Newsletter

REGULATORY BRAINBOX

OMC MEDICAL
Regulatory Services

Medical Devices Regulatory Consultancy

JULY NEWSLETTER

How we can help?

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

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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
- ✓ 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

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EUROPEAN UNION (EU)

EU Unveils Template for Notified Body Confirmation Letters Under Reg EU 2024/1860 | 26 July 2024

The European Union has released a new template for the notified body confirmation letter, as per Regulation (EU) 2024/1860. This template standardizes the notification of a formal application status, written agreements, and surveillance procedures, ensuring clarity and consistency across the regulatory framework. The move aims to streamline compliance and enhance oversight.

Bosnia and Herzegovina Joins EU4Health Programme | 23 July 2024

The Commission and the Council of Ministers of Bosnia and Herzegovina have signed an agreement to integrate the country into the EU4Health programme. Effective January 1, 2024, Bosnia and Herzegovina will access EU funding for crucial health initiatives, including cancer care, medicine stockpiling, mental health services, digital healthcare, and cross-border health threats. This move will significantly enhance the nation's health system and resilience.

EU Announces New Regulation on Quality and Safety Standards for Human-Origin Substances| 17 July 2024

The European Union has released a new Regulation on standards of quality and safety for substances of human origin intended for human application. Published in the Official Journal of the EU, this regulation aims to enhance the safety and effectiveness of these substances, ensuring higher standards in their application for medical and other purposes.

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

Title	Overview
Guidance on Classification Rules for in vitro Diagnostic Medical Devices under Regulation (EU) 2017/746 ***MDCG 2020-16 Rev.3***	The document aims to clarify the classification process, ensuring consistent application across the EU. It outlines detailed criteria and examples for categorizing IVDs, including those related to their intended purpose and risk levels. This revision addresses feedback from stakeholders and aligns with evolving regulatory practices, enhancing the clarity and predictability of device classification.
Guidance on standardisation for medical devices ***MDCG 2021-5 Rev.1***	This revision focuses on aligning device standards with regulatory requirements to ensure safety, effectiveness, and consistency in the market. It includes detailed recommendations for harmonizing technical standards, enhancing regulatory compliance, and supporting manufacturers in meeting EU regulations.
Q&A on practical aspects related to the implementation of the extended transitional period provided for in the IVDR, as amended by Regulation (EU) 2024/1860 ***Q&A***	The Q&A on the extended IVDR transitional period (Regulation (EU) 2024/1860) provides guidance on new deadlines, compliance strategies, and documentation requirements. It helps manufacturers and stakeholders navigate the updated timeline for aligning with the In Vitro Diagnostic Regulation.
Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607 - Extension of the MDR transitional period and removal of the "sell off" periods ***Q&A Rev. 2***	The Q&A on Regulation (EU) 2023/607 clarifies the extended MDR transitional period and the removal of "sell off" periods. Manufacturers now have extra time for MDR compliance, and devices under older directives cannot be sold past the new deadlines. The document offers guidance on adapting to these regulatory changes.

ALBANIA

Albania Expands List of Reimbursable Medicines, Adding 50 New Drugs | 24 July 2024

The Minister of Health and Social Protection, announced that the Council of Ministers approved an updated list of Reimbursable Medicines. The new list includes 1,345 alternative medicine drugs, up from 1,191. It features 50 new drugs, with 38 new active ingredients and 18 new dosage forms. The additions support a range of conditions, including oncological, cardiovascular, diabetes, kidney, asthma, and pulmonary diseases. Additionally, reimbursement for diabetes blood sugar testing strips has been expanded to further support those with diabetes.

Albania Welcomes First ECMO Device to Aid Patients with Severe Heart and Lung Conditions | 5 July 2024

The Minister of Health and Social Protection announced the introduction of the ECMO (Extracorporeal Oxygenation Membrane) machine to Albania. This advanced medical device functions as an artificial lung for patients with severe health issues, particularly when their heart and lungs are not working effectively. The ECMO machine continuously circulates blood, oxygenates it, and removes carbon dioxide, helping to stabilize critically ill patients.

ARGENTINA

ANMAT Participates in PAHO/WHO Workshops on Evaluating and Strengthening Health Product Regulatory Systems | 18 July 2024

ANMAT participated in PAHO/WHO workshops from July 9-12, training Latin American regulatory experts on evaluating and improving health product regulatory systems. The sessions covered the WHO Global Assessment Tool and performance indicators for transitioning to WHO Listed Regulatory Authorities. The workshops are part of the WHO's efforts to strengthen global regulatory systems.

New "Surveillance Inspections" for GMP Compliance to Start July 2024 | 25 July 2024

Starting July 1, 2024, temporary "surveillance inspections" will be introduced for GMP inspections of medicine and API manufacturers. These inspections will cover all aspects of the Pharmaceutical Quality System (PQS) but will be shorter, lasting about half the usual inspection time.

They may be conducted on-site, remotely, or in a hybrid format, and will be used only once per eligible site. Sites with a good compliance rating (A1 or A2) from their last inspection are eligible.

This change aims to address inspection backlogs caused by COVID-19 and ensure timely regulatory oversight. Additionally, TGA licensed sites that haven't been re-inspected in three years can apply for GMP certificates with an extended validity of four years.

New EU Measures Enhance Availability and Transparency of In Vitro Diagnostics | 10 July 2024

The European Union's Official Journal has published Regulation (EU) 2024/1860, amending existing regulations on medical devices and in vitro diagnostics. Key changes include extended transition periods for manufacturers adapting to new In Vitro Diagnostic Medical Device Regulation (IVDR) rules.

The additional time granted to companies depends on the type of device:

- all IVDs with a IVDD certificate (list A, list B and self-test devices) will have a transition period until December 2027;

- Class D devices, with a high individual risk and a high public health risk, such as HIV or hepatitis tests, will have a transition period until December 2027;
- Class C devices, with a high individual risk and/or a moderate public health risk, such as cancer tests, will have a transition period until December 2028;
- Class B devices, with a moderate individual risk and/or a low public health risk, such as pregnancy tests, and sterile devices class A, with a low individual risk and a low public health risk, such as blood collection tubes, have a transition period until December 2029.

The regulation specifies the conditions set to benefit from this additional time.

Manufacturers must now notify authorities and healthcare providers about any anticipated disruptions or discontinuations of devices six months in advance. Additionally, the gradual implementation of the European Database on Medical Devices (Eudamed) will enhance market transparency starting in early 2026.

European Medicines Regulatory Network Earns WHO Listed Authority Status | 4 July 2024

The European Medicines Regulatory Network (EMRN), including the Federal Agency for Medicines and Health Products (FAMHP), has been officially designated as a WHO Listed Authority by the World Health Organization.

This designation, achieved after an assessment from February to April 2024, acknowledges the network's compliance with international regulatory standards and practices. It encompasses the European Commission, the European Medicines Agency (EMA), and the 30 national medicines authorities within the European Economic Area. The EMRN is recognized as both a single entity and a Regional Regulatory System.

Anvisa Announces New Pilot Procedure for Product Registration Evaluation | 3 July 2024

Anvisa has clarified that a new screening procedure outlined in RDC 823/2023 will apply only to petitions submitted after the standard operating procedure (SOP) becomes effective. The procedure will not be retroactive. Initially, it will be tested through a pilot project involving three registration requests, focusing on quality documents to assess its functionality.

This pilot will help identify improvements before the final version of the procedure is published and applied to future petitions.

The new approach aims to enhance the efficiency and transparency of Anvisa's evaluation processes.

Anvisa Joins MDSAP Forum in Germany to Discuss Program Expansion and Updates | 3 July 2024

From June 24 to 28, Anvisa attended the MDSAP Forum and the Regulatory Authority Council (RAC) meeting in Essen, Germany. The forum, which saw participation from 27 countries including new MDSAP affiliate members Singapore, Mexico, and Kenya, focused on the strategic priorities of the MDSAP, such as program sustainability and efficiency.

Anvisa showcased its use of MDSAP reports and certificates, announcing an extension of the Good Manufacturing Practices Certificate (CBPF) validity from two to four years for MDSAP-participating companies, as per RDC 850/2024.

COSTA RICA

Portugal and Costa Rica Sign Memorandum for Digital Health Cooperation | 11 July 2024

On June 27, 2024, Portugal and Costa Rica signed a Memorandum of Understanding to enhance collaboration in digital health. The agreement, facilitated by the European Technical Assistance and Information Exchange (TAIEX) programme, aims to share expertise and improve various digital health initiatives. The memorandum was signed by Portugal's Minister of Health and Costa Rica's Vice Minister of Health.

The cooperation includes activities such as visits by experts, virtual workshops, and focuses on areas like data protection, epidemiological early warning systems, electronic medical records, teleconsultation improvements, and professional training.

Ministry of Health Updates Electronic Form Noti-FACEDRA for Improved Adverse Reaction Reporting| 8 July 2024

The Ministry of Health has announced updates to the electronic form Noti-FACEDRA, used for reporting side effects in medicines and vaccines. These updates, implemented at the end of June, aim to enhance the reporting process.

Key changes include strict date entry formats (day/month/year or month/year), mandatory detailed user information (province, canton, district, address, location, and type of center), a file attachment size limit of 2.5 MB, and restrictions preventing notifications from being sent from non-corresponding user profiles.

Health professionals and the pharmaceutical industry are advised to familiarize themselves with these new features to ensure compliance.

FRANCE

ANSM Signs Consensus Statement on EU Medical Device Regulatory System | 26 July 2024

On July 10, 2024, the ANSM hosted a workshop in Saint-Denis, organized by the HMA Core Group and supported by the European Commission, to evaluate the EU regulations for medical devices (2017/745) and in vitro diagnostic medical devices (2017/746). The workshop, attended by 19 delegations including heads of agencies and medical devices departments, aimed to identify current priorities, challenges, and solutions for the regulations.

The event concluded with a "consensus statement" acknowledging difficulties in regulation application while affirming confidence in the EU regulatory framework's relevance and robustness. Key priorities outlined include ensuring patient safety, maintaining device accessibility across Europe, and promoting innovation in public health technologies.

New EU Regulation Enhances Quality and Safety Standards for Substances of Human Origin | 19 July 2024

A new regulation has been published in the Official Journal of the European Union, aiming to strengthen the quality and safety standards for substances of human origin (SoHO) intended for human application. Effective from 2027, this regulation replaces the existing directives on blood, tissues, and cells that have been in place for about twenty years. It introduces a comprehensive approach to SoHO, offering better protection for recipients, children born through medically assisted procreation, and donors.

Key features include an expanded scope covering all SoHO except organs, enhanced surveillance by competent authorities, and improved collaboration and expertise among EU Member States. Member States and the European Commission have until 2028 to ensure compliance, including verifying the status of SoHO establishments and submitting information on authorised SoHO preparations.

Additionally, an EU digital SoHO platform will be established to increase visibility and facilitate information exchange on SoHO vigilance among EU citizens.

French Translation of Revised GMP Annex 1 on Sterile Medicinal Products Now Available | 15 July 2024

The French translation of Annex 1 of Good Manufacturing Practices (GMP) for sterile medicinal products, revised by the European Commission, has been published. This revised annex, effective from June 14, 2024, reflects regulatory, technological, and risk management advancements since 2009. The update aims to harmonize international practices, integrate new manufacturing technologies, clarify sterilization methods, and introduce rapid analysis techniques.

The ANSM led the collaborative effort with the EMA, PIC/S, and WHO since October 2018. A consultation with manufacturers ensured the translation's clarity. Compliance with point 8.123 regarding freeze-dryers will be required by August 25, 2024.

New Protocols for Managing Medical Device Shortages Effective September 2024| 5 July 2024

Starting September 1, 2024, new procedures will be implemented for anticipating and managing the unavailability of medical devices (MDs) and in vitro medical devices (IVMDs). These changes aim to ensure structured and proactive management by all stakeholders to prevent disruptions in patient care and address potential public health risks.

Key updates include the introduction of a risk analysis grid and redesigned flowcharts to assess and manage the criticality of situations, and simplified declaration forms for reporting issues. Despite these changes, the agency will continue to support manufacturers when their actions are insufficient, providing expertise and coordination to manage critical situations and ensuring transparency and patient safety.

The steps for managing unavailability involve preventive measures by manufacturers and coordinated efforts with the agency when necessary.

INDIA

New Initiative to Enhance Patient Safety in India Through Materiovigilance | July 2024

The Indian Pharmacopoeia Commission (IPC), an autonomous body under the Ministry of Health and Family Welfare, has taken a significant step towards improving patient safety in India with the launch of the Materiovigilance Programme of India (MvPI). Since 2018, the IPC has entrusted the National Coordination Center (NCC) with the responsibility of monitoring, recording, and analyzing adverse events associated with medical devices.

MvPI aims to equip medical device manufacturers with essential tools and techniques for effective adverse event reporting, ensuring compliance with MvPI guidelines, and promoting patient safety and device efficacy. By identifying the root causes of adverse events or risks associated with medical devices, MvPI seeks to suggest appropriate regulatory actions, ultimately enhancing patient safety across the country.

The program is expected to aid medical device stakeholders in making informed decisions about reporting adverse events, strengthening the materiovigilance system nationwide, and developing better quality management systems. The initiative targets medical device manufacturers, importers, distributors, as well as quality assurance and regulatory affairs professionals, fostering a collaborative approach to advancing patient safety in India.

A seminar discussing the program's objectives and outcomes is scheduled for September 3rd.

Spain’s Ministry of Health Outlines Procedure for EU4Health Funding Applications | 23 July 2024

The Spanish Agency for Medicines and Medical Devices (AEMPS) has announced that Spain's Ministry of Health has developed an internal procedure for assessing authorities and organizations seeking EU4Health funding for the 2024 work plan. This European program, aimed at enhancing public health across the EU, focuses on improving health policies, disease prevention, and healthcare accessibility. It also targets reducing health inequalities, promoting healthy lifestyles, and strengthening health systems. The full procedure is available on the Ministry of Health's website.

Spain’s Medicine Inspection Services Pass Joint Audit Program, Ensuring EU-Wide Compliance | 10 July 2024

Spain's inspection services for medicine manufacturing have successfully passed the Joint Audit Program (JAP) audit, coordinated by the Network of Heads of Medicines Agencies (HMA) and the European Commission. This audit, conducted by inspectors from Sweden, Germany, and the Czech Republic, confirmed that Spain's inspection services align with EU standards, enhancing international recognition and facilitating pharmaceutical exports. The success is attributed to the coordination between the Spanish Agency for Medicines and Health Products (AEMPS) and autonomous communities. The audit assessed documentation, inspection actions, and market control measures, including quality defect management and alert systems.

UNITED STATES OF AMERICA (USA)

Advancements and Regulations in Medical Device Sterilization | 24 July 2024

Medical devices are sterilized using methods like steam, dry heat, radiation, and ethylene oxide (EtO). EtO is essential for sterilizing many devices, especially those made of sensitive materials or with complex designs. About half of all sterile U.S. medical devices use EtO.

The FDA ensures safety through premarket reviews and recognized standards, particularly ANSI AAMI ISO 11135:2014 and ANSI AAMI ISO 10993-7:2008(R)2012. Changes in sterilization methods require FDA review for compliance.

The FDA and EPA regulate EtO use and mitigate its environmental and health impacts. The FDA promotes sterilization innovation through pilot programs and challenges, aiming to reduce EtO emissions. They also encourage using electronic materials to minimize EtO in packaging. Standards updates and town halls support the advancement of medical device sterilization.

SWITZERLAND

Swissmedic Offers 80% Fee Reduction for Certain Academic Clinical Trials with Medical Devices | 1 July 2024

Swissmedic has announced an 80% reduction in the flat-rate fees for authorizing certain academic clinical trials involving medical devices, effective immediately. To qualify, sponsors must confirm the absence of commercial third-party funding. Funding from universities, foundations, the Swiss National Science Foundation, or Innosuisse may still allow for fee reduction.

Applications require two documents: BW610_10_029e_FO_Application_fee_reduction and BW610_10_030e_VL_Application_fee_reduction_selfdeclaration, to be submitted with the authorization application in the '00.00_Swissmedic_forms' folder of the eDok submission.

Sponsors must notify Swissmedic if they receive commercial third-party funding during the trial.

Continuation of Coronavirus Self-Tests Dispensation in Switzerland Post COVID-19 Ordinance 3 Expiry | 1 July 2024

As of July 1, 2024, COVID-19 Ordinance 3, which provided the legal basis for dispensing rapid SARS-CoV-2 self-tests to the public, is no longer valid. Despite this, Swissmedic, at the request of the Federal Office of Public Health (FOPH), has approved an exception to continue the distribution of these self-tests.

This decision was made in the interest of public health to allow individuals to protect themselves and others, especially those at high risk

The self-tests will still be available through suitable outlets such as pharmacies, ensuring that the necessary specialist advice is provided.

MEXICO

Cofepris Introduces Draft Standard for Enhanced Technovigilance in Medical Devices | 26 July 2024

On July 24, 2024, Mexico's Federal Commission for the Protection against Sanitary Risks (Cofepris) published a draft of Mexican Official Standard 240 in the Official Gazette. This new standard aims to improve the installation and operation of technovigilance processes to better safeguard patient health and ensure the safety of medical devices in Mexico.

The draft incorporates international standards for enhanced oversight and will be open for public consultation for 60 days. This initiative aligns with Article 58 of the General Health Law and Article 38 of the Health Supplies Regulation, emphasizing the importance of timely reporting of adverse reactions from medical devices. The move reflects Cofepris' commitment to public health and effective regulation of the growing medical devices sector.

Cofepris Approves Dexrazoxane for Cancer Treatment, Expanding Access to Generic Drugs | 8 July 2024

On July 8, 2024, Mexico's Federal Commission for the Protection against Sanitary Risks (Cofepris) approved the sanitary registration of dexrazoxane, a generic drug designed to mitigate severe cardiac side effects from cancer treatments like doxorubicin.

This approval, part of Cofepris' recent biweekly update, also includes 19 other generic drugs, underscoring the agency's commitment to enhancing public health and equitable access to treatments. Cofepris' rigorous evaluation process ensures the safety, quality, and efficacy of approved health products, reflecting its dedication to transparency and patient well-being.

Cofepris Greenlights Clinical Trial for GORE Synthetic Cornea Device | 1 July 2024

On July 1, 2024, Mexico's Federal Commission for the Protection against Sanitary Risks (Cofepris) approved a clinical trial for the GORE synthetic cornea device, designed to restore vision in patients with corneal transparency loss. This innovative device, made from biocompatible plastic polymers, offers an alternative to corneal transplants for treating blindness.

The trial is part of a broader initiative where Cofepris authorized 14 new therapeutic protocols, including 20 drugs and 76 medical devices, such as angioplasty guidewires and defibrillators. These approvals follow rigorous evaluations to ensure high safety and efficacy standards, reflecting Cofepris's commitment to advancing medical treatments and maintaining transparency in healthcare.

Malaysia and South Korea Discuss Regulatory Reliance in Medical Device Approvals | 5 July 2024

A bilateral meeting between Malaysia's MDA and South Korea's MFDS explored cooperation on regulatory reliance in medical device pre-market approvals. Following the February 2024 MOU, the discussion focused on adopting the World Health Organization's Good Reliance Practice (GreIP).

The meeting aimed to streamline processes, reduce duplication, and enhance the efficiency of regulatory systems in both countries.

ASEAN Cosmetic Regulations Updated: New Ingredient Restrictions and Compliance Deadlines Announced | 5 July 2024

In 2005, the Philippines adopted the ASEAN Harmonized Cosmetic Regulatory Scheme to streamline cosmetic regulations. Recent updates from the 38th ASEAN Cosmetic Committee Meeting introduced significant changes to the ASEAN Cosmetic Directive (ACD). These include new restrictions on ingredients like Benzophenone-3 and Diethyltoluamide (DEET), with specific deadlines for compliance. Amendments to existing annexes simplify criteria and introduce a new method for detecting 1,4-Dioxane. The changes aim to improve safety and standardize regulations across ASEAN, taking effect 15 days after publication.

NMN's Rising Popularity and Regulatory Challenges in the Cosmetics Industry | 21 July 2024

β-Nicotinamide mononucleotide (NMN) is a naturally occurring nucleotide that boosts NAD+ levels, which is linked to improved immunity and metabolism. Often hailed for its "anti-aging" effects, NMN has surged in popularity as a cosmetic ingredient, with the highest number of notifications as a new ingredient. However, regulatory bodies like China's State Administration for Market Regulation (SAMR) have declared NMN's use in food and medicine products illegal, raising questions about its efficacy and potential future restrictions in cosmetics. This article examines the implications of NMN's regulatory status and its impact on the cosmetics industry.

New Regulations Strengthen Consumer Protection in China | 9 July 2024

Chinese Premier has signed a decree implementing the refined Regulations for the Implementation of the Nation's Law on the Protection of Consumer Rights and Interests, effective July 1, 2024. The updated regulations detail business operators' obligations, including ensuring consumers' personal and property safety, managing defective products, avoiding fraudulent advertising, maintaining price transparency and quality guarantees, protecting consumers' personal information, and safeguarding the rights of the elderly and minors.

The regulations also address online consumption, standardize complaint and compensation procedures, and prevent misuse of consumer complaints for market disruption. Governments are mandated to enhance guidance, supervision, and enforcement, while consumer associations are given defined duties.

China Implements Full Electronic Submission for Cosmetic Product Registration and Notification | 28 July 2024

On July 8, 2024, China's National Medical Products Administration (NMPA) announced that starting from September 1, 2024, all registration and notification materials for cosmetic products and new cosmetic ingredients (NCI) must be submitted electronically via the Cosmetics Registration and Notification Information Service Platform.

This mandate applies to domestic registrants, notifiers, responsible persons, and cosmetics manufacturers, eliminating the need for paper document submissions. Original and third-party certification documents must still be signed, sealed, and submitted in electronic form. The NMPA and provincial medical products administration departments will update their procedures to support this shift. The industry anticipates benefits such as reduced paperwork, lower manpower costs, and expedited processing times, with the transition period ensuring minimal disruption for ongoing submissions.

Indonesia Launches New Halal Certificate Registration System for Foreign Products | 28 July 2024

On July 15, 2024, the Indonesia Halal Product Guarantee Agency (BPJPH) announced the opening of the Foreign Halal Certificate Registration (RSHLN) channel on the Halal Information System (Sihalal). This development is in line with the Halal Product Assurance Law, which allows foreign halal products with recognized certifications to enter the Indonesian market without needing new certifications, provided their certificates are registered with BPJPH.

BPJPH has agreements with 37 Overseas Halal Institutions (LHLNs) from 16 countries/regions, simplifying the process for importers. The registration process involves creating an account on Sihalal, submitting necessary documents, undergoing verification, making payment, and receiving the RSHLN number. This new system aims to streamline industrial and trade activities of halal products in Indonesia.

South Korea Updates Cosmetic Labeling Requirements to Enhance Consumer Safety | 8 July 2024

On January 31, 2024, South Korea's Ministry of Food and Drug Safety (MFDS) announced proposed amendments to the Enforcement Rule of the Cosmetics Act, aiming to strengthen cosmetic labeling requirements for consumer safety, particularly for special cosmetics like "external genital cleansers" and "eyelash perm wave products." Key changes include mandatory disclosure of ingredient lists and precautions for these products, the allowance of certification results from private institutions in advertising, and streamlined administrative measures for managing business information.

The regulation was enacted on July 9, 2024, with specific provisions for small-volume cosmetics becoming effective one year later. Additionally, the Regulation of Labelling Cosmetics Precautions for Use and Fragrance Allergens was updated to include new guidelines for "eyelash perm wave products." The revisions aim to improve cosmetic safety and support the domestic cosmetic certification industry in South Korea.

2024年7月更新的ISO標準列表：

- ISO 11040-4:2024 - Prefilled syringes — Part 4: Glass barrels for injectables and sterilized subassembled syringes ready for filling
- ISO 11040-7:2024 - Prefilled syringes — Part 7: Packaging systems for sterilized subassembled syringes ready for filling
- ISO 10009:2024 - Quality management — Guidance for quality tools and their application
- ISO/TS 5777:2024 - Health informatics — The architecture of internet healthcare service network
- ISO/TS 9321:2024 - Health informatics — General requirements of multi-centre medical data collaborative analysis
- ISO/TS 20428:2024 - Genomics Informatics — Data elements and their metadata for describing structured clinical genomic sequence information in electronic health records