Clarivate

Regulatory compliance of controlled substances and suspicious order monitoring: A comparative analysis

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Abstract

The regulation of Controlled Substances (CS) and the implementation of Suspicious Order Monitoring (SOM) systems have become critical facets of modern public health and law enforcement policy across the globe. With rising concerns around opioid epidemics, illicit trafficking of psychotropic drugs, and the growing prevalence of novel psychoactive substances (NPS), regulatory authorities are under pressure to develop robust, transparent, and interoperable mechanisms for managing drug supply chains.

This article explores the global landscape of controlled substance and suspicious order monitoring regulation, with a focus on recent legislative updates, national monitoring systems, and collaborative frameworks for mitigating their misuse. CS and SOM regulations from selected countries across Europe, Middle East and Africa, Asia Pacific, North America and Latin America are analysed, revealing the evolution of regulatory policies, patterns in enforcement mechanisms, and inter-regional cooperation models for controlled substances and suspicious order monitoring.

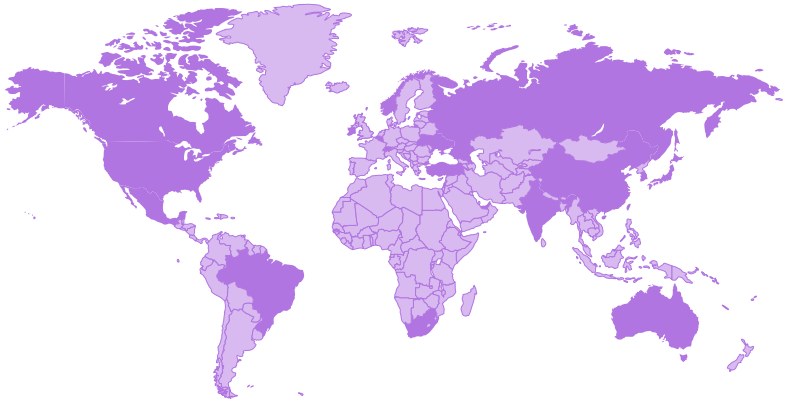
The research delves into legislative updates, collaborative frameworks, and enforcement mechanisms used to counter drug misuse, and emphasizes regional collaboration and digital tracking systems. This article aims to guide stakeholders in policy alignment, risk mitigation, and operational harmonization within the global controlled substances supply chain, including visual charts and tables to support the comparative analysis.

Methodology

The data for this research was extracted from official legal documents, government regulatory portals, and national health agencies of the countries in scope by creating a comparative qualitative content analysis to study changes in legal frameworks, import/export controls, monitoring systems, Manufacturing, Handling, and inter-country collaborations.

Markets in scope

18 selected countries across regions, namely, EMEA (Norway, Switzerland, Turkey, Ukraine, Belgium, Ireland, United Arab Emirates, Russia and South Africa), APAC (Australia, China, India, Japan and South Korea) and Americas (USA, Canada, Mexico and Brazil). The country coverage in this article is shown below.



Keywords

"Controlled Substances," "Drug Scheduling," "Narcotics Regulation," "Psychotropic Substances," "Precursors," and "Suspicious Order Monitoring," "Diversion Control," "Prescription Monitoring Programs," "Digital Reporting Systems," "Euphoric".

Topics in scope

a) Schedules of controlled substances, b) Prescription Controls, c) Production and Manufacturing Controls, d) Labelling and packaging controls, e) Records, document and admin controls, f) Supply chain controls, g) Disposal and h) Suspicious order monitoring.

Date range

"01 October 2021" to "30 June 2025".

Document types in scope

Circulars, Decisions, Decrees, Directives, Guidelines, Laws, Regulations, Resolutions, Orders, Ordinance, Standard Operating Procedures, Federal Register Announcement, Form, Information Note, Notification, Report.

Document types out of scope

Agreement, Checklist, Citizen Petition, Committees and Working Groups, Communication, Consultation, Fact Sheet, Inspection Report, Letter, Meeting, Newsletter, Other type, Presentation, Press Release, Product Information.

Evolving global mechanisms for controlled substance regulation and suspicious order monitoring

The global landscape of pharmaceutical and narcotic control is undergoing a profound transformation. With increasing public health challenges related to drug misuse, synthetic opioid proliferation, and illegal cross-border trafficking, countries are tightening regulatory oversight on Controlled Substances (CS) while simultaneously enhancing Suspicious Order Monitoring (SOM) mechanisms. These dual pillars CS regulation and SOM systems are central to ensuring medical necessity is balanced with abuse prevention, and that supply chain integrity is preserved across borders. Controlled Substances refer to drugs and chemicals whose manufacture, possession, and use are regulated due to potential for addiction or abuse. lincluding narcotic drugs and psychotropic substances, pose significant challenges to public health, safety, and law enforcement globally. Governments and international bodies have implemented stringent regulations to control their distribution, usage, and disposal. These substances are typically categorized into schedules or classes depending on their medical utility and abuse potential. International bodies such as the United Nations Office on Drugs and Crime (UNODC), the World Health Organization (WHO), and regional authorities like the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) establish standards and recommend best practices. However, actual implementation differs by country and region.

International frameworks such as the 1961 Single Convention on Narcotic Drugs, the 1971 Convention on Psychotropic Substances, and the 1988 UN Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances provide foundational legal templates. National systems then adapt these conventions into domestic laws through drug scheduling, licensing, and compliance mandates. Countries such as the USA, Canada, China, Brazil, and Ireland regularly update their schedules based on World Health Organization (WHO) recommendations and emerging global risks, such as the spread of synthetic cannabinoids and fentanyl analogues.

The DEA's ARCOS system in the USA enables near real-time tracking of high-risk substances

Suspicious Order Monitoring (SOM), while historically underemphasized, has emerged as an essential regulatory component, especially in the context of digital health infrastructure and pharmaceutical logistics. SOM refers to systems used by manufacturers, distributors, and regulators to detect and report anomalous patterns in drug orders such as unusual volumes, geographic spikes, or irregular frequencies. For instance, the DEA's ARCOS system in the USA enables near real-time tracking of high-risk substances, allowing proactive intervention before diversion or abuse occurs. The intersection of CS and SOM is particularly critical as countries move from reactive to preventive regulatory approaches. The SOM system is increasingly becoming a strategic priority for governments. Several nations including India, Australia, Japan, and South Korea have integrated SOM features into their broader CS licensing platforms. Others, like Mexico and South Africa, are building capacity through digitization efforts such as electronic prescription portals and digital import/export authorization.

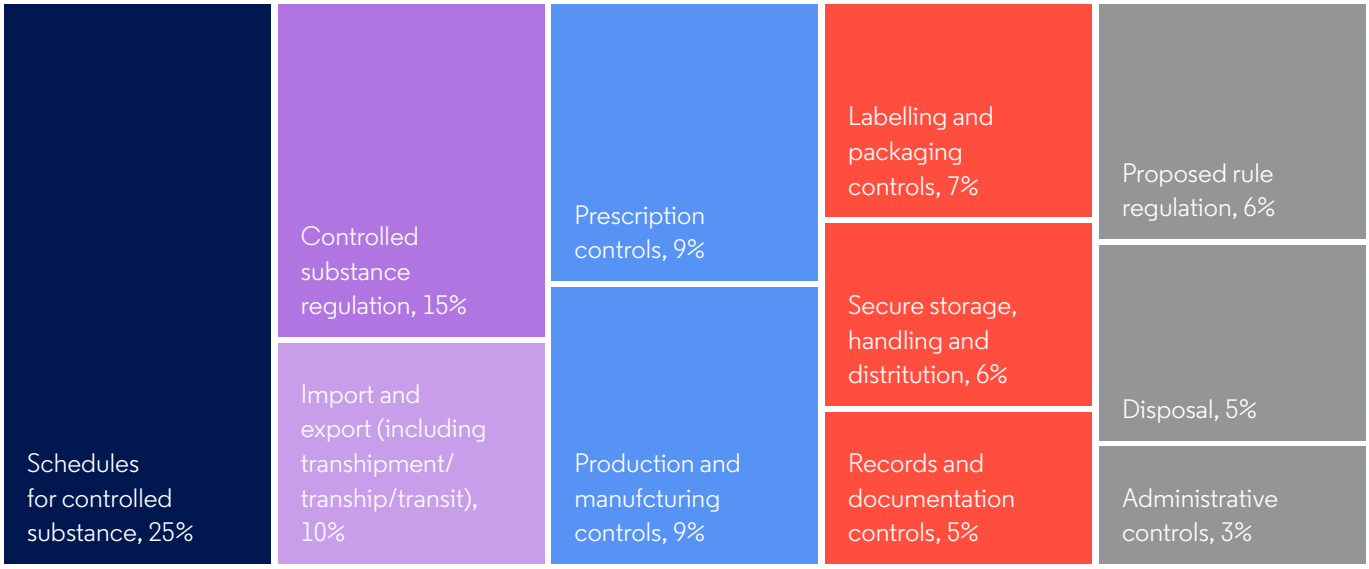
The role of international collaboration should not be understated. Mechanisms such as the INCB's I2ES system plays a significant role in promoting transparency and interoperability between jurisdictions for importing and exporting controlled substances by providing an online platform for exchanging authorizations and data, GCC-HealthNet centralized drug registration system which aims to harmonize pharmaceutical regulations among its member states (Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, and UAE), simplifying drug registration and potentially impacting the control of pharmaceutical products that could be diverted for illicit use, and UNODC

(United Nations Office on Drugs and Crime) data-sharing frameworks develops and promotes frameworks for data sharing and analysis to counter the world drug problem. The UNODC also collaborates with countries to monitor illicit crop cultivation using various methods, including GIS and satellite imagery, to gather data for policy development and tackling drug production.

With increasing globalization, regional collaboration and harmonized legislation have become vital for monitoring and preventing misuse. This article consolidates regulatory and operational insights across multiple regions offering a comparative analysis of how CS regulation and SOM practices are evolving in tandem. It examines legal frameworks, digital tools, regional platforms, and collaborative networks that together shape the current and future state of drug control governance. Through this integrated lens, the study aims to highlight best practices, how various countries regulate controlled substances and suspicious order monitoring regulations, the changes they have implemented in recent years, and support global efforts to mitigate controlled substance regulations.

The top 3 most frequently updated topics are the **schedules of CS (25%),** followed by **CS regulations (15%)** and **import/export (10%).** The most frequently updated topics are shown in the figure below.

Most frequently updated topics



Leading markets in publishing new or updated regulations

The top 5 markets in terms of volume of publications of New and Updates in the existing regulations were USA, Switzerland, Canada, South Korea and Belgium. The full list of markets in scope aligned by volume of publication (New and Updated) is provided in the figure below.

Comparative Regional Overview

EMEA

Norway, Switzerland, Turkey, Ukraine, Belgium, Ireland, UAE, Russia and South Africa are in scope for analysis in this region.

CS Regulatory Evolution

Across EMEA, regulatory control is generally aligned with the UN Conventions, particularly the Single Convention on Narcotic Drugs (1961) and the Convention on Psychotropic Substances (1971). Countries like Belgium and Ireland have embedded EU directives into national laws, offering precise scheduling of controlled substances, with Belgium utilizing Royal Decrees and Ireland relying on Statutory Instruments (S.I.). For instance, both countries (Belgium and Ireland) have frequently updated schedules under Royal Decrees and Misuse of Drugs Acts respectively. Recent updates (2023–2024) show enhanced classification systems, digital submission portals, and mandatory reporting mechanisms to ensure transparent tracking of narcotic substances. Belgium and Ireland typically issue CS updates biannually.

Norway and Switzerland, though not members of the European Union, demonstrate strong alignment with EU regulatory practices. In Norway, the Norwegian Medicines Agency oversees controlled substances. The regulatory framework includes annual updates, such as the Regulation No. 199 of 2013 on Drugs, which was amended in January 2022, and the primary CS regulation (Regulation No. 2354/2021). Norway collaborates with other EU/EEA countries through shared intelligence and reporting mechanisms, maintaining alignment with EU directives despite its non-member status. Switzerland operates independently of the EU but maintains a well-established regulatory system through Swiss medic and the Federal Office of Public Health (FOPH). Its controlled substances are governed by the Narcotics Act and Ordinance on Narcotics Control, with the latest updates as recent as 2024. Switzerland publishes monthly updates to its List of Authorised Human Medicines Containing Narcotics and regularly revises the Narcotics List Ordinance to reflect changes in controlled substances. The country also collaborates with international organizations, including the International Narcotics Control Board (INCB) and the World Health Organization (WHO), for monitoring, reporting, and enforcement purposes.

Ukraine and Turkey are in transition. Ukraine is gradually modernizing its legislation in alignment with the EU, especially concerning psychotropic substances. The primary regulatory framework revised annually such as Circulation of Drugs, Psychotropic Substances, Their Analogue and Precursors in Ukraine and approval of the list of narcotic drugs, psychotropic substances and precursor, while specific lists of narcotic substances are updated more frequently. Meanwhile, Turkey regulates narcotics under the Turkish Medicines and Medical Devices Agency (TMMDA). Turkey maintains a robust pharmaceutical control framework and has increased scrutiny of prescription systems post-2021. This includes implementing measures like electronic prescriptions and tracking systems for controlled substances. It adheres to the Law No. 2313 and subsequent circulars, Green Prescription drugs and Red List of Prescription Drugs.

Russia operates under Federal Law No. 3-FZ/1998 on narcotic drugs and psychotropic substances, with robust recent updates in 2023 and 2024 including new analogue classifications and licensing regulations and list of narcotic drugs, psychotropic substances and their precursors which are updated biannually. Russia enforces strict classification and handling of narcotics and psychotropics through regularly revised lists, with the Ministry of Health maintaining tight oversight on all activities involving controlled drugs, including prescription and storage protocols. In contrast, South Africa regulates controlled substances under the Medicines and Related Substances Act, 1965, using a schedule-based approach with updates typically every 5–7 years. The South African Health Products Regulatory Authority (SAHPRA) oversees licensing, import/export, and disposal, supported by detailed operational guidelines.

The UAE enforces strict control under the Ministry of Health and Prevention. The country implements Federal Law

No. 14 of 1995 with periodic update and Controlled Drug Prescriptions having annual update. UAE integrates its surveillance systems with GCC countries and maintains stringent penalties to deter abuse, making it one of the most tightly regulated nations in the MENA region.

While all EMEA countries maintain strict controls, Western European nations tend to update their regulations more frequently and provide advanced digital tracking systems. In contrast, Middle Eastern and Eastern European countries are still progressing toward standardization and technological modernization. Norway, Belgium, Switzerland, and Ireland typically issue frequent updates related to controlled substances, focusing on scheduled substance lists, prescription controls, list revisions, import/export licensing, and the adoption of electronic systems. Russia has recently implemented extensive regulatory changes, including new rules for storage and precursor handling. South Africa's core legislation has remained unchanged since 2017; however, its operational guidelines have evolved. The UAE has notably expanded its controlled substance regulations in recent years.

SOM Monitoring and Collaboration

In the EMEA region, Suspicious Order Monitoring (SOM) systems and collaborative frameworks vary significantly in their sophistication and level of integration. Countries such as Belgium, Ireland, Switzerland, and Norway have implemented robust SOM mechanisms, often integrated with their national Controlled Substance (CS) regulatory frameworks. Belgium uses the Drug Precursors Monitoring Unit under the Federal Agency for Medicines and Health Products (FAMHP), which coordinates suspicious transaction reporting through multiple channels, including email and notification forms. Ireland relies on a national compliance system, which follows EU drug precursor regulations and mandates reporting of suspect activity. Norway, although not an EU member, applies EU GDP Guidelines and uses an internal SOM oversight mechanism under the Norwegian Medicines Agency (NoMA) that aligns with REGULATION (EC) No. 273/2004 and Council Regulation (EC) No. 111/2005. These regulations require all transactions involving drug precursors to be fully documented, with suspicious transactions promptly reported to competent authorities. Switzerland's SOM controls are governed by the Ordinance on Narcotics Control (812.121.1) and the Medicinal Products Act; wherein suspicious orders are flagged to Swiss medic and escalated to the Federal Police. The country also participates in the INCB I2ES platform for import/export verification. Some platforms in the region offer real-time monitoring and are linked with regional alert-sharing systems such as EUROPOL, the European Medicines Agency (EMA), and the Schengen Information System (SIS) for cross-border coordination. Switzerland maintains digital compliance mechanisms, enabling efficient data exchange on suspicious pharmaceutical activities.

Meanwhile, Turkey and Ukraine have adopted partial digital SOM systems. Turkey enforces the Regulation on Controlled Delivery (2004/2013), requiring that public prosecutors approve monitored movements of controlled chemicals. Ukraine's SOM system is still maturing, with regulatory instruments becoming more structured following reforms introduced after 2022. Although geographically outside of Europe, the United Arab Emirates (UAE) aligns with EMEA practices through Gulf Cooperation Council (GCC) SOM networks and real-time reporting protocols. In the UAE, real-time CS monitoring is enabled by a combination of legal instruments, including the Federal Decree-Law on Anti-Money Laundering, the Narcotic, Controlled & Semi-Controlled Medications Management Policy, MOHAP Drug Monitoring Guidelines, and the goAML platform goAML (anti-money laundering tool), developed by the UNODC.

Across the EMEA region, countries are increasingly relying on electronic prescriptions, digital supply chain tracking, and mandatory reporting obligations. However, disparities remain in cross-border data interoperability and the centralization of alert mechanisms. Ongoing efforts such as EU-led collaborative initiatives and WHO regional workshops aim to harmonize SOM practices, enhance early detection of diversion or trafficking, and prevent the misuse of controlled substances. Collectively, these evolving frameworks underscore a regional shift toward harmonized surveillance and strengthened international cooperation to ensure the safety and integrity of controlled substance markets in the EMEA region.

The EU Early Warning System is a network consisting of the EMCDDA, Europol, the European Medicines Agency, the European Commission and the national early warning systems of 30 countries (28 EU member states, Norway and Turkey).

Table: EMEA CS/SOM Systems Coverage

Country	Digital platform	Responsible agency	Cross-border alert sharing
Belgium	FAMHP eHealth and Pharmanet CS Narcoreg system Monitoring System	Federal Agency for Medicines and Health Products (FAMHP)	EUROPOL, EMCDDA Early Warning System
Ireland	Health Products Regulatory e-System	Health Products Regulatory Authority (HPRA)	EUROPOL, EMCDDA Early Warning System
Norway	Norwegian Prescription Database (NorPD)	Norwegian Medicines Agency (NoMA)	EUROPOL, EMCDDA, Nordic Cooperation Early Warning System
Russia	Roszdravnadzor CS Monitoring System	Federal Service for Surveillance in Healthcare (Roszdravnadzor)	INCB, UNODC
South Africa	SAHPRA CS Monitoring & e-Permit System	South African Health Products Regulatory Authority (SAHPRA)	INCB, UNODC
Switzerland	Swissmedic e-Monitoring Platform	Swissmedic	EU and SIS, EMCDDA
Turkey	TITCK Track & Trace System (ITS) for CS	Turkish Medicines and Medical Devices Agency (TITCK)	EUROPOL, EMCDDA, Early Warning System
Ukraine	Semi-digital CS Registry (State Service for Medicines & Drugs Control)	State Service of Ukraine on Medicines & Drugs Control	INCB, UNODC
United Arab Emirates	MOHAP Unified Electronic Platform	Ministry of Health and Prevention (MOHAP)	GCCHC

- EUROPOL: European Union Agency for Law Enforcement Cooperation
- EMCDDA: European Monitoring Centre for Drugs and Drug Addiction
- SIS: Schengen Information System
- GCCHC: Gulf Cooperation Council Health Council
- INCB: International Narcotics Control Board
- UNODC: United Nations Office on Drugs and Crime

APAC

Australia, China, India, Japan and South Korea are in scope for analysis in this region.

CS Regulatory Evolution:

The Asia-Pacific region shows marked variation in the evolution and enforcement of controlled substances regulation, shaped by public health imperatives, drug misuse patterns, and international treaty obligations. Across Australia, Japan, South Korea, China, and India, regulatory maturity is generally high, though the pace of digital transformation and frequency of updates differ by country.

In Australia, the Therapeutic Goods Administration (TGA) oversees CS control through the Narcotic Drugs Act 1967 and enforces scheduling under the Poisons Standard (SUSMP) by the TGA which determines the scheduling of medicines and chemicals, including controlled substances, based on their potential for misuse and therapeutic effectiveness. Updates to the schedules are issued quarterly via the TGA website, reflecting both international treaty updates and national health trends. India's regulatory authority, the Central Drugs Standard Control Organization (CDSCO), operates under The Narcotic Drugs and Psychotropic Substances (Regulation of Controlled Substances) Order, 2013 and Narcotic Drugs and Psychotropic Substances (NDPS) Act, 1985. While updates are less frequent, 2021 onward saw a stronger push for digital CS licensing via the Sugam portal, which now includes registration, sale, and import/export of Schedule X and narcotic products.

Japan enforces CS regulation under the Narcotics and Psychotropics Control Act, managed by the Ministry of Health, Labour and Welfare (MHLW). Japan is notable for maintaining highly detailed lists of regulated substances, updated annually, and strictly categorizing all narcotics and psychotropics under national law. The country is known for maintaining comprehensive and frequently updated List of banned & controlled substance and Controlled Substances List under Schedules of controlled substances section. Strict prescription and dispensing regulations apply to narcotic drugs, including mandatory recordkeeping, storage protocols, and practitioner-level licensing, monitored both physically and digitally. In South Korea, the Ministry of Food and Drug Safety (MFDS) manages the scheduling of narcotics under the Narcotics Control Act. Quarterly revisions are based on global drug trends and WHO recommendations. The Act on the Control of Narcotics, first enacted in 2000 and subsequently revised multiple times, the most recently in 2025 mandates strict prescription and dispensing protocols, centralized digital record keeping, and auditing of manufacturers, importers, exporters, and healthcare institutions.

China's CS regulation is supervised by the National Medical Products Administration (NMPA). China maintains multiple Schedules of narcotics and psychotropics substances updates its CS list periodically. In 2019, China implemented a class-wide control mechanism, becoming the first country to regulate all fentanyl-related substances. This regulatory innovation prevents the market from shifting to slightly altered chemical structures to evade law enforcement. Notably, synthetic opioids, fentanyl analogues, and new psychoactive substances

(NPS) have been prioritized in recent updates due to rising global concern over their misuse.

Overall, APAC countries are aligning more closely with international frameworks, such as the INCB, UNODC, and WHO, while strengthening domestic regulatory controls. The evolution is particularly evident in countries like Australia and Japan, which exhibit timely updates, digitized control, and public transparency of scheduling lists.

SOM Monitoring and Cross-border Collaboration:

The SOM infrastructure across APAC varies in its stage of development and international integration. However, regional players like Japan, South Korea, and Australia have built strong digital SOM platforms, while others like India and China are scaling up digitization and inter-agency collaboration.

Australia maintains a mature and integrated Suspicious Order Monitoring (SOM) framework that supports real-time tracking and inter-agency collaboration for controlled substances. The monitoring system is governed primarily by the Therapeutic Goods Administration (TGA) and the Office of Drug Control (ODC). Australia's SOM capabilities are incorporated within broader electronic regulatory platforms such as the Electronic Recording

and Reporting of Controlled Drugs (ERRCD), which is used by multiple states and territories for end-to-end monitoring of Schedule 8, It allows pharmacies and prescribers to report and track dispensing and supply of high-risk substances. Australia also engages in cross-border collaboration through partnerships with international regulatory bodies and platforms such as the International Narcotics Control Board (INCB) via the I2ES system for import/export verification and data exchange. The country's digital infrastructure supports alignment with WHO recommendations and UNODC protocols, making Australia a key contributor to global drug safety and surveillance initiatives.

India is expanding SOM capability via systems like the Sugam Portal and the Electronic Drug Distribution Network (EDDN) under the The Central Bureau of Narcotics (CBN), under the Department of Revenue, and the Central Drugs Standard Control Organization (CDSCO). Although SOM coverage is not yet real-time the CBN Portal and Drug Licensing System (DLS) are stepping stones toward a more comprehensive SOM ecosystem and regulatory reforms under the NDPS Act, 1985 increasingly demand digital recordkeeping and mandatory transaction reporting. India also participates in SAARC forums and bilateral working groups to enhance regional monitoring of high-risk substances. Japan employs a decentralized SOM model through Narcotic Control Departments under MHLW. The model relies on digitized documentation of all transactions involving narcotic drugs. Japan's participation in the INCB I2ES platform supports international import/export verification.

South Korea has developed a multi-agency, data-driven infrastructure for Suspicious Order Monitoring (SOM), overseen by the Ministry of Food and Drug Safety (MFDS). A central component of the country's SOM capability is the Narcotics Information Management System (NIMS). This platform captures real-time data from manufacturers, distributors, and healthcare institutions. It monitors inventory levels, prescription data, and unusual order quantities. Authorities use this system to identify trends and flag potential diversions. South Korea's SOM efforts are also aligned with INCB's I2ES platform for import/export monitoring. Additionally, regional cooperation is maintained through bilateral engagements with ASEAN nations, and participation in UNODC initiatives. In China, though real-time surveillance is still limited, China mandates reporting of unusual sales patterns and prescription trends, enforced. China shares data with international bodies like INCB, I2ES, ASEAN Working Group on Narcotics Control especially for import/export authorization.

Despite disparities, APAC countries tend to revise substance schedules annually. China, South Korea, and India focus on modifying precursors and fentanyl analogues, while Japan emphasizes pharmaceutical regulations. Storage and transport regulations have also been tightened across the region. there is a collective regional momentum toward digitization, with efforts to unify SOM protocols through ASEAN Drug Monitoring Initiatives, WHO SEARO (South-East Asia Regional Office), and country-specific bilateral agreements. APAC's SOM landscape continues to mature, driven by an urgent need to reduce diversion risks and respond to rising synthetic drug threats.

In APAC, cross-border alert sharing is led by WHO SEARO and ASEAN, as well as INCB and SAARC.

Table: APAC CS/SOM Systems Coverage

Country	Digital platform	Responsible agency	Cross-border alert sharing
Australia	Medicines Shortage Information Initiative, TGA CS Licensing System (via INCB I2ES)	Therapeutic Goods Administration (TGA), Australian Border Force (ABF), Department of Health	INCB via I2ES, New Zealand, USA, and Pacific Island Nations
China	National Drug Control Information System	National Medical Products Administration (NMPA) & China National Narcotics Control Commission	ASEAN, WHO, Japan, South Korea
India	Sugam Portal, Electronic Drug Distribution Network (EDDN)	Central Drugs Standard Control Organization (CDSCO) under Ministry of Health and Family Welfare	SAARC, WHO SEARO
Japan	Narcotic Control Management System (NCMS)	Narcotics Control Department, Ministry of Health, Labour and Welfare (MHLW)	ASEAN, INCB I2ES China, South Korea
South Korea	Narcotics Information Management System (NIMS), Customs Monitoring Portal	Ministry of Food and Drug Safety (MFDS) and Korea Customs Service (KCS)	ASEAN, INCB, WHO, Japan, China

- INCB via I2ES: International Narcotics Control Board International Import and Export Authorization System
- ASEAN: Association of Southeast Asian Nations
- WHO SEARO: World Health Organization South-East Regional Office
- SAARC: South Asian Association for Regional Cooperation

Americas

USA, Canada, Mexico and Brazil are in scope for analysis in this region.

CS Regulatory Evolution

The Americas present some of the most mature and stringent CS frameworks, integrating advanced scheduling, digital tracking, and strong public health controls. The United States has a comprehensive and highly structured regulatory framework for controlled substances and one of the most robust and frequently updated CS regulatory systems globally governed by the Drug Enforcement Administration (DEA). The foundational legislation is codified under Title 21 of the Code of Federal Regulations (CFR), particularly Part 1308, which defines controlled substances across five schedules (I–V) based on abuse potential, medical use, and safety. The DEA actively manages the scheduling and reclassification of substances. In recent years, the U.S. has implemented a range of regulatory actions, including Rescheduling of marijuana and temporary or permanent scheduling of various synthetic opioids, such as brorphine, metonitazene, and multiple fentanyl analogs, Control of List I chemicals such as phenethyl bromide and propionyl chloride, used in illicit drug manufacture. Annual and emergency updates reflecting new psychoactive substances and analogues, guided by FDA, World Health Organization (WHO), and United Nations Office on Drugs and Crime (UNODC).

Canada's regulatory approach to controlled substances is built on a robust legislative foundation led by Health Canada's Office of Controlled Substances (OCS). Among the most consistently updated components are the Controlled Drugs and Substances Act (S.C. 1996, c. 19), which define the classification of substances and adapt to emerging drug trends, such as new synthetic opioids or psychotropic compounds. The Narcotic Control Regulations (NCR) are frequently amended to refine rules on production, distribution, and possession of narcotics. The Precursor Control Regulations (PCR) are also regularly revised to address risks related to the manufacture of illicit drugs. Collectively, these instruments reflect Health Canada's proactive approach to aligning with international conventions and addressing domestic challenges in drug control and public health. Canada's model prioritizes both public health protection and supply chain integrity, adopting a risk-based approach that is aligned with international conventions such as The Single Convention on Narcotic Drugs, 1961, The Convention on Psychotropic Substances, 1971, and The United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988.

In Mexico, the Secretariat of Health (Secretaría de Salud) oversees the regulatory framework for controlled substances. The General Law of Health, originally published in 1984 and most recently amended in June 2024, defines narcotics, psychotropics, and precursor substances under Articles 234–299. It aligns domestic law with international treaties and mandates detailed scheduling under Article 234/245, which classifies substances into five groups. The Regulation of Health Supplies, last amended in May 2021, complements this by setting guidelines for manufacturing, distribution, labelling, and monitoring of these substances. The system emphasizes stringent control high-risk drugs requiring electronic prescription systems for distribution.

Brazil's regulatory authority for controlled substances is the National Health Surveillance Agency (ANVISA), which governs through a consolidated framework built around Ordinance SVS/MS No. 344/1998, also known as the Brazilian Controlled Drugs and Substances Act. This core legislation establishes rules for the control, classification, and handling of narcotic and psychotropic substances, aligning with international conventions including the Single Convention on Narcotic Drugs and the Convention on Psychotropic Substances. Several Resolutions of the Collegiate Board (RDCs) have updated this ordinance over time, most notably are RDC No. 734 of July 2022, and RDC No. 936 of November 2024, which includes updated lists of controlled substances. The regulation differentiates among narcotic, psychotropic, and prohibited substances, each with specific monitoring requirements. Recent revisions address not only scheduling but also import/export procedures, prescription check book formats, health surveillance information, and personal use exemptions. Updates are managed through ANVISA's official publication portal and dedicated dashboards for regulated substances.

SOM Monitoring and Cross-border Collaboration

The United States uses an advanced, nationwide Suspicious Order Monitoring (SOM) ecosystem centered on ARCOS (Automation of Reports and Consolidated Orders System). Managed by the DEA, ARCOS enables real-time and retrospective tracking of controlled substance transactions from manufacturers to distribution points. Key features include Mandatory electronic reporting by manufacturers and distributors of all transactions involving Schedule I and II substances. Integration with state-level Prescription Drug Monitoring Programs (PDMPs) to triangulate end-user and retail-level data. The DEA uses data from ARCOS

Brazil's Suspicious Order Monitoring (SOM) landscape is embedded within its anti-drug enforcement and financial intelligence frameworks.

and the Controlled Substance Ordering System (CSOS) to detect anomalies in supply chains. Additionally, cross-agency collaboration includes Bilateral data-sharing agreements with Canada and Mexico under the North American Drug Dialogue (NADD) and Engagement with INCB's I2ES system for cross-border verification of import/export activities.

Canada maintains a highly coordinated Suspicious Order Monitoring (SOM) system integrated with its CS licensing framework, led by Health Canada's Office of Controlled Substances (OCS). The system includes Digital submission portals such as the Drug Submission Platform (DSP) and CTLS (Cannabis Tracking and Licensing System) for controlled substances and precursor chemicals, including mandatory reporting of suspicious transactions under the Precursor Control Regulations. While Canada does not yet operate a real-time SOM platform, it emphasizes a compliance-heavy model of paper or digital audit logs, manual verification, and dealer responsibility for proactive monitoring. Loss and theft events are closely tracked to support national risk profiling. Any incident of loss, theft, or suspected diversion of controlled substances or chemical precursors must be immediately reported to Health Canada. This includes all transactions that may suggest a link to illegal drug manufacturing or trafficking. Canada also engages in bilateral and multilateral intelligence sharing, particularly with the U.S. DEA, and UNODC contributing to cross-border investigations and supply chain integrity assessments across North America.

In Mexico, Suspicious Order Monitoring (SOM) is indirectly enforced through Good Manufacturing Practices (GMP) and criminal law. According to NOM-059-SSA1-2015 – Good Manufacturing Practices for Medicinal Products mandates that distributors must monitor transactions and investigate irregularities in the sale patterns of high-risk drugs, particularly narcotics and psychotropics. Any unusual sales trends suggestive of diversion or misuse must be thoroughly reviewed and, when necessary, reported to the appropriate federal health authority. SOM-related responsibilities are complemented by enforcement mechanisms under the Federal Penal Code, which criminalizes diversion-related activities such as unauthorized possession, trafficking of narcotic substances. Authorities are empowered to seize and destroy narcotics when connected to offenses or redirect them for legal and scientific purposes following strict federal protocols. While Mexico does not currently operate a real-time SOM platform, it incorporates SOM principles via regulatory obligations embedded in manufacturing, distribution, and criminal compliance frameworks. Cross-border intelligence sharing is conducted through cooperation with INCB, U.S. DEA, and regional Latin American health agencies under treaty obligations.

In the Americas, cross-border alert sharing is led by INTERPOL, UNODC and INCB, as well as MERCOSUR in Latin America.

Brazil's Suspicious Order Monitoring (SOM) landscape is embedded within its anti-drug enforcement and financial intelligence frameworks. Agencies are empowered under Federal Law No. 11.343/2006, Brazil's cornerstone drug law. Law No. 12.683/2012 further strengthens AML mechanisms, enhancing surveillance over financial flows that may be linked to illegal narcotic transactions. Additionally, Brazil enforces international SOM standards as a signatory to the United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, implemented via Decree No. 154/1991. This enables collaboration with entities such as INCB, Interpol, and neighbouring Latin American countries to exchange alerts and intelligence. Brazil's SOM functionality is robustly managed via its law enforcement, financial intelligence, and international treaty obligations.

Table: Americas CS/SOM Systems Coverage

Country	Digital platform	Responsible agency	Cross-border alert sharing
Canada	CTLS (Cannabis Tracking and Licensing System)	Health Canada: Office of Controlled Substances (OCS)	USA (via bilateral agreements), UNODC, INCB
United States of America	ARCOS (Automation of Reports and Consolidated Orders System)	DEA (Drug Enforcement Administration)	Canada, Mexico, Australia (via bilateral agreements), UNODC, INCB, INTERPOL
Mexico	DIGIPRIS (partial integration)	COFEPRIS Mexican Secretariat of Health (Secretaría de Salud)	USA (via bilateral agreements), UNODC, INCB, INTERPOL
Brazil	BSPO (Balanço de Substâncias Psicoativas e Outras Sujeitas a Controle Especial)	COAF (financial intelligence) & DENARC/DISE under Civil Police	MERCOSUR, INCB, INTERPOL, UN treaties

- INTERPOL: International Criminal Police Organization
- INCB: International Narcotics Control Board
- UNODC: United Nations Office on Drugs and Crime
- MERCOSUR: Mercado Común del Sur (Southern Common Market)

Conclusions

All the analysed markets have CS/SOM related digital platforms and promote cross-border alert sharing, although the extent of their implementation varies among markets. While most still operate in a periodic electronic reporting manner, ARCOS in USA represents a leading example, with near real-time batch reporting in addition to monthly reporting. Some markets like India, China, South Africa or Mexico have systems with limited functionality and still lack full integration. Canada and Australia stand-out for their cross-border alert sharing.

The comparative analysis of Controlled Substance (CS) regulations and Suspicious Order Monitoring (SOM) practices across 18 countries reveals critical patterns, gaps, and collaborative strengths in global compliance frameworks. The supporting heatmaps, regulatory evolution charts, and SOM capability tables clearly highlight regional contrasts in digital adoption, frequency of legislative updates, and real-time monitoring.

Key takeaways include the identification of leading markets such as the United States, Canada, Australia, Switzerland, and Japan, which consistently show high frequency of new regulatory publications and digital SOM infrastructure. These countries not only demonstrate strong internal governance but also serve as collaborative anchors for bilateral and multilateral frameworks. The findings also allow us to answer several pressing questions. For instance, top-performing markets in terms of legislative output and updates are led by the USA, Australia, Switzerland, South Korea, and Belgium. Moreover, countries like Canada and Australia stand out for their cross-border alert sharing and intelligence coordination, offering scalable models for regional harmonization. Countries like India, South Africa, and Mexico show limited or evolving SOM frameworks, with partial digitization or manual reporting still in place. While these markets maintain foundational legislation for CS control, the lack of dedicated SOM platforms or real-time tracking tools poses challenges for early detection of diversion or trafficking. Additionally, standardized alert-sharing mechanisms are absent in several jurisdictions, creating data silos that hinder regional enforcement collaboration.

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This assessment underscores the need for low- and middle-income markets to adopt more frequent regulatory reviews and integrated digital SOM solutions. Additionally, the observed intergovernmental collaborations and digital intelligence-sharing platforms can serve as effective templates for other nations aiming to modernize and globalize their CS compliance ecosystems. This article advocates for broader standardization, increased real-time monitoring, and expanded international cooperation to address the rising complexity and risks of controlled substance diversion and trafficking.

Regulatory Sources

Market	CS and SOM regulatory sources (non-exhaustive)
Australia	- Federal Register of Legislation- Narcotic Drugs Act 1967 No. 53, 1967 - Federal Register of Legislation- Psychotropic Substances Act 1976 No. 87, 1976 - Office of drug control- List of drug substances requiring permission to import and/or export and its changes related to prohibition - Single Convention of Narcotic Drugs 1961 - National Real Time Prescription Monitoring (RTPM).
Belgium	- Royal Decree No. 2017/31231 on Regulating Narcotic Drugs, Psychotropic Substances - Amended Royal Decree of 27-12-2021 published on 12-01-2022 amending the Royal Decree of 06-Sep-2017 regulating narcotic, psychotropic and soporific substances - ROYAL DECREE OF 27-12-2021 PUBLISHED ON 12-01-2022 amended by ROYAL DECREE OF 23-03-2022 PUBLISHED ON 12-04-2022 (Royal decree amending the royal decree of 6 September 2017 regulating narcotic and psychotropic substances).
Brazil	- Ministry of Health Surveillance Secretariat- ORDINANCE No. 344, OF MAY 12, 1998 - Agência Nacional de Vigilância Sanitária- List of substances subject to special control in Brazil - Law 9.613 (Anti-Money Laundering Law). - Law 12.683, of July 9, 2012 (Anti-Money Laundering Law).
Canada	- Health Canada- Controlled Drugs and Substances Act (S.C. 1996, c. 19) - Health Canada- Narcotic Control Regulations (CRC, c. 1041) - Health Canada- Precursor Control Regulations (SOR /2002-359) - Health Canada- SOR/97-229 - SCHEDULE I - Recording and reporting of suspicious transactions for controlled substances and precursors (CS-GD-025).
China	- State council gazette - Order No. 442 5on Narcotic Drugs and Psychotropic Substances Management Regulations - National Health Commission on Adjusting the Catalog of Psychotropic Drugs (2024 No. 54) - National medical product administration- Announcement of the National Medical Products Administration, the Ministry of Public Security, and the National Health Commission on Adjustments to the Catalogue of Psychotropic Drugs (No. 54 of 2024)
India	- Act No. 61 of 1985 - Schedules and List of Drugs - Ministry of Finance- Notification No. G.S.R. 191(E) - India code- The Narcotic Drugs and Psychotropic Substances Act, 1985 - The prevention of money-laundering act, 2002. - The NDPS (Regulation of Controlled Substances) Order, 1993
Ireland	- Law Reform Commission- Act No. 12/1997, Misuse of Drugs Act, 1977. - Stationery Office- S.I. No. 173/2017- Misuse of drugs regulations 2017. - Misuse of Drugs (Amendment) Regulations 2022. - Stationery Office- S.I. No. 176/ 2022 -MISUSE OF DRUGS ACT 1977.
Japan	- Narcotics and Psychotropics Control Law (Act No. 14 of 1953) - Promulgation of a Cabinet Order Designating Narcotics, Narcotic Raw Materials, Psychotropics, and Narcotic Psychotropic Raw Materials and a Cabinet Order Partially Amending the Order for Enforcement of the Narcotics and Psychotropics Control Law - Controlled Substances List - List of banned & controlled substance. - Handling of Narcotic and Psychotropic Raw Materials

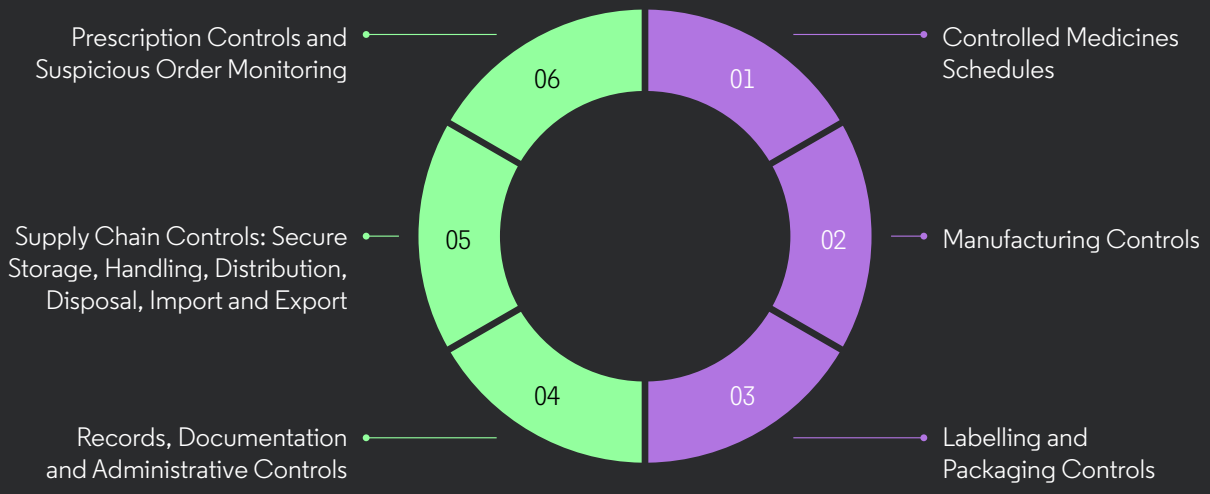
Market	CS and SOM regulatory sources (non-exhaustive)
Mexico	- General law of Health (published in the Official Gazette of the Federation on February 7, 1984, DOF 01-06-2021) - Regulation of Health Supplies (published in the Official Gazette of the Federation on February 1998, DOF 31-05-2021) - Good Manufacturing Practice for medicinal products (NOM-059-SSA1-2015) 16.8.3.2.
Norway	- Ministry of Health and Care Services- Regulation No. 199/2013 updated Regulation No. 2354/2021 Regulations on Narcotics. - Ministry of Health and Care Services- The Regulation no. 199 of 14 February 2013 on drugs. - Ministry of Health and Care Services- Amendment to the Regulation no. 199.
Russia	- Federal Assembly of the Russian Federation- Federal Law No. 3-FZ/1998 On narcotic drugs and psychotropic substances. - Government of Russian Federation- Resolution of the Government of the Russian Federation of June 30, 1998, No. 681/2025 - Government of Russian Federation- Decree of the Government of the Russian Federation dated 02/07/2024 No. 135 "On amendments to certain acts of the Government of the Russian Federation".
South Africa	- Medicines and Related Substances Act, 1965 (Act 101 of 1965) - Guideline for Importation and Exportation of Medicines - Guideline for Importation and Exportation of Medicines: Regulatory Compliance Unit - Guidelines for the Destruction of Schedule 5 Medicines/Substances - Drugs and Drug Trafficking Act No. 140 of 1992 [No. 14143]
South Korea	- Act No. 6146/2000 amended Act No. 18443/2021 on Narcotics Control Act - Prime Minister's Decree No. 2011, Enforcement Rules of the Narcotics Control Act - Enforcement Decree of the Narcotic Drugs Control Act.
Switzerland	- The Federal Assembly of the Swiss Confederation- Act No. 812.121 of 3 October 1951 (Status as of 15 May 2021) Federal Act on Narcotics and Psychotropic Substances (Narcotics Act, NarcA) - The Federal Assembly of the Swiss Confederation- Ordinance No. 812.121.1 May 2011 (Stand am 1. January 2013) Ordinance on Narcotics Control (Narcotics Control Ordinance, BetmKV)
Turkey	- Presidency of the Republic of Turkey- Official Gazette No. 25494/2004 Regulation on Controlled Chemical Substances - Presidency of the Republic of Turkey- Law No. 2313/1993 amended Law No. 11697/2018 Inspection of Drug Substances - Official Gazette No. 25494/2004 Regulation on Controlled Chemical Substances
Ukraine	- Document 60/95-BP, Revision on July 5, 2020, on the basis - 644-IX On Circulation of Drugs, Psychotropic Substances, Their Analogs and Precursors in Ukraine - About narcotic drugs, psychotropic substances and precursors (Information of the Verkhovna Rada of Ukraine (VVR), 1995, No. 10, Article 60) - On the approval of the Procedure for the acquisition, transportation, storage, release, use and destruction of narcotic drugs, psychotropic substances and precursors in health care institutions.

Market	CS and SOM regulatory sources (non-exhaustive)
United Arab Emirates	- The State of the United Arab Emirates Ministry of the Interior General Directorate of Security Affairs Department of Drug Control- Federal Law No. 14 of 1995 regarding combating narcotic drugs and psychotropic substances. - Federal Law by Decree No. (30) of 2021 On Combating Narcotics and Psychotropic Substances - Narcotic, Controlled & Semi- controlled Medications Management Policy
United States of America	- FDA- Chapter II-Part 1308 of Title 21–Food and Drugs - DEA- Suspicious Orders Report System (SORS). - List of Scheduling Actions, Controlled Substances and Regulated Chemicals - 21 CFR Part 1301: Registration of manufacturers and distributors - 21 CFR Part 1304: Records and reports of CS - 21 CFR Part 1305 & 1306: Prescriptions and order forms - 21 CFR Part 1312: Import/export of CS - 21 CFR Part 1316: Administrative functions - 21 CFR Part 1317: Drug disposal

Addressing Regulatory Compliance Solutions

Objective

Clarivate supports pharmaceutical companies by providing tailored monitoring programs of the controlled medicines regulatory landscape in 100+ international markets



Methodology

A blend of technology-based scripting of the Regulators' websites, translational and automation services and manual content curation by local subject matter experts to ensure timely high-quality data.

Programs can be carried out as standalone periodic reports or powered by workflow enabled platforms to expedite and facilitate action plans.

Just a flavour

1,000+ unique data sources are monitored for 100+ markets, detecting 10+ changes on a weekly basis to be impact assessed.

To learn more about our Consulting Services please visit:
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Contact our regulatory consulting experts today: regulatory.consulting@clarivate.com

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