Shaping a world-class medical device regulatory regime in Hong Kong, China

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Hong Kong, China is undergoing a transformative shift in its approach to medical product regulation, driven by the convergence of artificial intelligence (AI), biomedical advancements, and a strategic goal to position itself as an international hub for medical innovation.[1] For over two decades, the Medical Device Administrative Control System (MDACS) of the Department of Health (DH) has served as a cornerstone in safeguarding public health in relation to medical devices (MDs). Building on this foundation, the DH is progressing towards a comprehensive statutory framework aimed at upholding the highest standards of safety and quality, while fostering an environment that supports medical innovation.

The local regulatory framework for medical devices

At present, Hong Kong, China has yet to establish an overarching piece of legislation to govern the full lifecycle of MDs, including their manufacture and supply. Depending on their characteristics, certain MDs may fall within the scope of existing laws, such as the Pharmacy and Poisons Ordinance (Cap 138), the Radiation Ordinance (Cap 303), the Trade Descriptions Ordinance (Cap 362), the Consumer Goods Safety Ordinance (Cap 456), and so forth.

The DH introduced the voluntary MDACS in 2004 as a transitional arrangement to safeguard safety, quality, and performance, as well as to enhance public awareness of MD safety. Implemented by the DH, this initiative was designed as a pragmatic, phased approach to prepare the industry for a future statutory framework.

Consistent with best practices adopted globally, MDACS operates through a two-pronged approach covering pre-market control and post-market surveillance. At its core lies a risk-based device classification framework aligned with international standards established by the International Medical Device Regulators Forum,[2] formerly the Global Harmonization Task Force. This system categorises MDs according to factors such as level of invasiveness, duration of contact with the body, and potential for harm in the event of malfunction. General MDs are classified into four classes, from Class I (lowest risk) to Class IV (highest risk),[3] while In Vitro Diagnostic MDs are categorised from Class A (lowest risk) to Class D (highest risk).[4]

Under the voluntary MDACS, only medium- to high-risk devices—namely Class II and above General MDs, and Class B and above In Vitro Diagnostic MDs—are eligible for listing, establishing a form of pre-market control with regulatory oversight proportionate to the potential risks posed to public health. Complementing this, the system incorporates an adverse event reporting mechanism for all MD classes under the post-market surveillance, through which manufacturers, importers, and users can report incidents, thereby supporting timely risk identification, recurrence prevention, and harm mitigation.

The MDACS also covers the listing of traders, including importers, distributors, and local manufacturers, who are key players in the MD supply chain. The framework places emphasis on the role of Local Responsible Persons, who serve as the primary link between the DH and MD manufacturers. They play a pivotal role in post-market activities such as incident reporting, recalls, and corrective actions, ensuring robust and effective oversight.

Fostering regional and international collaboration

With its internationalised background, Hong Kong, China has traditionally enjoyed access to a wide range of medical technologies from around the world and has spearheaded numerous medical innovations. Throughout its phased implementation, MDACS has placed high importance on regulatory harmonisation and convergence with international standards. In addition to the evaluation of MDs by Conformity Assessment Bodies recognised by the DH, which are accredited organisations that independently assess and certify MDs to ensure compliance with

safety, quality, and performance standards set out under the MDACS, marketing approvals from eight reference regulatory jurisdictions are also accepted. As of the end of October 2025, more than 8300 MDs have been listed under MDACS, encompassing both locally manufactured and imported devices.

The phased development of Hong Kong's MD regulatory system has been underpinned by close collaboration with diverse stakeholders. Ongoing engagement with industry, academia, and research institutions has been instrumental in refining MDACS. Timely updates of guidance documents on emerging MD technologies, risk management, and post-market surveillance have supported a practical and efficient regulatory pathway for new devices, benefiting both innovators and patients.

Collaboration also extends into the Greater Bay Area (GBA), which is a key strategic priority. The DH has actively engaged with the Guangdong–Hong Kong–Macao Greater Bay Area Center for Medical Device Evaluation and Inspection of the National Medical Products Administration. Joint activities, including seminars and training, have supported the local industry in navigating the Chinese Mainland's regulatory and registration processes, thereby fostering healthcare innovation and regional cooperation.

A related policy, the "special measure of using Hong Kong registered drugs and MDs used in Hong Kong public hospitals in the GBA" (港澳藥械通), established in 2021, allows designated GBA healthcare institutions to use MDs that are in use in Hong Kong public hospitals and deemed urgently needed for clinical purposes, subject to approval by Guangdong Province regulatory authorities. As of October 2025, this measure has enabled the use of 73 MDs across 45 designated institutions.[5] Through this approach, state-of-the-art and innovative MDs of clinical and health benefits can gain expedited access to the Chinese Mainland and enhance the health of Chinese Mainland residents. These initiatives form part of a broader plan to promote regulatory innovation for medical products in the GBA, aligning with Hong Kong's unique position as a super-connector in the region. Guided by co-operation agreements and Memorandum of Understanding, the Government has worked closely with the National Medical Products Administration and relevant authorities to create greater synergy in the cross-boundary regulatory oversight of medical products, including MDs.[6,7]

On the international front, the DH contributes actively as a member of the Global Harmonization Working Party, where it has led a Work Group on post-market surveillance.[8] Participation in such platforms enables Hong Kong to help shape harmonised documents and ensure its regulatory framework aligns with global best practices.

In August 2025, the DH signed a Memorandum of Understanding with Singapore's Health Sciences Authority,[9] covering regulatory cooperation on MDs. These collaborations underscore Hong Kong's commitment to building strong international partnerships and advancing a more interconnected, resilient, and innovation-friendly regulatory ecosystem.

Transitioning to an innovation-friendly statutory regime

The DH is systematically advancing MDACS towards a comprehensive statutory framework through key supporting measures. A significant driver has been the Government's policy of procuring MDACS-listed devices in the public healthcare sector, including those procured by the DH and the Hospital Authority. This has incentivised the industry to list their products, resulting in increased listings and readiness for a smooth transition to mandatory regulation.

In parallel, the DH has proactively addressed challenges arising from novel technologies. New guidance documents and technical references have been developed for complex domains such as software as a MD, cybersecurity, AI-enabled MDs, and personalised MDs.[10] These initiatives provide the industry with clearer expectations, helping innovators and entrepreneurs bring advanced technologies to market responsibly and efficiently.

To further enhance regulatory efficiency, the DH fully digitalised the listing process by launching the Medical Device Information System in 2024.[11] This one-stop e-service platform enables online applications and post-market surveillance management, improving public service delivery and internal operations. Building on this, the DH will leverage emerging technologies—such as AI—to streamline evaluations, accelerate approvals, and strengthen data-driven regulatory oversight.

Building a hub for medical and health innovation

In line with international trends, the Government is advancing preparatory work for legislation, targeting the introduction of a legislative proposal into the Legislative Council in 2026.

This is a key component of a broader initiative to establish the Hong Kong Centre for Medical Products Regulation (CMPR) in 2026 under the DH.[12,13] Planned since June 2024 by its Preparatory Office, the CMPR will consolidate regulation of Western and Chinese medicines, as well as MDs, under a single statutory framework. It will institutionalise mechanisms for pre-market approval, conformity assessment, and post-market surveillance.

The unified regime is designed to safeguard public health while remaining responsive to rapid scientific and technological advances. Capacity-building initiatives are underway to augment regulatory capabilities. With legislation empowering the CMPR and the Government's commitment to become a "leading, internationally renowned medical products regulatory authority, driving excellence and innovation", Hong Kong, China is laying the foundation for a regulatory system that protects patients and promotes the research, development, and commercialisation of cutting-edge medical products.[14]

Wider Government initiatives to foster a fertile health R&D ecosystem provide important synergies. The Hetao Shenzhen-Hong Kong Science and Technology Innovation Co-operation Zone is being developed as a world class research hub and catalyst for GBA growth, covering life and health technology and AI.[15] Complementing this, infrastructure such as the GBA International Clinical Trial Institute,[16] located within Hetao, will provide one-stop platforms to support clinical trials and accelerate the translation of scientific research into tangible patient benefits. A Real-World Study and Application Centre will also be established, alongside development of clinical databases and biobanks, to position Hong Kong as a leading global hub for real-world studies.[17,18]

A new vision for tomorrow's health

The DH is committed to creating a regulatory framework that balances stringent safety controls with the necessary flexibility to encourage innovation. This includes proactive engagement with innovators and timely guidance for next-generation technologies—such as AI-enabled MDs and precision medicines—while actively monitoring global best practices.

Realising this vision requires close collaboration among innovators, manufacturers, healthcare professionals, and researchers, whose involvement in research, commercialisation, and regulatory dialogue is essential to transforming technological advances into better health outcomes. By reinforcing its safety framework and cultivating an innovation-friendly ecosystem, Hong Kong, China is pursuing a proactive strategy to build global leadership in healthcare technology and advance towards a safer, healthier future.

Author contributions

All authors contributed equally to the conception, preparation, and editing of the manuscript. All authors approved the final version for publication and take responsibility for its accuracy and integrity.

Conflicts of interest

All authors have disclosed no conflicts of interest.

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