Newsletter

REGULATORY BRAINBOX

OMC MEDICAL
Regulatory Services

Medical Devices Regulatory Consultancy

OCTOBER NEWSLETTER 2025

How we can help?

- ✓ Authorised Representative services across the globe
- ✓ EU MDR/FDA/ROW
- ✓ Translation services
- ✓ Local country listing

Contact Us

www.omcmedical.com

info@omcmedical.co.uk

+44 7458300825

SPECIAL OFFER
15% OFF

On EU Language Translation*

*Terms and conditions apply; we only use actual translators and not machine translations

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
- ✓ Clinical evaluation and CRO Services
- ✓ Post-market surveillance
- ✓ Authorised Representative Services - EU, Swiss, UK and ROW.,
- ✓ Importer services - EU, Swiss
- ✓ Internal and External Auditing services
- ✓ Regulatory Staffing
- ✓ Regulatory Training

+44 7458300825 | info@omcmedical.co.uk

CONTENTS

MEDICAL PRODUCTS

CONTENTS

COSMETICS

ISO STANDARDS

EUROPEAN UNION (EU)

New Harmonised Standards Published Under the MDR | 20 October 2025

The European Commission has published Commission Implementing Decision (EU) 2025/2078, dated 17 October 2025, which updates the list of harmonised standards under the EU Medical Devices Regulation (MDR) 2017/745.

This latest amendment introduces four new harmonised standards, further strengthening the regulatory framework and ensuring alignment with the latest technological and safety developments in the medical device sector.

The newly added standards are:

- EN 13795-1:2025 – Surgical clothing and drapes – Part 1: Surgical drapes and gowns
- EN 13795-2:2025 – Surgical clothing and drapes – Part 2: Clean air suits
- EN 14683:2025 – Medical face masks – Requirements and test methods
- EN 14180:2025 – Sterilisers for medical purposes – Low temperature steam and formaldehyde sterilisers – Requirements and testing

These inclusions provide manufacturers with up-to-date technical specifications that, when applied, confer a presumption of conformity with the relevant MDR requirements. Manufacturers using earlier versions of these standards should review the updates and assess whether revisions to their technical documentation or declarations of conformity are needed.

European Commission Updates Central List of Experts for MDR and IVDR Panels | 03 October 2025

The European Commission released an updated central list of experts available to serve on the Medical Device and In Vitro Diagnostic Device Expert Panels established under Regulations (EU) 2017/745 (MDR) and 2017/746 (IVDR).

This update follows the first evaluation of applications submitted in response to the new EXPAMED call for expressions of interest.

The expert panels play a crucial role within the MDR and IVDR frameworks, offering scientific advice and technical opinions on high-risk medical devices and IVDs, including those assessed under the Clinical Evaluation Consultation Procedure (CECP).

By refreshing the central list, the Commission has expanded the pool of recognised experts who can be called upon to join or support panel activities as needed. This move strengthens the system's capacity, flexibility, and overall regulatory support.

For manufacturers, notified bodies, and other regulatory stakeholders, this development highlights the continued evolution of the expert panel network—introducing new expertise that may shape how consultations, opinions, and scientific guidance are provided in the future.

UNITED STATES OF AMERICA (USA)

FDA Releases Internal Filing Checklists to Boost Transparency and Cut Delays | 23 October 2025

The U.S. FDA has made public the internal filing checklists used by the Center for Drug Evaluation and Research (CDER) to assess the completeness of new drug and biologics applications. The initiative aims to increase transparency and reduce filing deficiencies that can delay the review of promising therapies.

By giving sponsors access to these tools, the FDA hopes to prevent avoidable Refuse to File (RTF) decisions, which in the past have delayed applications by over a year on average. The checklists, now included in CDER's updated MAPP 6025.4 "Good Review Practices: Refuse to File", are expected to improve communication and streamline the submission process, though final filing decisions will continue to depend on regulatory and scientific evaluation.

SWITZERLAND

Switzerland Updates Adoption Process for EU Medical Device Rules | 21 October 2025

Switzerland has refined how EU medical device legal acts, harmonised standards, and common specifications are applied nationally—ensuring continued alignment with the EU MDR (2017/745) and IVDR (2017/746).

Key updates:

- **Publication in the Federal Gazette:** New harmonised standards and common specifications become applicable once designated by Swissmedic and officially published.

- **FDHA amendments:** The Federal Department of Home Affairs can now swiftly update MedDO and IvDO annexes to reflect EU or technical developments.

- **Federal Council declarations:** EU delegated and implementing acts can be directly declared applicable in Switzerland, maintaining regulatory consistency without legislative delays.

- **Direct application of EU acts:** Certain technical or administrative provisions are automatically adopted and published by Swissmedic, ensuring Switzerland keeps pace with evolving EU requirements.

These mechanisms strengthen Switzerland's regulatory alignment with the EU and help ensure seamless compliance for manufacturers placing devices on both markets.

New "Discard" Functionality Introduced in swissdamed UDI Devices Module | 01 October 2025

The swissdamed UDI Devices module now includes a discard function. This feature allows users to remove registered UDI-DIs that contain incorrect information which cannot be corrected through a standard update due to system business rules.

The function is intended solely for correcting erroneous submissions, not for making legitimate device changes. Once a UDI-DI is discarded, it is deleted from the system and no longer visible in public searches. However, the same UDI-DI can be registered again with correct data if needed.

ARGENTINA

ANMAT Updates GMP Certification Process for Foreign Manufacturing Sites | 28 October 2025

ANMAT has updated its process for issuing Good Manufacturing Practice (GMP) certificates to overseas medicinal product facilities through Provision 7998/25. The new system incorporates reliance principles, allowing ANMAT to use inspections and certifications from trusted international regulatory authorities.

GMP certificates may now be granted to facilities:

- In PIC/S member countries,
- In MERCOSUR countries, or
- Holding GMP certificates from recognized national regulators (e.g., PAHO-listed authorities).

This provision replaces the previous regulation and introduces a new INAME-issued certificate format. The update aims to speed up evaluations, optimize resources, and enhance global regulatory cooperation.

ANMAT will review applications within 40 working days and may request additional information or conduct remote/onsite checks as needed, reinforcing medicine quality and safety oversight for imports.

Argentina Implements New GCP Standards for Clinical Studies | 09 October 2025

Argentina has approved a new Good Clinical Practice (GCP) framework through Provision No. 7516/25, effective December 1. The regulation adopts ICH E6 (R3) standards and sets national procedures for Phase I–III clinical pharmacology studies related to new indications, dosages, formulations, or other changes requiring clinical evidence.

The update strengthens participant protection, data integrity, and ethical standards, aligning Argentina with international regulatory practices and supporting its participation in global clinical research.

ATGA Releases Updated Australian UDI Bulk Upload Template | 30 October 2025

The Therapeutic Goods Administration (TGA) has issued version 2.8 of its Australian UDI Bulk Upload Template, a Microsoft Excel tool used for submitting unique device identification (UDI) information to the Australian UDI Database (AusUDID).

This updated version supports batch uploads of up to 200 UDI entries at a time. Key changes include improved guidance within the template's instruction tab and the removal of an incorrect mandatory label related to natural rubber latex.

The bulk upload tool forms part of the broader UDI resource collection available on the TGA's UDI Hub, which also includes the Data Dictionary, release notes, and detailed guidance documents for industry.

Australia Updates Therapeutic Goods Testing Regulations Effective 2025 | 01 October 2025

Australia's Therapeutic Goods Administration (TGA) ensures the safety, performance, and quality of therapeutic products through regulatory oversight and laboratory testing. To modernise and strengthen these processes, the government has updated the testing framework outlined in Part 5 of the Therapeutic Goods Regulations.

Following a public consultation held from June to August 2024, the majority of stakeholders supported proposed improvements to the testing procedures.

From 1 October 2025, new amendments will replace the existing Part 5, aiming to make regulatory testing clearer, more efficient, flexible, and aligned with current and future testing methods.

Under the revised framework, authorised Australian Public Service employees will be able to act as analysts to select and test product samples. Testing may also be performed by other qualified individuals or organisations. Once testing is completed, an official certificate will be issued detailing the testing performed and results.

Transitional measures will be in place to allow products already obtained before the rule change to continue being tested under the previous system, ensuring uninterrupted regulatory oversight.

Anvisa Releases Updated Manual for Medical Device and SaMD Regularization | 22 October 2025

Anvisa has issued a revised version of its Manual for the Regularization of Medical Equipment and Software as a Medical Device. The update forms part of ongoing efforts to align regulatory guidelines with Brazil's latest medical device framework.

The refreshed manual incorporates key regulations, including:

- RDC 751/2022 – Risk classification, registration/notification pathways, labeling, and instructions for use
- RDC 657/2022 – Requirements for Software as a Medical Device (SaMD)
- RDC 848/2024 – Essential safety and performance standards for medical devices and IVDs

This updated resource offers detailed guidance for companies on the full regularization process—from obtaining operational authorization to product registration or notification.

It also includes clarity on regulatory classification and practical examples to support compliance.

Industry associations were consulted during development to ensure alignment with sector needs.

The initiative aims to promote clearer regulatory understanding, improve submission quality, and ultimately reduce requests for clarification and application rejections within Anvisa's device review process.

Anvisa Streamlines GMP Certificate Petitions for Medical Devices | 20 October 2025

Brazil's health authority, Anvisa, has introduced a unified set of subject codes for Certificate of Good Manufacturing Practices (CBPF) petitions for medical devices, including in vitro diagnostics. This update is designed to simplify regulatory submissions, cut administrative burden, and align procedures with current legislation, particularly RDC 665/2022 — which already consolidates GMP requirements for medical devices.

The harmonisation applies to all products, whether made in Brazil or abroad, and covers applications under the Medical Device Single Audit Program (MDSAP). The move is expected to speed up certification workflows and enhance alignment with international practices.

Existing CBPF applications will not be affected, even if submitted under previous subject codes. Additionally, during renewal, manufacturers producing both medical devices and IVDs may opt to renew only one associated process — ideally the one nearing expiry — provided all relevant product information is consolidated within the petition.

SAUDI ARABIA

Saudi Arabia Launches AI System to Monitor Traveller Medication | 30 October 2025

The Saudi Food and Drug Authority has launched RASID, an AI-powered system designed to regulate controlled medications carried by travellers entering the country. Introduced at the Global Health Exhibition, the tool automates verification of prescriptions and medical reports, helping speed up procedures and reduce errors — including those caused by multilingual labels and handwritten documents.

Developed by the SFDA's AI Lab (SAIL), RASID supports over 50 languages and marks a shift toward proactive, tech-driven monitoring. The initiative aligns with Saudi Vision 2030 goals to enhance healthcare efficiency and foster innovation.

Saudi Arabia Launches National Pharmacopoeia with Halal Standards | 27 October 2025

Saudi Arabia has introduced its first Saudi Pharmacopoeia, a national reference for medicine quality and safety, unveiled during the Global Health Exhibition in Riyadh. The new standard sets unified requirements for pharmaceuticals and includes a dedicated Halal chapter, making it the first of its kind to formally incorporate Islamic compliance in drug regulation.

Developed by the Saudi Food and Drug Authority, the pharmacopoeia aims to strengthen local manufacturing, support alignment with global regulatory frameworks, and attract international investment. It will serve as an official reference for drug specifications, testing methods, and quality assurance, helping drive innovation, research, and increased confidence in pharmaceutical products across the Kingdom.

Saudi Arabia Joins ICMRA as First Full Member from MENA | 26 October 2025

Saudi Arabia's Food and Drug Authority (SFDA) has been accepted as a full member of the International Coalition of Medicines Regulatory Authorities (ICMRA), becoming the first regulator from the MENA region to achieve this milestone.

The membership recognises the Kingdom's progress in advancing pharmaceutical regulation and its commitment to global best practices and public health protection. Announced during the ICMRA Summit 2025 in Amsterdam, the move allows the SFDA to actively contribute to shaping ICMRA policies and initiatives, supporting Saudi Arabia's Vision 2030 health transformation goals.

ICMRA brings together leading medicines regulators worldwide to collaborate, share expertise, and improve drug and vaccine safety, quality, and effectiveness.

China Issues 15 New Recommended Medical Device Standards | 30 October 2025

The National Medical Products Administration (NMPA) has released 15 recommended industry standards for medical devices under Announcement No. 106 of 2025. The update includes YY/T 0910.2-2025, which sets requirements for acceptance and stability testing of medical imaging display systems used in medical electrical equipment.

These standards aim to improve quality control, technical consistency, and industry development in China's medical device sector. While currently recommended, they are expected to influence regulatory reviews, testing expectations, and future compliance requirements.

Manufacturers, importers, and testing institutions are encouraged to review the new standards and align testing and quality systems to support market access and product performance in China.

China Announces Findings from Medical Device Quality Inspection | 29 October 2025

China's medical device regulator has released results from recent product quality sampling checks, identifying 14 batches across 10 device categories that failed to meet required standards.

Non-compliant products included laser therapy devices, hearing aids, balance training equipment, dental X-ray machines, wound dressings, intraocular lenses, surgical electrodes, infusion sets, medical masks, and HCG test kits. Issues ranged from performance and safety parameters to filtration efficiency and test specificity.

Regulators have instructed provincial authorities to take prompt enforcement actions in line with medical device supervision regulations. Manufacturers must conduct risk assessments, initiate product recalls where necessary, investigate root causes, and implement corrective measures.

The findings have been formally published and relevant companies are required to disclose recall progress and compliance actions.

China Issues Batch 97 of Generic Reference Drug Catalogue | 23 October 2025

China's NMPA has released Batch 97 of the Generic Reference Preparation Catalogue, specifying approved reference drugs that must be used in equivalence studies for generic products.

The updated list aims to strengthen quality and consistency standards for generics and offers clearer guidance for manufacturers, CROs and testing labs. Companies developing generics in China should review the latest catalogue to ensure their chosen comparator drugs comply and avoid regulatory delays.

Staying updated with each catalogue release remains important for smooth generic drug registration in China.

SÚKL Warns Distributors to Verify Quality of Pharmaceutical Ingredients| 23 October 2025

The Czech State Institute for Drug Control (SÚKL) has reminded distributors of medicinal substances and excipients to strictly follow legal requirements when supplying ingredients to authorised facilities.

Distributors must only provide substances that meet European Pharmacopoeia standards, or—if not listed—standards from the Czech Pharmacopoeia or another recognised pharmacopoeia.

They must ensure each ingredient has official documentation confirming compliance with pharmacopoeial quality requirements, including microbiological standards. This documentation must be available to customers on request.

SÚKL warns that failure to meet these obligations could result in serious legal consequences, including fines of up to CZK 5 million.

Ethiopia Achieves WHO Maturity Level 3 in Medicine Regulation| 01 October 2025

Ethiopia has been awarded Maturity Level 3 (ML3) by the World Health Organization for its national medicine regulatory system, becoming the ninth African nation to reach this standard. This recognition confirms that Ethiopia now has a well-functioning and internationally aligned framework to ensure the safety, quality, and effectiveness of medical products.

The Ethiopian Food and Drug Authority (EFDA) earned ML3 following a WHO assessment completed in September 2025. This milestone boosts confidence among citizens and global partners, strengthens access to quality medicines, and supports the growth of the local pharmaceutical sector.

Achieving ML3 also positions Ethiopia for future eligibility as a WHO Listed Authority, further advancing its role in global public health.

Finland to Add New Symbol for Medicine Safety Materials | 30 October 2025

Finland's Medicines Agency (Fimea) is introducing a new symbol to make medicine safety materials for healthcare professionals easier to identify and distinguish from marketing content. The symbol will appear gradually as documents are updated.

A recent University of Helsinki study found that many healthcare professionals struggle to recognise official risk minimisation materials, reinforcing the need for clear visual markers.

These materials are essential for supporting safe and effective use of medicines, especially those with higher risks. Fimea will continue to publish all related materials on its website.

Fimea Launches New SoHO Information Hub Ahead of EU Regulatory Changes | 27 October 2025

Fimea has introduced a new section on its website dedicated to Substances of Human Origin (SoHO), providing clear and updated guidance on regulations, authorisations, and oversight for both professionals and the public.

The update comes in preparation for the EU SoHO Regulation (EU 2024/1938), which expands the definition of SoHO to include materials such as breast milk and faecal microbiota, in addition to blood, tissues, and cells. The new rules will broaden regulatory requirements and increase the number of supervised operators in Finland, with inspections expected to rise from about 50 to over 100.

The new site section consolidates relevant information to support a smooth transition to the strengthened regulatory framework.

Finland Adds Third IVDR Notified Body, Strengthening EU Position | 21 October 2025

Finland has designated SGS Fimko Oy as a notified body under the EU In Vitro Diagnostic Medical Devices Regulation (IVDR), with the listing published in the European Commission's NANDO database on 21 October 2025.

This makes SGS Fimko the third IVDR-designated notified body in Finland and increases the EU total to 19. With three notified bodies, Finland now ranks second in Europe, following Germany with four.

The Finnish Medicines Agency (Fimea) designates and supervises notified bodies, which support both domestic and international manufacturers in conformity assessments under the IVDR.

INDIA

India Issues Final Classification List for Class A Non-Sterile, Non-Measuring Medical Devices | 31 October 2025

India's Central Drugs Standard Control Organization (CDSCO) has released the final list of Class A (non-sterile, non-measuring) medical devices under the Medical Devices Rules, 2017. This follows the draft list issued in January 2025.

Under the existing rules (G.S.R 777(E), dated 14 October 2022), Class A devices in this category are exempt from licensing; however, manufacturers and importers must still obtain a registration number through the CDSCO online portal in accordance with Chapter IIIB of the Medical Devices Rules.

The newly published list confirms which products fall under Class A non-sterile, non-measuring classification. Applicants should note:

- The intended use descriptions provided are for guidance. Manufacturers may specify their own intended use as long as it aligns with the CDSCO classification.
- The list is dynamic and may be updated periodically.
- Devices that are sterile or include a measuring function will not qualify under this exemption and will be subject to appropriate classification requirements.

The update reinforces regulatory clarity and supports streamlined compliance for low-risk medical devices in India.

CDSCO publishes updated BIS "MHD" standards list for 2025| 22 October 2025

The Central Drugs Standard Control Organization (CDSCO) has released a notification presenting the updated list of standards under the Medical Equipment and Hospital Planning (MHD) division of the Bureau of Indian Standards (BIS) for 2025.

This updated compilation includes the latest IS standard numbers applicable to various medical equipment and hospital planning categories. It serves as an important reference for manufacturers and importers to verify compliance with the Medical Devices Rules, 2017.

CDSCO Releases Draft Guidance on Medical Device Software Under MDR 2017 | 21 October 2025

India's Central Drugs Standard Control Organisation (CDSCO) has issued a draft guidance document focused on medical device software regulated under the Medical Devices Rules, 2017. The draft aims to provide clearer regulatory expectations and align Indian requirements with global best practices.

The document outlines the scope, definitions, classification framework, applicable standards, and technical documentation and quality management system requirements for medical device software. It is intended to assist applicants when submitting license applications for manufacturing or importing medical device software intended for sale or distribution in India.

Stakeholders are invited to review the draft and submit feedback via the designated Google form within 30 days of publication.

NORWAY

Norway strengthens use of standardized medicinal data to support safe and consistent medicine use | 07 October 2025

Norway's Medical Products Agency has announced plans to enhance collaboration with industry and health-system partners to ensure correct terminology is used from the very beginning when structuring medicinal data.

The initiative focuses on aligning with IDMP (Identification of Medicinal Products) based on the five ISO standards, which is essential for accurate data sharing and integration across digital health systems, including national eHealth solutions.

This effort is also aimed at supporting future cross-border data exchange within Europe, particularly for electronic prescriptions and in line with broader European digital health initiatives such as the European Health Data Space (EHDS).

To support this transition, the agency has released online resources that include standardized terminology for substances, coding systems, and ATC classifications used for authorized medicines — as well as similar references for dietary supplements.

Argentina Streamlines Cosmetic Establishment Authorization Process | 29 October 2025

Argentina's ANMAT has issued Order No. 7939/2025, introducing a new declaration-based system for businesses involved in the manufacturing, import, and distribution of cosmetics, personal hygiene products, and perfumes. The rule takes effect 60 working days after publication and replaces prior authorization regulations.

Key Points

- **Declaration System:** Companies must submit a sworn digital declaration to receive a registration number and may operate immediately, subject to later ANMAT verification. Existing authorized facilities have 180 working days to file the new declaration. Older packaging with previous authorization details can remain in the market for up to three years.

- **GMP Compliance:** All establishments must meet applicable Good Manufacturing Practice requirements, including those under Order No. 6477/2012 for cosmetic manufacturing. Documentation must be maintained, and facilities remain subject to inspection.

The update simplifies administrative procedures while maintaining strong safety and quality controls.

India Set to Introduce Modern Regulatory Law for Drugs, Devices, and Cosmetics | 04 June 2025

India is preparing to replace its long-standing Drugs and Cosmetics Act of 1940 with a new Drugs, Medical Devices and Cosmetics Act, 2025. The updated law aims to overhaul and modernize the regulatory framework covering pharmaceuticals, medical devices, and cosmetic products.

The proposed legislation strengthens quality control systems, expands market surveillance, and introduces stricter oversight to ensure product safety. It will empower the Central Drugs Standard Control Organization (CDSCO) with clear statutory authority to carry out rigorous quality checks, monitor manufacturing standards, and take swift action against counterfeit or substandard products, including those meant for export.

Key features of the draft law include digitizing licensing processes, improving coordination between central and state authorities, and enhancing laboratory testing capabilities. The bill is expected to be tabled in Parliament during the upcoming Winter Session for review and approval.

China Launches Pilot Program for Cosmetic Electronic Labels| 21 October 2025

China's National Medical Products Administration (NMPA) has announced the launch of a pilot program for cosmetic electronic labels, marking a significant step toward digital transformation in cosmetic regulation and consumer transparency.

The initiative aims to enable cosmetics to provide product information through electronic labels (e-labels) instead of relying solely on physical packaging. This modernized format is designed to improve accessibility of product details, support regulatory oversight, and enhance consumer confidence.
Under the pilot, participating cosmetic companies will be able to link consumers to detailed product information via scannable digital tools such as QR codes or online platforms.

This may include key data like:

- Product name and function
- Ingredient list
- Usage instructions and precautions
- Shelf life and storage guidance
- Manufacturer and responsible person details
- Regulatory approval information (where applicable

The program also supports real-time updates, ensuring consumers always access the latest, accurate information — a notable advantage over static printed labels.

The NMPA emphasizes that electronic labels are intended to complement, not replace, essential on-pack information. Mandatory details such as product name, net content, production batch number, expiry information, and key warnings must remain visible on physical packaging.

This pilot aligns with global regulatory trends as markets move toward smart labeling solutions, sustainability, and transparency. If successful, it may pave the way for broader adoption of e-labels across China's cosmetic sector.

What This Means for Industry Stakeholders

- Manufacturers & Importers: Opportunity to modernise labeling systems; ensure digital information management readiness
- Consumers: Quicker access to product information and updates
- Regulators: Enhanced traceability and regulatory data access

The NMPA is expected to refine the program based on pilot outcomes before wider rollout. Companies operating in the China cosmetics market should monitor developments closely and evaluate future compliance needs.

China Introduces Two-Tier Cosmetic Ingredient System | 20 October 2025

China's National Medical Products Administration (NMPA) has released Announcement No. 61 of 2025, updating the management of its Inventory of Existing Cosmetic Ingredients (IECIC).

The new system divides ingredients into two categories:

- List I – existing ingredients already recognised for use in China
- List II – new ingredients that have completed the required three-year post-registration safety monitoring

Key revisions include the removal of "maximum historical usage levels" from List I, standardised naming across Chinese/INCI/English formats, and updated remarks in line with China's cosmetic safety standards. Two ingredients have now entered List II, marking the first additions under the new framework.

The IECIC will also move to a dynamic online update system, meaning future changes will be published directly on the NMPA website instead of through formal announcements.

China Announces First Innovation Guidance List for New Cosmetic Ingredients | 20 October 2025

China's National Institutes for Food and Drug Control (NIFDC) has released its inaugural list of innovative cosmetic ingredients chosen for R&D and market-entry guidance. The initiative supports the development, evaluation, and application of new cosmetic ingredients in China.

A total of 16 new cosmetic ingredients were selected after a thorough review based on factors such as early market-entry potential, suitability for China's market needs, ability to replace imported ingredients, and contribution to sustainable development.

A public consultation on the selected ingredients is open from October 20–24, 2025.

While included in the program, these ingredients are not yet pre-approved for quality or safety. Companies must still complete required notification or registration processes. The NIFDC will provide guidance throughout R&D and regulatory submissions to support compliance and innovation.

Thailand Clarifies Rules for Cosmetic Formula Changes With Same Product Name | 17 October 2025

The Thai FDA has introduced clear guidance for cosmetic companies looking to update product formulations while keeping the original product name. This move aims to support product innovation and ingredient updates, while maintaining transparency and consumer safety in the market.

Under the new guidance, cosmetic brands may reformulate a product — such as by adding, removing, or modifying ingredients — without changing its name, but they must submit a new notification for the updated formula. Companies are also required to maintain documentation linking the old and new formulas, ensure labels reflect the updated ingredients, and keep safety and product information current.

If both the name and formula change, a standard new product notification is still required.

The Thai FDA notes that this approach allows manufacturers and importers to improve formulations and respond to market or regulatory needs, while ensuring consumers are not misled. The updated rules aim to balance compliance, transparency, and brand continuity in Thailand's cosmetic sector.

Indonesia Implements New Ingredient Risk Assessment Rules for Health & Beauty Products | 16 October 2025

Indonesia's BPOM has enforced a new regulation requiring risk assessments for ingredients used in natural medicines, supplements, quasi-drugs and cosmetics. Initially issued as a draft in November 2024, the rule became effective on 3 October 2025.

The regulation mandates pharmaceutical-grade ingredients for certain higher-risk dosage forms, based on BPOM's evaluation.

A four-step framework guides industry compliance:

- Identify hazards linked to the ingredient
- Determine safe exposure levels using toxicology data
- Assess consumer exposure based on product use
- Characterise overall risk and require pharmaceutical-grade ingredients if safety concerns arise

Companies can use BPOM's outlined method to ensure product safety during registration and market circulation.

Indonesia Updates Cosmetic Licensing & GMP Requirements Under Risk-Based System | 17 October 2025

Indonesia has issued revised rules for cosmetic business licensing and GMP compliance, aligned with its risk-based regulatory framework. Taking effect in October 2025, the changes simplify documentation, clarify review timelines, and introduce practical updates for cosmetic manufacturers and importers.

Key Highlights

Cosmetic Notification

- Refillable perfumes no longer require notification.
- Defined processing timelines:
  - Non-fragrance cosmetics: 14 working days
  - Fragrance products, cosmetic kits, export-only: 3 working days
  - Company/manufacturer changes: 14 working days
  - Packaging changes: 3 working days
  - Recommendation letter: 12 working days
- Products must begin manufacturing or distribution within 6 months of notification.

GMP Certification

- Processing timeline:
  - 35 working days for new applications, renewals, and technical changes
  - 10 working days for administrative updates
- GMP certificates may cover multiple buildings for one dosage form.
- GMP fulfilment certificates may include multiple dosage forms if submitted in one application.

These updates reinforce efficiency and regulatory clarity for cosmetic businesses operating in Indonesia.

SPAIN

Spain Plans New Accessible Labelling Rules for Consumer Products | 15 October 2025

Spain has notified the WTO of plans to introduce mandatory accessible labelling for key consumer products — including cosmetics, food and hazardous substances — to better support consumers with disabilities, particularly those with visual impairments. Public comments are open until 14 November 2025, with the measure expected to be adopted in December 2025.

Under the proposal, essential product information — such as product name, responsible company details, ingredients, safety warnings and expiry dates — must be accessible. This may be achieved through Braille, QR codes or other accessible formats. Packaging with space (minimum 10×1 cm) will require the product name in Braille, with additional tactile and digital access features where Braille is not fully used.

Manufacturers, importers and distributors will share responsibility for ensuring compliance. Once in force, the regulation will take effect immediately, with a two-year transition period for existing stock, which may be updated using stickers or similar solutions to meet the new requirements.

BRAZIL

Brazil Bans Two Chemicals in Nail Products to Protect Consumer Health | 29 October 2025

Brazil's health authority has announced a ban on two chemicals commonly used in gel nail products — TPO and DMPT — following concerns over cancer and reproductive health risks. The measure, disclosed on 29 October 2025, aligns the country with recent regulatory actions in the European Union.

The substances, typically found in gel systems cured under UV or LED light, are now prohibited in all cosmetic formulations. Studies have indicated potential long-term harm, particularly for professionals with frequent exposure, prompting authorities to act as a precautionary safety measure.

Under the new rules, manufacturing, imports, and new registrations of products containing these ingredients are banned immediately. Sales and professional use must cease within 90 days, after which remaining products must be withdrawn from the market.

The decision underscores Brazil's ongoing efforts to strengthen consumer and occupational safety in the cosmetics sector.

Brazil Proposes New Rules for Artisanal Cosmetic Products| 13 October 2025

Brazil has opened public consultations (13 October–26 November 2025) on draft regulations for artisanal cosmetics, including hygiene products, perfumes, and related items. The rules aim to support small, manual producers making low-risk products with simple formulations. Final regulations are expected to take effect 60 days after publication.

Key Points

- Applies to low-risk, small-batch cosmetic products made without industrial machinery
- Products must have simple formulas, low microbiological risk, and only basic/non-therapeutic claims
- Producers must manually control all production steps and are fully responsible for product safety
- Eligible categories include items like solid soaps and air fresheners, with specific labeling and claim rules.

Requirements

- No Anvisa product registration or company authorization needed
- Basic hygiene/GMP practices required; max 6-month shelf life
- Labels must show product name, ingredients, producer contact, manufacture date, expiry, and "ARTISANAL"

The proposal aims to encourage traditional cosmetic craftsmanship while ensuring consumer safety and transparency.

Brazil Opens Sandbox for Personalised Cosmetics Innovation | 20 October 2025

Brazil has launched applications for its Regulatory Sandbox pilot for personal care products, cosmetics, and personalised perfumes. The program allows companies to test customised product models and in-store formulation technologies under temporary, flexible regulatory conditions, monitored by Anvisa.

Eligible applicants include AFE-licensed manufacturers/importers, retailers, and companies offering personalization technologies. Applications are open until 18 January 2026, with full details available in Call Notice 18/2025.

ANMAT Launches Simplified Online Authorization for Cosmetic & Hygiene Product Facilities | 27 October 2025

Argentina's health authority has issued Provision No. 7939/25, introducing a new digital system to authorize facilities involved in importing, manufacturing, and handling cosmetics, hygiene products, and certain household items.

Under the system, companies will submit an online sworn declaration confirming compliance with Good Manufacturing Practices and will automatically receive authorization to operate, significantly reducing wait times and paperwork.

ANMAT will conduct post-approval checks to ensure compliance, maintaining public-health safeguards while streamlining processes. The provision takes effect 60 administrative working days after publication in the Official Gazette.

Health Canada Updates Cosmetic Notification Form | 09 October 2025

Health Canada has updated the Cosmetic Notification Form (CNF) and guidance as of October 6, 2025, with key improvements to streamline submissions and support upcoming rules.

Main Changes

- **Contact details:** Users can now auto-populate contact information from saved entries.

- **Ingredient field update:** “Other Chemical Name” is now “If no INCI name is available, the Chemical Name,” reinforcing INCI use wherever possible.

- **Fragrance allergen checkbox:** Added ahead of new disclosure rules taking effect April 12, 2026, requiring allergen reporting above 0.01% in rinse-off and 0.001% in leave-on products.

- **Label upload prompt:** The system now flags missing labels for products with certain regulated ingredients (e.g., coal tar dyes), ensuring required warnings are provided.

Health Canada may request additional documents to confirm compliance.

List of ISO standards updated in October 2025

- ISO 9185:2025 - Protective clothing — Assessment of resistance of materials to molten metal splash
- ISO 17730:2025 - Dentistry — Fluoride varnishes
- ISO 18618:2025 - Dentistry — Interoperability of CAD/ CAM systems
- ISO 7376-2:2025 - Anaesthetic and respiratory equipment — Part 2: Video laryngoscopes
- ISO 19223-3:2025 - Lung ventilators and related equipment — Vocabulary and semantics — Part 3: Respiratory care
- ISO 5092:2025 - Additive manufacturing for medical — General principles — Additive manufac turing of non-active implants
- ISO 5832-2:2025 - Implants for surgery — Metallic materi als — Part 2: Unalloyed titanium