MDR) and In Vitro Diagnostic Medical Devices Regulation (IVDR).

The guidance aims to enhance the quality and reliability of conformity assessment and notified bodies, ultimately contributing to the safety and efficacy of medical devices and in vitro diagnostic devices.

MHRA releases guidance on Vigilance System for Urogynaecological Surgical Mesh Implants | 11 June 2024

The MDCG 2024-1-5 document offers comprehensive guidance on the vigilance system for CE-marked medical devices, particularly focusing on urogynaecological surgical mesh implants used for Pelvic Organ Prolapse (POP) repair and Stress Urinary Incontinence (SUI). It outlines procedures for monitoring the safety and performance of these devices post-market, including the reporting of adverse events and incidents and implementing corrective and preventive actions.

This guidance emphasizes the importance of specific considerations for urogynaecological surgical mesh implants, highlighting the need for thorough clinical evidence and robust post-market surveillance. By detailing the requirements for these implants, the document aims to ensure the highest safety standards and effective monitoring, thereby enhancing patient safety and device reliability.

Australian Government Announces New Regulatory Changes for Medical Devices |26 June 2024

The Australian government is set to introduce updated regulations for medical devices, including new conformity assessment evidence requirements, a reliance pathway for Class III devices, and application requirements. These changes will take effect on 15 June 2024 for software-based medical devices and prescription spectacle lenses, and 1 July 2024 for medical devices containing microbial, recombinant, or animal substances.

Key changes include excluding devices containing tissues, cells, or substances of microbial or recombinant origin and specific animal-derived materials. Software-based medical devices will have an alternate transition pathway for higher risk classification, and manufacturers or sponsors must submit ARTG inclusion or TGA conformity assessment applications by 1 November 2024. Mandatory audits will be limited to high-risk devices and IVDs.

TGA Enhances Safety Review for High-Risk Medical Devices in Clinical Trials | 7 June 2024

The Therapeutic Goods Administration (TGA) is implementing new measures to review safety information on high-risk implantable and cardiac invasive medical devices in first-in-human clinical trials. Starting 5 April 2024, the Clinical Trials Notification form will require detailed device information and include an attachment feature for the Investigator's Brochure.

Legislative updates, effective 28 November 2023, will allow TGA to mandate safety information and inspect clinical trials for compliance with Good Clinical Practice. TGA reviews will not delay trial starts and no additional fees will be charged.

BRAZIL

Anvisa Addresses Incomplete Document Availability for In Vitro Diagnostic Devices | 27 June 2024

Anvisa informs companies of ongoing maintenance for its document repository after issues with subject code 80204, which should have immediately made Instructions for Use (IFUs) available on the portal following protocol submission.

The problem arose due to updates in late May coinciding with new technical regulations (RDC 830/23). Anvisa assures that despite receiving documentation, IFUs have not consistently appeared on the portal as intended, with corrections underway by its IT department.

SINGAPORE

Screening Time Metrics for HSA Applications, Oct 2023 - Mar 2024 | 4 June 2024

HSA's target screening turn-around time is 50 working days from application receipt to acceptance or withdrawal, excluding response time. For new and major variation applications accepted between Oct 01, 2023 and Mar 31, 2024, the mean screening time was 31.0 WD for NDA, 33.9 WD for GDA, and 20.7 WD for MAV applications.
Below are bi-annual updates of the mean applicant response time for the new and major variation applications:

Period		NDA	GDA	MVA
01.10.2023 to 31.03.2024	Number of Applications	61	101	58
	Mean Applicant Response Time (WD)	29.6	41.4	16.9

UNITED KINGDOM (UK)

Joint Transparency Principles for Machine Learning Medical Devices | 13 June 2024

The MHRA, FDA, and Health Canada have collaboratively developed guiding principles to enhance the transparency of machine learning medical devices. These principles align with previously established guidelines and provide best practice recommendations for transparency across all medical devices.

Guidance on SaMD and AIaMD: Information for Manufacturers, Healthcare Professionals, Researchers, and Patients | 13 June 2024

MHRA provides essential information for manufacturers, healthcare professionals, researchers, and patients about software as a medical device (SaMD) and AI as a medical device (AIaMD). In the UK, many such products are regulated as medical devices or in vitro diagnostic devices (IVDs). The guidance includes important software group outputs that could be helpful in the regulation and application of these technologies in health and social care.

UNITED STATES OF AMERICA (USA)

Exploring Synthetic Data for Advancing Medical AI: FDA's CDRH Regulatory Science Research | 11 June 2024

As part of the FDA's Center for Devices and Radiological Health (CDRH) AI Program, regulatory science research is exploring the use of synthetic data to supplement medical patient datasets. Synthetic data, generated using computational techniques, can potentially aid in the rapid development and assessment of medical AI models.

This can lead to timely, accurate diagnoses and reduce health access disparities. Large, diverse datasets are often necessary for developing and assessing medical devices, but acquiring real patient data can be costly, limited by safety and privacy concerns, or affected by low disease prevalence.

Synthetic data offers a safer, more efficient alternative for obtaining labeled examples, easing the burden on medical device developers.

Addressing Bias and Enhancing Generalizability in AI-Enabled Medical Devices | 11 June 2024

The FDA's Center for Devices and Radiological Health (CDRH) AI Program is working on addressing bias and improving the generalizability of AI models. The program aims to ensure health equity by ensuring safe and effective technologies for all patients. However, concerns in the AI community suggest that AI models could exacerbate healthcare inequalities.

A key regulatory gap is analyzing and mitigating bias in AI-enabled medical devices, particularly during training and testing phases. Ensuring model generalizability and robustness under varying conditions is crucial for the safety and effectiveness of AI-enabled devices.

Regulatory Challenges and Assessment Paradigms for AI-Enabled Medical Devices | 11 June 2024

The FDA's Center for Devices and Radiological Health (CDRH) regulates AI-enabled devices, but new clinical indications and AI types require innovative assessment paradigms for safety and effectiveness. Current AI devices primarily focus on diagnostics, but emerging devices for prognosis, treatment response prediction, risk assessment, therapy, image enhancement, and multi-class classification require unique assessment metrics and standards.

The integration of natural language processing and large language models in medical device development raises new evaluation considerations, and research into data harmonization and handling missing data challenges is ongoing.

FDA's Accredited Persons Program: Streamlining the 510(k) Process and Oversight | 04 June 2024

The Accredited Persons Program, established under the FDA Modernization Act of 1997, streamlines the 510(k) process by accrediting third-party review organizations. These organizations, previously known as accredited persons, conduct primary reviews of 510(k) submissions for eligible medical devices.

The FDA publishes performance metrics of these third parties, including rates of non-substantially equivalent outcomes, average hold occurrences, and average time to determine substantial equivalence.

The FDA maintains a list of accredited review organizations on their website. The FDA can suspend or withdraw accreditation if a third party fails to comply with regulatory requirements, poses a public health risk, or acts inconsistently with program objectives.

Swissmedic Updates Registration Process for Economic Operators | 26 June 2024

Swissmedic has been required to register Swiss economic operators since May 26, 2021, to obtain a Swiss Single Registration Number (CHRN) due to the lack of access to the EUDAMED European database. However, changes will be implemented with the launch of the Actors module on August 6, 2024, which will streamline registration procedures. Until July 26, 2024, applications and notifications will be accepted as PDF forms, with online applications only considered after that.

The CHRN@swissmedic.ch email inbox will be replaced with an online contact form. Swissmedic plans to introduce voluntary device registration options in 2025, followed by mandatory registration later, to improve transparency and oversight of medical devices on the Swiss market.

Swiss Federal Council Approves Amendments to Human Research Act Ordinances | 21 June 2024

Swissmedic has recently published two important documents aimed at enhancing regulatory clarity and safety in the field of medical devices:

Title	Overview
BW690_00_001e_VL FSC-Example of a Product List	This document provides a detailed example of a product list under the FSC (Federal System of Coordination) framework. It is designed to assist manufacturers and stakeholders in effectively compiling and managing product information in compliance with Swiss regulatory requirements.
N615_10_004d_CL Checkliste für die Inspektion von Systemen der Vigilance betreffend Medizinprodukten	This document, available in German, French, or Italian, outlines a checklist for inspecting vigilance systems related to medical devices. It focuses on the notification of serious incidents and safety notices, aiming to streamline reporting procedures and ensure timely and accurate handling of device-related incidents.

CMDh Updates on Medicinal Products Containing Estragole and Regulatory Changes | 30 June 2024

The CMDh advises holders of medicinal products and herbal medicinal products containing estragole to ensure compliance with guidelines from the HMPC, accessible on the EMA website. Marketing authorization holders are urged to review BASG's publication and take necessary actions.

Additionally, CMDh updates include revised templates for MRP/RUP request forms and updated data requirements for MRP/DCP authorization applications, as well as changes to the ASMF worksharing procedure and Q&A updates on MDR and IVDR regulations.

ANMAT Participates in PAHO/WHO Meeting to Strengthen Regional Regulatory Capacities | 14 June 2024

On June 12 and 13, ANMAT participated in a meeting of the National Reference Regulatory Authorities (NRAs) of the Pan American Health Organization (PAHO/WHO) in Washington DC. The meeting aimed to strengthen the regulatory capacities of health authorities in the region. On the second day, health authorities and observers from Costa Rica, Ecuador, Honduras, and Paraguay discussed the current state of their agencies and opportunities to improve their regulatory systems.

The NRAs are top-rated national regulatory authorities evaluated by PAHO, ensuring the safety, quality, and efficacy of medicines in their countries. Besides ANMAT, the group includes Anvisa (Brazil), FDA (USA), Health Canada (Canada), ISP (Chile), INVIMA (Colombia), CECMED (Cuba), and COFEPRIS (Mexico).

ANMAT Gains Regulatory Member Status in International Council for Harmonization (ICH) | 07 June 2024

On June 4 and 5, ANMAT was promoted to a Regulatory Member of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) during a meeting in Fukuoka, Japan. Since 2019, ANMAT had been an observer member.

After meeting all necessary requirements, including adopting ICH guidelines and participating in working groups, its request for regulatory member status was approved. This new status allows ANMAT to join the Council committee, propose discussion topics, and participate more actively in decision-making, further establishing its role as a high-level health surveillance authority internationally and contributing to regulatory convergence and trust.

ARMENIA

New Assessment Fees for Medicinal Products and Medical Devices in Armenia | 06 June 2024

As of May 8, 2024, Armenia has implemented amendments to the laws "On Medicinal Products," "On Medical Aid and Population Services," and "On State Duty." These changes introduce a state duty for expertise in regulating the circulation of medicinal products and medical devices, as outlined by the Law "On State Duty."

Pharmaceutical companies and medical device manufacturers must now factor in these additional costs. The new fees aim to enhance the quality and safety of medicinal products and medical devices in Armenia, benefiting both healthcare providers and patients.

Stakeholders should review the new procedures and amounts detailed in the Law "On State Duty" to ensure compliance. Regulatory bodies will offer guidance to help navigate these changes.

BHUTAN

BFDA Mandates Testing Reports for Ethylene Glycol and Diethylene Glycol in Oral Liquid Preparations| 25June 2024

The Bhutan Food and Drug Authority (BFDA) has issued a notification requiring all Market Authorization Holders, Importers, and Manufacturers of pharmaceutical oral liquid preparations to submit certified testing reports for ethylene glycol (EG) and diethylene glycol (DEG). This measure comes in response to recent global incidents where these toxic industrial solvents contaminated oral medications, resulting in serious health risks, particularly among children.

The BFDA emphasizes the critical need for stringent regulatory measures to ensure that EG and DEG levels in these preparations remain within safe limits. Stakeholders are urged to comply with these requirements to safeguard public health and maintain confidence in medical products.

CHINA

China Approves 82 Innovative Drugs and 138 Medical Devices Since 2022 | 19 June 2024

China's National Medical Products Administration has announced the approval of 82 innovative drugs and 138 innovative medical devices since 2022. Deputy Director Huang Guo highlighted recent achievements, including advancements in CAR-T therapy, monoclonal antibodies, traditional Chinese medicines, and AI-enhanced medical technologies.

The administration has streamlined approval processes, aligning standards with international norms to facilitate faster market entry for both domestic and foreign manufacturers. This effort supports China's goal of enhancing healthcare through accelerated innovation and regulatory reform.

CROATIA

HALMED Releases PSUSA Procedure Outcomes for Medicinal Products in Croatia| 13 June 2024

Croatia's Agency for Medicinal Products and Medical Devices (HALMED) has released the results of the PSUSA procedures for authorized medicinal products in Croatia. The information is now available on HALMED's website under the "Medicinal products/Variation applications - referrals, PSUSA procedures and PRAC signals/Instructions for variation applications following the outcome of the PSUSA procedure."

HALMED mandates marketing authorization holders to ensure the latest scientific knowledge in medicinal product information, and if PSUSA procedure outcomes require updates to the Summary of Product Characteristics and Package Leaflet, they must submit necessary variations.

Egyptian Medicines Authority Launches Fifth Phase of 'Together towards Safe Medicine' Initiative | 27 June 2024

The Egyptian Medicines Authority has announced the launch of registration for the fifth phase of the "Together towards safe medicine" initiative aimed at enhancing pharmaceutical vigilance in pharmacies. This initiative targets public, community, and hospital external pharmacies, aiming to improve the implementation of pharmaceutical vigilance activities.

The goal is to ensure the safety and effectiveness of medicines for Egyptian patients. Participating pharmacies will receive continuous support and follow-up from the Egyptian Medicines Authority's pharmacovigilance team. Pharmacists working in community pharmacies across Egypt or in external hospital pharmacies are eligible to register for this free initiative.

Egyptian Medicines Authority Introduces Digital Services for Public Engagement and Oversight | 15 June 2024

The Egyptian Medicines Authority has launched five new digital services to enhance public engagement and oversight in pharmaceutical matters. These services include checking medicine availability, reporting side effects, and notifying violations like counterfeit or expired medications.

Citizens can also seek pharmaceutical advice and report inappropriate advertising. Accessible 24/7 via the authority's website, these initiatives aim to promote drug safety and ensure the responsible use of medicines while safeguarding user confidentiality.

Egyptian Drug Authority Advances Drug Tracking System Through New Cooperation Agreement | 07 June 2024

The Egyptian Drug Authority recently signed a memorandum of understanding with the Unified Procurement Authority during the Africa Health Excon conference.

This memorandum aims to enhance cooperation between the two authorities in implementing the drug tracking system. This system plays a crucial role in monitoring medicines from production to consumption, ensuring their safety and quality by preventing the entry of counterfeit or expired drugs into the market.

This system plays a crucial role in monitoring medicines from production to consumption, ensuring their safety and quality by preventing the entry of counterfeit or expired drugs into the market. The agreement aims to disseminate the drug tracking system among relevant stakeholders by providing necessary data and ensuring compliance with regulations.

This initiative reflects the Egyptian Drug Authority's commitment to advancing and widely implementing the drug tracking system, fostering collaboration with relevant bodies in this endeavor.

Enhancing Pharmaceutical Supply Monitoring and Management ALBVVG | 07 June 2024

The Arzneimittel-Lieferengpassbekämpfungs- und Versorgungsverbesserungsgesetz (ALBVVG), published on 26 July 2023 in the Federal Law Gazette, enhances the responsibilities of the Federal Institute for Drugs and Medical Devices (BfArM) and its Advisory Council for Delivery and Supply Shortages. This law mandates the BfArM to continuously monitor and evaluate the supply of medicines in Germany, establishing a rapid alert system for critical shortages of off-patent medicines.

Effective from 27 July 2023, the BfArM is required to publish a list of essential paediatric medicinal products, developed in collaboration with paediatric specialists and the Advisory Council, ensuring availability of age-appropriate formulations. Additionally, the law allows pharmacies to substitute unavailable medicines listed under certain conditions, without needing to consult the prescribing doctor, to mitigate shortages during the 2023/2024 infection season.

Ensuring Medical Device Safety Through Statistical Principles | 14 June 2024

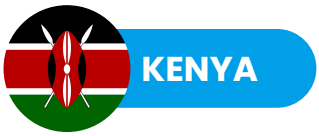
Medical device safety and efficacy are heavily reliant on strict statistical principles, as mandated by national laws and standards like DIN EN ISO 14155. These principles ensure product safety and effectiveness through meticulous planning, implementation, and evaluation.

Key aspects include clear formulation of hypotheses, preparing statistical design and analytical methods, sample size planning, significance level of 5% for hypothesis testing, and rigorous criteria for interim analyses. Safety considerations are paramount, with defined criteria for halting investigations based on subject safety.

Thorough documentation of deviations and amendments is essential for maintaining transparency and study validity. Adherence to these principles strengthens the reliability and validity of clinical investigations.

Guide to Labels and Leaflets of Human Medicines | 21 June 2024

This guide provides essential instructions for labeling and package leaflets of human medicines authorized nationally, through mutual-recognition (MR), or decentralized (DC) procedures. It ensures clarity and accuracy in information for healthcare professionals and patients, excluding products authorized through the centralized procedure. Compliance with these guidelines is critical for regulatory adherence and patient safety across authorization pathways.



New Board Inaugurated to Enhance Health Product Quality and Safety in Kenya | 10 June 2024

Kenya's National Quality Control Laboratory (NQCL) has appointed a new Board of Management to enhance health product standards. The board will focus on improving efficiency in health service delivery and implementing innovative productivity strategies. Kenya aims to achieve WHO Maturity Level 3 by 2025, requiring the board to navigate regulatory landscapes and product demands.

The board will set new benchmarks in quality control, emphasizing trust, quality, and reliability. The newly appointed board members will ensure the safety and efficacy of health products.

DRAP Launches National Pharmacovigilance Centre for Drug Safety | 12 June 2024

The Drug Regulatory Authority of Pakistan (DRAP) has established the National Pharmacovigilance Centre (NPC) to ensure the safety of therapeutic goods. This made Pakistan the 134th member of the WHO Programme for International Drug Monitoring in 2018.

DRAP's 2022 Pharmacovigilance Rules and guidelines detail the responsibilities of stakeholders and provide step-by-step instructions for pharmaceutical companies to set up pharmacovigilance systems. Despite these efforts, few companies have established such centres.

To address this, DRAP will conduct virtual training sessions for registration holders in July 2024. Companies are urged to register for these sessions to enhance their pharmacovigilance capabilities and ensure medication safety.

JAZMP Warns of Inadequate Anti-Tampering Devices on Drug | 06 June 2024

The Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (JAZMP) has reported issues with inadequate anti-tampering devices (ATDs) on medications. As required by EU regulations and national law, ATDs must show visible and irreversible damage if tampered with, to detect unauthorized access.

While specific ATD designs are not mandated, JAZMP recommends following the EN ISO 21976:2020 standard. Manufacturers must ensure proper ATDs are in place before releasing products. JAZMP urges stakeholders to report any damaged or suspicious ATDs, treating such cases as potential quality issues or falsifications. Regular quality controls will also check ATD adequacy.

New Regulations Enhance Transparency in European Clinical Trials Database | 11 June 2024

Beginning June 18, new regulations will restrict public access to essential trial data in the European Clinical Trials Database (CTIS) overseen by the EMA. Previously, most trial information was public, excluding specific documents. AEMPS recommends sponsors adapt to eliminate data deferral mechanisms, ensuring compliance with the updated transparency guidelines. Existing trials will gradually conform to these rules by 2024, maintaining confidentiality for initial documents while enhancing transparency in future submissions.

Anvisa Urges Reporting of Adverse Reactions from Cosmetic Products | 21 June 2024

Anvisa released Security Report No. 01/2024 emphasizing the importance of recognizing and reporting adverse reactions caused by cosmetic products. The report aims to safeguard public health by ensuring consumers are informed about identifying potential adverse reactions and registering incidents through Anvisa's official channels.

While cosmetic products are generally safe, adverse reactions can range from mild irritations to severe allergies requiring medical attention. Anvisa stresses the critical role of reporting incidents via Limesurvey or e-Notivisa for citizens, Notivisa for companies and healthcare professionals, and Limesurvey for other professionals.

These reports enable Anvisa to take necessary actions to maintain product safety in the Brazilian market.
Anvisa encourages active participation from consumers and healthcare professionals in reporting adverse reactions promptly to uphold public health standards.

FAMHP Warns of Skin Reactions from UV Exposure with Certain Medications | 21 June 2024

The FAMHP warns that certain medications can cause severe skin reactions when exposed to UV light, from sunlight or artificial sources like sunbeds. These photosensitising medicines can lead to photodermatoses, with reactions appearing as phototoxic (like severe sunburn) or photoallergic (eczema-like rashes). Common medications include antibiotics, antidiabetics, psychopharmaceuticals, and others. Precautions include avoiding midday sun, using high SPF sunscreen, wearing protective clothing, and considering alternative medications. Healthcare providers should inform patients and advise discontinuing suspect medications if skin reactions occur.

UNITES STATES OF AMERICA (USA)

U.S. FDA Begins Enforcement of Facility Registration and Product Listing on July 1, 2024 | 28 June 2024

Starting July 1, 2024, all cosmetic companies intending to enter the U.S. market must undergo mandatory FDA registration, which includes facility registration and product listing. This requirement urges cosmetic stakeholders to promptly complete the necessary submissions.

On December 29, 2022, the Modernization of Cosmetics Regulation Act of 2022 (MoCRA)was signed into law. This legislation represents the first significant update to the Federal Food, Drug, and Cosmetic Act (FD&C Act) since its inception in 1938. MoCRA grants the FDA enhanced authority to enforce regulations on cosmetics and introduces new compliance obligations for manufacturers and distributors, emphasizing facility registration and product listing.

Key Requirements

Facility Registration	*All cosmetic product manufacturers and processors in the U.S. must register with the FDA, updating their facilities within 60 days of changes and renewing biennially. Foreign facilities must designate a U.S. agent for effective FDA communication.*
Product Listing	*The manufacturer, packer, and distributor of cosmetics in the U.S. must list each product with the FDA annually, renewing the listing. This includes products with identical formulations or minor variations in color, fragrance, flavor, and quantity. The listing must be renewed annually.*

The FDA has postponed the enforcement deadline for the MoCRA to July 1, 2024, to allow more preparation time for the industry. Small businesses and drug-related businesses can still avoid facility registration and product listing if their products do not include high-risk cosmetics, contact the eye mucous membrane, or have specific characteristics. However, these exemptions are not applicable if the businesses produce products solely categorized as cosmetics.

Australia Updates Therapeutic Goods Act to Adopt PIC/S Good Manufacturing Practice Guidelines | 14 June 2024

On June 3, 2024, Australia updated its Therapeutic Goods Act 1989 to adopt the PIC/S Guide to Good Manufacturing Practice (GMP), excluding specific Annexes. A transition period from June 3 to September 2, 2024, allows manufacturers to prepare for compliance with the new Annex 16, effective September 3, 2024.

The update includes clarifications and new requirements aimed at enhancing manufacturing practices. The Therapeutic Goods Administration will support companies during the transition and report deficiencies if necessary adjustments are not made..

Amendments to Australia's Poisons Standard: Enhancing Cosmetic Safety and Regulatory Updates | 11 June 2024

The Therapeutic Goods Administration (TGA) of Australia has proposed amendments to the Poisons Standard, which categorizes substances used in medicines and cosmetics based on risk and benefit assessments.

The amendments primarily focus on five substances: sildenafil, allyl esters, glyoxylic acid, intravenous potassium salts, and sulfonamides. The amendments aim to address potential risks associated with dermal and ocular exposure, particularly for workers and consumers in the cosmetic industry. They also include requirements for specific warning statements and safety directions.

Detailed proposed amendments involve the creation of new entries to restrict the exemptible concentration of glyoxylic acid in cosmetics, as well as the provision of specific warning statements and safety directions, as outlined below:

- **Schedule 6 - Poisons**

Glyoxylic acid, including its salts and esters, is not allowed in cosmetic products or agricultural chemicals, except in salon-use preparations with up to 12% w/v of glyoxylic acid, unless labelled in accordance with Work Health and Safety laws, as amended periodically.

- **Appendix E, Clause 3 (First Aid Instructions for Poisons)**

For advice on poisoning, contact a Poisons Information Centre or a doctor immediately. If swallowed, do not induce vomiting. If in eyes, hold eyelids apart and flush continuously with running water until advised to stop by a Poisons Information Centre or a doctor, or for at least 15 minutes.

- **Appendix F, Clause 4 (Poisons That Must Be Labelled with Warning Statements and Safety Directions)**

1. Avoid contact with eyes.
5. Wear protective gloves when mixing or using.
6. Wash hands after use.
31. Do not use on broken skin.

Amendments to Australia's Poisons Standard: Enhancing Cosmetic Safety and Regulatory Updates | 11 June 2024

The National Medicines Regulatory Authority (NMRA) of Sri Lanka has mandated all cosmetic manufacturing sites to obtain ISO 22716 certification from the Sri Lanka Standards Institute (SLSI), effective from May 1, 2024. This change replaces the previous Good Manufacturing Practice (GMP) inspections for cosmetics plants.

Existing approved sites have a grace period until May 31, 2026, while pending sites will undergo GMP inspections. New applicants must submit a site master file with detailed information about the site and products to be manufactured.

Thailand Adopts Amendments to Regulations for Alcohol-Based Hand Sanitizers | 07 June 2024

Thailand has recently adopted amendments to its regulations governing alcohol-based hand sanitizers, focusing on revising concentration thresholds and deviation limits for alcohol content. These changes aim to streamline access to alcohol-based hand sanitizers and enhance regulatory clarity.

The adopted documents include:
1. Announcement of the Ministry of Public Health on Determining Important Substances and Specifications for Alcohol-based Hand Hygiene Cosmetics Prohibited from Production, Importation, or Sale, B.E. 2024

2. Announcement of the Ministry of Public Health on Determining Criteria for Deviation Limits of Key Substances in Alcohol-based Hand Hygiene Cosmetics, B.E. 2024

Previously notified to the WTO on February 2, 2024, these amendments are effective immediately, marking a shift towards facilitating availability while ensuring compliance with updated regulatory standards.

Japan Proposes Standard Analytical Method for Δ9-THC in Cannabis-Derived Products | 03 June 2024

On May 30, 2024, Japan's Ministry of Health, Labour and Welfare (MHLW) issued a draft Standard Analytical Method for measuring Δ9-THC content in cannabis-derived products. This method, open for public comment until June 29, 2024, employs LC-MS/MS or LC-QTOF MS techniques to ensure compliance with regulatory limits on Δ9-THC levels (up to 0.10 mg/kg in beverages, 10 mg/kg in oils, and 1 mg/kg in other products). The draft aims to standardize testing for Δ9-THC and Δ9-THCA-A in these products, allowing for alternative methods with equivalent sensitivity and accuracy.

AEMPS Updates Compliance Measures for Sunscreens Following New Test Results | 28 June 2024

In its September 2024 information note, the Spanish Agency for Medicines and Health Products (AEMPS) reported changes to previous measures on three sunscreen companies tested by the OCU. These companies provided additional studies confirming their products met the claimed sun protection factor (SPF) and ultraviolet-A protection factor (FP-UVA).

AEMPS highlighted ongoing variability in applying the UNE EN ISO 24444 technical standard, complicating accurate SPF measurement. The Agency is advocating for method improvements and clearer SPF labeling.

List of Updated ISO standards for June 2024

- ISO 18128:2024 - Information and documentation — Records risks — Risk assessment for records management
- ISO 8637-1:2024 - Extracorporeal systems for blood purification — Part 1: Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators
- ISO 8637-3:2024 - Extracorporeal systems for blood purification — Part 3: Plasmafilters