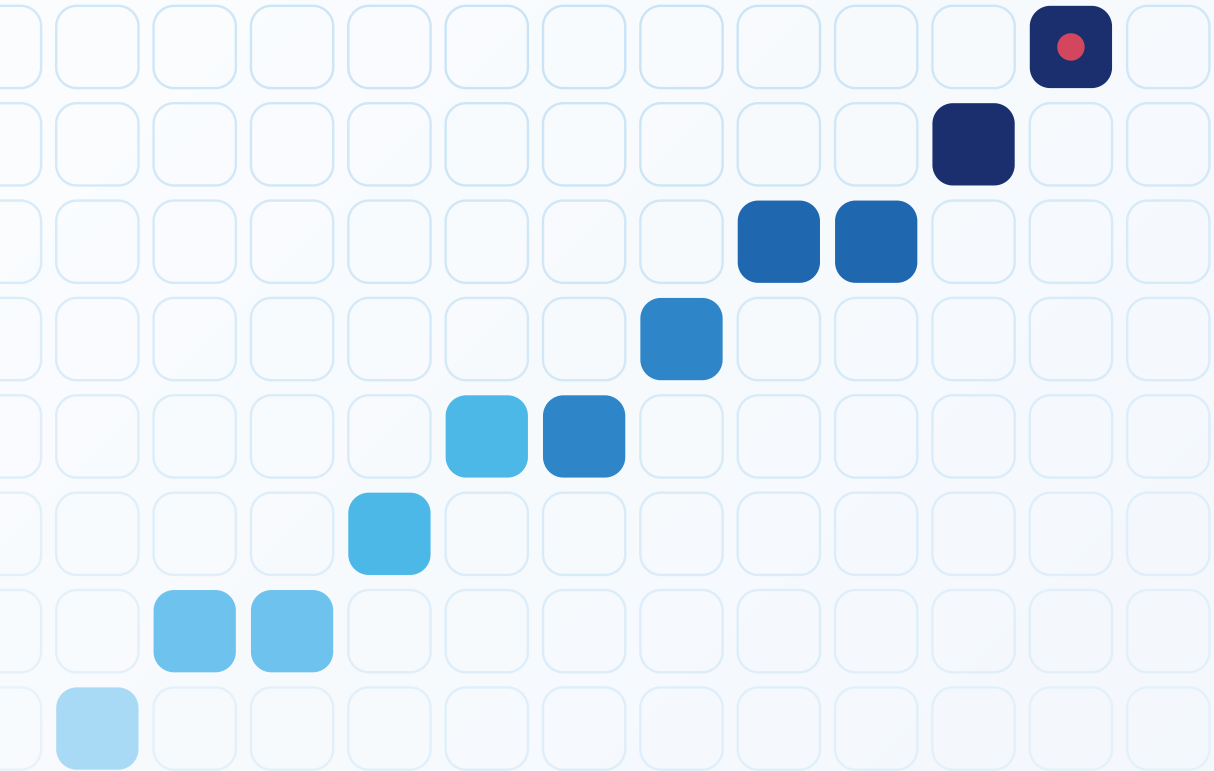
APACMed
The voice of MedTech

Innovative Medical Device Pathways

APACMed Position Paper



REGULATORY AFFAIRS

Executive Summary

Innovative medical device pathways aim to support earlier access to technologies that address unmet healthcare needs while maintaining robust standards of safety, quality and performance. Their value to patients depends on whether regulatory support translates into timely funding and clinical availability.

This paper compares pathways across selected APAC and reference markets, examining eligibility criteria, regulatory support, pathway uptake, and connections with downstream HTA, reimbursement and procurement. Drawing on the landscape and industry experience, it identifies barriers to patient access and proposes shared priorities and stakeholder-specific actions.

The review shows substantial variation in what qualifies as innovative and what support is available. Some pathways emphasise technological novelty, while others prioritise unmet need, clinical benefit or public-health value. Support ranges from priority review to early scientific advice, staged assessment, dedicated case management and flexible evidence generation. Public reporting on uptake is uneven, limiting comparisons of pathway performance. In many markets, regulatory innovation designation remains weakly connected to Health Technology Assessment (HTA), reimbursement and procurement.

Key barriers to timely patient access

- **Differences in pathway eligibility criteria can lead to uneven access to innovation support across markets**
- **Fragmented regulatory, HTA and funding processes can prolong the journey to clinical care**
- **Faster regulatory review does not necessarily lead to earlier funding or adoption**
- **Unclear or inflexible evidence expectations can delay access to novel technologies**
- **Requirements linked to local development, local content or domestic preference can restrict access to globally developed innovation.**
- **Limited international collaboration and regulatory reliance can lead to unnecessary duplication of assessment efforts**

The landscape also highlights useful practices, including IVD-specific eligibility criteria, staged regulatory review, earlier coordination of evidence requirements and mechanisms connecting assessment with downstream access. These provide examples that can inform improvements adapted to local health system needs.

Across the landscape, three broader themes emerge. Innovation pathways remain fragmented across markets, with substantial differences in eligibility and the support available. Regulatory acceleration alone does not ensure timely patient access where HTA, funding and procurement remain disconnected. Earlier coordination, evidence alignment and integrated access planning can help reduce these gaps, while preserving the respective roles of regulators, HTA bodies and payers.

APACMed priorities

Based on these findings, APACMed identifies four priorities for strengthening innovative medical device pathways:

01 **Build a better-connected evidence and access pathway** through earlier regulatory, HTA and payer engagement, coordinated evidence planning and parallel processes where feasible.

02 **Design innovation pathways that provide meaningful and proportionate support**, with transparent eligibility criteria, appropriate regulatory support and evidence approaches that can accommodate novel technologies and evolving evidence.

03 **Strengthen international regulatory collaboration and reliance** to reduce unnecessary duplication and support more efficient use of regulatory and industry resources across markets.

04 **Improve transparency and demonstrate contribution to patient access**, including clearer pathway information and measures that go beyond designation counts and regulatory review times.

Detailed recommendations and actions for industry, regulators, HTA bodies and payers, and policymakers are set out in Section 4. APACMed will use this paper to support focused dialogue in priority markets and work with local partners to identify practical improvements that enable timely and sustainable patient access.

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1. Introduction

Innovative medical devices can address unmet medical needs, improve diagnosis and treatment, and support more effective healthcare delivery. For patients to benefit, these technologies must progress through development, regulatory assessment, funding and clinical adoption. A growing number of regulatory authorities have introduced dedicated pathways to support this journey while maintaining appropriate regulatory expectations for safety, quality and performance.

However, approaches differ across markets in their eligibility criteria, evidence requirements, regulatory support and connections with health technology assessment (HTA), reimbursement and procurement. Faster regulatory review does not necessarily translate into earlier clinical availability. Fragmented processes and limited coordination can delay access to technologies that could benefit patients and health systems.

For the purpose of this landscape, the paper focuses primarily on **official pathways that recognise innovative medical devices or provide innovation-related support during development and assessment**. These include breakthrough device designation, innovation-specific pathways and relevant priority review mechanisms. Eligibility is determined by each jurisdiction's framework; the paper does not seek to establish a new universal definition of innovation.

Depending on the framework, eligible technologies may demonstrate one or more of the following characteristics:

- Introduce novel or advanced technologies, including digital health, AI-enabled devices, robotics or advanced biomaterials
- Provide meaningful clinical benefit over existing alternatives
- Address unmet or poorly met medical needs, including in serious or life-threatening conditions
- Offer significant public-health value

Pathway support may include early scientific advice, priority review, staged assessment, flexible evidence planning or enhanced post-market monitoring. These mechanisms differ in their scope and practical benefits, and innovation designation alone does not establish a technology's suitability for funding or adoption.

In vitro diagnostic medical devices (IVDs) require particular consideration. Their contribution to patient care often arises through the clinical decisions they enable, and they may be funded as tests or clinical services rather than as individual products. Assessment bodies, evidence requirements and funding routes can therefore differ from those for other medical devices.

Meaningful clinical benefit for IVDs may include:

- Enabling more appropriate treatment selection, stratification or de-escalation
- Replacing an invasive or higher-risk diagnostic procedure
- Shortening time to diagnosis or enabling earlier detection with demonstrated benefits for patient care
- Consolidating sequential tests into a single assay where this improves clinical decision-making or care delivery
- Supporting timely responses to significant public-health needs

The following mechanisms and device categories are outside the scope of the landscape:

- Emergency use authorisations and temporary crisis-driven regulatory measures
- Compassionate use or expanded access programmes
- Orphan or rare-disease-specific device pathways where disease rarity is the sole or principal basis for eligibility
- Humanitarian use exemptions or equivalent mechanisms
- Devices that do not qualify for or seek innovation-specific regulatory support.

This position paper is intended to support policymakers, regulators, HTA bodies, payers and industry stakeholders in developing pathways that enable timely and sustainable patient access. Drawing on the cross-market landscape and industry experience, it identifies barriers across the access journey and proposes shared principles and stakeholder-specific actions. These focus on earlier evidence planning, proportionate assessment and reassessment, meaningful pathway support, and stronger coordination and international collaboration, while respecting local health system needs and independent decision-making.

2. Key Barriers to Timely Patient Access

For patients, the benefit of an innovative medical device depends on whether it becomes available in clinical care. Dedicated regulatory pathways can support this objective, but their impact also depends on how well they connect with evidence generation, health technology assessment (HTA), funding and clinical adoption, including incorporation into clinical guidelines where relevant. Drawing on industry experience across the markets reviewed, the following barriers can limit or delay patient access:

- **Patients may benefit unevenly from innovation pathways across markets**: Differences in definitions and eligibility criteria mean that a technology recognised as innovative in one market may not qualify for comparable support elsewhere. This can affect how quickly technologies addressing similar patient needs are assessed and made available.

- **Fragmented regulatory and access processes can delay patient access**: Regulatory, HTA, reimbursement and procurement processes are not always well coordinated. Separate evidence requirements, sequential assessments and funding categories that do not accommodate novel technologies can create delays. As a result, faster regulatory review does not necessarily translate into earlier funding, clinical adoption or patient access.

- **Unclear or inflexible evidence expectations can delay access to novel technologies**: Requirements for head-to-head comparisons or local clinical evidence can be difficult to anticipate or meet for technologies with few established comparators. Limited flexibility for appropriate alternative study designs, multicentre or bridging data, real-world evidence or staged evidence generation can further delay assessment while evidence develops.

- **Local development, local content and domestic preference requirements can restrict access to globally developed innovation**: Requirements linked to local patents, development or manufacturing activities, local-content rules or domestic procurement preferences may limit access to innovation pathways or downstream adoption for technologies developed elsewhere, even where they could address local unmet medical needs.

- **Limited international collaboration and regulatory reliance can lead to unnecessary duplication of assessment efforts**: Where authorities make limited use of relevant assessments and scientific work undertaken by trusted regulators, additional work may be required to address questions already examined elsewhere. Greater use of regulatory reliance can reduce duplication and conserve regulatory and development resources, while preserving national decision-making and consideration of local needs.

3. Landscape Analysis

Against this backdrop, APACMed conducted a comparative review of innovative medical device pathways across selected APAC and reference markets. The landscape examines eligibility, regulatory processes and practical benefits, pathway uptake where data are available, and connections to downstream funding and access. The full landscape is provided in Annex A. The analysis below draws out the key commonalities and differences observed across these pathways.

The pathways reviewed are not all equivalent in design. They broadly fall into several models: priority-review mechanisms that primarily accelerate assessment; innovation designations that combine prioritisation with enhanced regulatory support; and development-stage advisory mechanisms. In some markets, these regulatory approaches are also linked more closely with downstream HTA or funding processes. Some pathways combine more than one of these features. The analysis therefore compares the functions and practical benefits of these approaches rather than treating them as directly equivalent programmes.

3.1. The scope of "innovative medical device" varies across markets

The pathways reviewed do not apply a common definition of an innovative medical device. Differences arise at two levels: which devices are eligible to enter the pathway, and what characteristics qualify a device as innovative or deserving of priority support.

Eligible device scope:

Device Scope	Market
Medical devices incl. IVDs	Australia, EU, Japan, Korea, Chinese Taipei, US
Class III & IV, incl. eligible IVDs	Canada
Class II & III, incl. IVDs	China – Green Channel
Domestic Class III; imported Class II/III, incl. IVDs	China – National NMPA Priority Registration
Devices under Act 737, incl. IVDs; TRL 3–9	Malaysia
Class B–D incl. eligible IVDs, Full Evaluation only	Singapore

Beyond these product-level differences, the basis for qualification also varies considerably. Some pathways focus primarily on technological novelty, while others prioritise clinical benefit, unmet need or broader public-health and strategic priorities.

Basis for qualification	Examples
Technological novelty / first-of-kind	China Green Channel, EU, Japan, Malaysia, Korea
Significant clinical benefit / improvement	Australia, Canada, Singapore, Korea, US
Unmet medical need	Australia, Canada, EU, Japan, Malaysia, Singapore, Korea, US
Public-health or strategic priority	Australia for IVDs, China Priority Registration, Korea, Chinese Taipei
Market-specific development conditions	China IP requirements; Japan-first/simultaneous filing; Malaysia TRL requirements

Overall, innovation is not defined solely by technological novelty. Across the landscape, pathways may instead, or additionally, recognise a device because of the clinical need it addresses, the magnitude of improvement it offers, or its relevance to wider public-health priorities. Market-specific eligibility conditions can also affect how accessible innovation pathways are to globally developed technologies, reinforcing the value of transparent and proportionate criteria.

Good practice example – Australia: IVD-specific eligibility Australia's Priority Applicant Determination includes an IVD-specific eligibility criterion based on whether early availability would provide a major public health benefit. This recognises that the value of an innovative diagnostic may not always be captured through the same clinical-advantage criteria used for therapeutic devices, and provides a useful example of tailoring innovation criteria to the characteristics of different technologies.

3.2. Innovative pathways differ in the regulatory support they provide

Once a device qualifies, the regulatory benefit associated with designation varies considerably. Most pathways do not create a separate approval route or reduce the applicable safety, quality or performance requirements. Instead, they differ in the degree of prioritisation, regulatory interaction and flexibility provided during development and review.

Type of regulatory support	Examples
Priority / accelerated review	Australia, Canada, Singapore, Chinese Taipei, China Priority Registration, Korea
Priority review + enhanced regulatory interaction	China Green Channel, Japan, US
Development-stage regulatory advice	Malaysia
Staged review / early assessment of evidence	Korea
Flexibility in pre- and post-market evidence generation	US, EU
Dedicated case management / coordination	Japan, China Green Channel, US

Overall, the pathways range from relatively simple queue prioritisation to much more active regulatory support throughout product development. Faster review is therefore only one possible benefit of innovation designation; in several markets, the additional value lies in earlier dialogue, staged assessment, case management or greater flexibility in evidence planning. Some jurisdictions are also using regulatory sandboxes or controlled testing environments to support early engagement and evidence generation for emerging technologies.

Software-based and AI-enabled medical devices may require particular consideration because their performance and functionality can evolve over the product lifecycle. Innovation pathways may therefore need to accommodate iterative development, planned changes, proportionate evidence generation and appropriate post-market monitoring, including Predetermined Change Control Plans (PCCPs) where applicable.

Good practice example – Korea: staged regulatory review Korea's Innovative Medical Device framework allows designated technologies to access staged review during development, including assessment of safety, performance, clinical investigation planning and technical documentation before the final marketing-authorisation submission. This illustrates how an innovation pathway can provide value beyond queue prioritisation by supporting earlier regulatory dialogue and addressing evidence issues progressively during development.

3.3. Fee models vary across innovative pathways

Fee structures are not consistent across the landscape. Five of the reviewed markets do not charge a separate pathway or designation fee, with manufacturers remaining subject to the standard fees associated with registration, conformity assessment or marketing authorisation. Other pathways apply additional charges for priority processing, pathway evaluation or enhanced advisory and consultation services.

Fee approach	Examples
No separate pathway / designation fee	Canada, China, EU, Korea, US
Separate priority / pathway fee	Australia, Chinese Taipei
Fees linked to enhanced advisory or consultation services	Japan, Malaysia
Application and pathway evaluation fees	Singapore

Overall, there is no common approach to pathway fees, with additional charges applying either to priority processing or to enhanced regulatory support in some markets.

3.4. Pathway uptake and reporting vary widely

Public reporting on pathway uptake is uneven across the landscape. Some authorities publish cumulative designation or approval figures, while others provide only individual decisions, historical examples or no quantitative uptake data. Where figures are available, they are also not directly comparable, as they may refer to designations, applications, determinations or approved products.

Uptake pattern	Examples
Substantial reported uptake	China, Korea, US
Low number of published pathway determinations/designations	Australia, Japan
Too early to assess meaningfully	EU, Malaysia
No / limited cumulative public data identified	Canada, Chinese Taipei

Overall, pathway utilisation appears highly uneven. Limited reported uptake in some longer-established pathways raises questions about their accessibility, attractiveness or practical benefit, but uptake figures alone do not explain the underlying causes. At the same time, inconsistent reporting makes it difficult to compare pathway performance across markets.

3.5. Regulatory innovation pathways vary in how far they connect to downstream funding and access

Across the landscape, regulatory innovation status does not have a consistent relationship with downstream funding. In some markets, regulatory and funding processes remain largely separate, while others provide earlier coordination, parallel assessment, pricing recognition or temporary access mechanisms.

Type of linkage	Examples
Regulatory and funding processes largely separate	Australia, Canada, Malaysia, Singapore, Chinese Taipei
Earlier HTA / payer engagement or evidence alignment	EU, US
Potential pricing recognition linked to innovation status	Japan
Parallel regulatory and access assessment	Korea
Temporary / conditional access while evidence develops	Korea

The degree of coordination also affects evidence planning. Where regulatory and funding assessments are separate, manufacturers may need to address different clinical, economic or health-system evidence requirements at different stages. In more integrated models, earlier dialogue or parallel assessment can allow these requirements to be considered during development rather than only after regulatory approval.

Overall, the landscape shows a spectrum from fully separate regulatory and funding processes to increasingly coordinated models that connect regulatory review with HTA, payer engagement, pricing or temporary access.

Good practice example – Korea: integrated regulatory and access assessment Korea's Integrated Review mechanism provides one of the clearest examples in the landscape of regulatory and downstream access processes being considered in parallel. For eligible technologies, innovative-device designation, benefit/non-benefit status and health technology assessment can be considered in parallel across the relevant authorities, reducing the need for fully sequential processes before clinical entry. Subsequent reimbursement assessment may still follow separately. This demonstrates how earlier cross-agency coordination can help address delays between regulatory review and clinical access.

3.6. Funding support takes different forms across markets

Where innovation is recognised within downstream funding or access processes, the resulting support also differs across markets. Support may take the form of pricing recognition, temporary or conditional coverage, patient co-payment mechanisms, or other arrangements that allow earlier clinical use while evidence continues to develop.

Type of funding / access support	Examples
Pricing or premium recognition	Japan
Technology-specific / add-on payment	Korea
Post-listing reassessment based on additional evidence	Japan
Temporary / conditional access while evidence is generated	Korea
Selective coverage or higher patient co-payment	Korea
Balance billing / defined patient co-payment mechanisms	Chinese Taipei
Emerging dedicated coverage mechanisms	US

Importantly, funding support does not necessarily mean premium reimbursement. Some models instead focus on enabling earlier access to a technology while managing uncertainty through temporary coverage, reassessment or patient cost-sharing. Korea, for example, allows certain innovative technologies to enter clinical use under temporary or selective-benefit arrangements while additional evidence is generated. Japan uses a different model, providing a specific pricing add-on for certain Pioneering Medical Devices, while its Challenge Application system allows post-listing reassessment where additional clinical evidence becomes available.

Overall, the landscape shows that recognition of innovation within funding systems can take several forms, ranging from pricing incentives to temporary access, rather than a single model of accelerated reimbursement.

Case study – Chinese Taipei: funding innovative diagnostics Chinese Taipei's NHI coverage of next-generation sequencing provides an example of a funding mechanism designed around an emerging diagnostic technology. The model combines defined reimbursement amounts with patient balance billing and eligibility conditions relating to providers and clinical governance. It illustrates how funding approaches can be adapted to support access to innovative technologies while managing budget and evidence considerations, although the implications of patient co-payment for equitable access also need to be considered.

4. Recommendations

Innovative medical device pathways should help patients benefit from safe, effective technologies that address unmet needs. Achieving this requires coordination across regulatory assessment, HTA, funding and clinical adoption. Particular consideration may be needed for software-based and AI-enabled medical devices, where iterative development, lifecycle changes and evolving evidence can create additional regulatory and HTA challenges. The recommendations below identify shared priorities and specific actions for each stakeholder group, while recognising differences in national mandates, resources and health system needs.

4.1. Recommendations for all stakeholders

Coordinate evidence planning early across the patient-access pathway

Regulators, HTA bodies, payers and manufacturers should establish opportunities for joint dialogue during development, ideally before pivotal studies begin, with relevant patient and clinical input where appropriate. This should clarify clinical and economic evidence needs, relevant comparators, patient outcomes and implementation considerations. Regulatory innovation designation can provide a trigger for such engagement. Regulatory approval and funding should remain independent decisions, but earlier coordination can reduce avoidable evidence gaps and delays between them.

Make pathways transparent and measure their contribution to patient access

Relevant agencies should publish clear eligibility criteria, procedures, evidence expectations, timelines, fees and decision-making processes. Pathway performance should be assessed beyond designation counts or regulatory review times, including reductions in duplicative assessments, overall time to market, and time from regulatory approval to funding and clinical availability, where measurable. Patient and clinician input should help identify whether pathways address meaningful unmet needs.

4.2. Recommendations for industry

Seek early regulatory, HTA and payer engagement

Manufacturers should engage with regulators, HTA bodies and payers as early as possible during development to clarify evidence expectations, relevant comparators, patient outcomes and potential access requirements. Early dialogue can help identify differences between regulatory and downstream evidence needs before pivotal studies and reduce avoidable gaps later in the access pathway.

Develop integrated evidence plans across the product lifecycle

Regulatory and market-access evidence planning should be considered together rather than sequentially. Evidence strategies should address meaningful patient and health-system outcomes and, where uncertainty remains at launch, include appropriate plans for post-market, real-world or additional clinical evidence, and fulfil agreed post-market evidence commitments, to support subsequent assessment and reassessment.

Share pathway experience and outcome data

Industry should contribute practical experience from the use of innovative-device pathways, including challenges, timelines and outcomes where appropriate. Sharing this experience through industry associations and structured stakeholder engagement can help authorities identify where pathways are working as intended and where their design or implementation could be improved.

4.3. Recommendations for regulators

Establish common principles for identifying technologies that merit innovation support

Authorities should work towards greater convergence in terminology and transparent eligibility criteria, based on common principles including unmet clinical need, meaningful clinical or safety benefit, technological novelty and public-health value. Criteria should accommodate the distinct contribution of diagnostics to diagnosis and clinical decision-making. Requirements linked to local patents, development activities or other localisation requirements should be reviewed to ensure they do not unnecessarily restrict access to globally developed technologies that address local patient needs.

Provide meaningful regulatory support and proportionate evidence approaches

Innovation designation should offer clearly defined support appropriate to the technology, such as early scientific advice, priority review, dedicated case management or staged assessment. Evidence requirements should remain scientifically robust while allowing justified use of alternative study designs, real-world evidence and planned post-market evidence generation. Requirements for local clinical evidence should be proportionate and scientifically justified, taking into account whether relevant international evidence can appropriately support the assessment. Applicants should understand the support available and their evidence obligations from the outset.

Strengthen international cooperation and regulatory reliance

Authorities should make appropriate use of relevant assessments, evaluations and regulatory decisions from trusted regulators to streamline regulatory processes and reduce unnecessary duplication. International cooperation and information-sharing should support reliance-based approaches, including recognition and abridged review where appropriate. Innovation designations in other jurisdictions may inform consideration of eligibility for local innovation support, while remaining distinct from marketing-authorisation decisions. Reliance should preserve national decision-making and consideration of local needs.[1]

[1] For further discussion on the practical implementation of regulatory reliance, see APACMed's From Concept to Practice: Advancing Regulatory Reliance for Medical Devices - https://apacmed.org/from-concept-to-practice-advancing-regulatory-reliance-for-medical-devices/

4.4. Recommendations for HTA bodies and payers

Ensure assessment and funding mechanisms can accommodate novel technologies

HTA and funding processes should provide a clear route for technologies that do not fit existing comparators, reimbursement categories or payment structures. Assessments should consider relevant patient outcomes and health system value, including improvements in diagnosis, treatment selection and care delivery. Evidence requirements should be proportionate to the characteristics of the technology and its role in the clinical pathway, with clear opportunities for early advice and, where appropriate, stakeholder-initiated proposals for assessment.

Connect initial assessment with planned reassessment as evidence develops

HTA bodies and payers should establish proportionate approaches to managing uncertainty across the technology lifecycle. Where appropriate, time-limited or conditional funding could support access alongside further evidence generation. Such arrangements should specify the data required, responsibilities, review milestones and criteria for continuing, modifying or withdrawing funding. Reassessment should consider new evidence and relevant changes to the technology or clinical practice.

4.5. Recommendations for policymakers

Enable coordination across agencies and address structural barriers to access

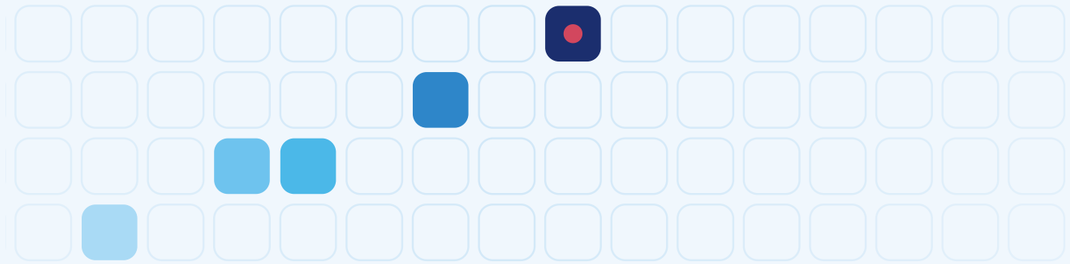
Policymakers should establish mechanisms connecting regulatory, HTA, funding and procurement processes, with clear responsibilities and adequate resources. Where feasible, advice and assessment activities should proceed in parallel to reduce unnecessary sequential delays. Reforms should also address barriers beyond approval, including funding categories, procurement rules and readiness for clinical implementation, such as appropriate clinical guidance or training where relevant, informed by patient and clinician needs. Policymakers should also identify and address legal or institutional barriers that may unnecessarily restrict regulatory reliance and international cooperation.

5. Conclusion

Innovative medical device pathways should help patients benefit from safe, effective technologies that address unmet healthcare needs. The landscape shows substantial variation in eligibility, regulatory support and connections with funding and clinical adoption. Their success should therefore be judged by their contribution to timely and sustainable patient access, alongside the efficiency of regulatory assessment.

The findings highlight opportunities to strengthen existing approaches through common eligibility principles, meaningful regulatory support, proportionate evidence requirements and greater international collaboration and reliance. Earlier joint dialogue coordinated evidence planning and parallel processes where feasible can help reduce avoidable delays. Planned reassessment as evidence develops, supported by appropriate funding mechanisms, can also help manage uncertainty across the technology lifecycle. Regulatory, HTA and funding decisions should retain their respective mandates while contributing to a better-connected access journey.

Progress requires shared action by policymakers, regulators, HTA bodies, payers, healthcare professionals, patients and industry. APACMed will use this paper to support focused dialogue in priority markets, identify practical opportunities for improvement and work with local partners to advance the recommendations. These efforts should reflect local health system needs and resources, with clear responsibilities and measures of progress towards patient access, while maintaining robust standards of safety, quality and performance.



Annex A. Landscape of Innovative Medical Device Pathways

METHODOLOGY

This landscape was developed through desk research of publicly available information from regulatory authorities, guidance documents and published materials, complemented by input from APACMed member companies. It compares selected innovative medical device pathways across key APAC and reference markets, with a focus on eligibility, process, practical benefits, funding implications and pathway uptake where information is available.

Markets were selected to capture a range of established, emerging and reference-market approaches, based on pathway maturity, relevance to the APAC medical technology sector and availability of reliable public information. The landscape is illustrative rather than exhaustive.

HOW TO USE THIS LANDSCAPE

This landscape is intended as a practical cross-market reference on innovative medical device pathways. It brings together information on eligibility, process, practical benefits, funding considerations and pathway uptake to help readers understand how different jurisdictions approach innovation in practice.

For manufacturers, the regulatory sections can help assess whether a product may qualify for an innovative pathway, what the pathway changes in practice, and what evidence, timing or engagement considerations may need to be anticipated. The reimbursement and funding sections should be considered in parallel, to understand whether regulatory acceleration is connected to HTA, reimbursement or other access mechanisms, and where separate market access planning may still be required.

For policymakers and other stakeholders, the landscape provides a comparative view of how different systems are structured and where approaches may offer useful lessons for other jurisdictions.

DISCLAIMERS

This landscape is based on desk research and publicly available information obtained from official regulatory authority websites, guidance documents, and published materials. The information presented reflects the status of innovative medical device pathways as of the date of publication.

While every effort has been made to ensure accuracy and completeness, regulatory frameworks are subject to change, and implementation practices may vary in practice. This document is intended for informational purposes only and does not constitute legal or regulatory advice.

Manufacturers and stakeholders are encouraged to consult the relevant regulatory authorities directly and conduct their own due diligence before making regulatory or business decisions.

Australia

REGULATORY PATHWAY

Priority Applicant Determination

BACKGROUND

- **Regulator**: Therapeutic Goods Administration (TGA)
- **Introduced**: 2018
- **Applies to**: Medical devices, including in vitro diagnostic medical devices (IVDs).
- **Purpose**: Gives eligible medical device applications priority in the TGA review queue. [1]

WHAT DOES THE PATHWAY DO?

The Priority Applicant Determination is not a separate approval route. If granted, it gives an eligible application priority for: TGA conformity assessment; or inclusion in the Australian Register of Therapeutic Goods (ARTG). The device must still meet the applicable regulatory requirements for its class and submission route. [1]

ELIGIBILITY CRITERIA

Device must satisfy all three criteria: [1]

1. **Life-threatening or seriously debilitating condition**: The intended purpose of the new device is the monitoring, treatment, prevention or diagnosis of a life-threatening or seriously debilitating condition.
2. **Unmet need or significant improvement, either**:
   i. no medical devices with that intended purpose are of a kind included in the ARTG
   ii. if one or more medical devices with that intended purpose are of a kind included in the ARTG (the existing devices), there is substantial evidence demonstrating that the safety or performance of the new device when used for that intended purpose provides a significant improvement compared to the existing devices.
3. **Major clinical advantage (or in the case of IVDs, 'major public health benefit'), either**:
   i. the new device is a breakthrough technology AND there is evidence that it offers a major clinical advantage over existing technology
   ii. there is evidence that the device offers a major clinical advantage over existing alternatives included in the ARTG
   iii. the new device is an IVD medical device and its early availability in Australia will result in a major public health benefit.

PROCESS

1. Sponsor applies for Priority Applicant Determination.
2. If granted, the relevant conformity assessment or ARTG application receives priority in the review queue.
3. The determination ceases after 6 months if no corresponding conformity assessment or ARTG inclusion application is submitted. If the corresponding application is submitted within that period, the determination remains in force while the application is processed. [1]

REGISTRATION FEE

- ARTG inclusion priority determination: AUD 12,591
- TGA conformity assessment priority determination: AUD 11,967
- This fee is in addition to the fees paid depending on the pathway selected, classification of the medical device or IVD, and the application audit assessment fees applied. [2]

PATHWAY UPTAKE

- TGA's published determination notices list 13 Priority Applicant Determinations with effective dates up to 30 June 2025: 10 for conformity assessment and 3 for ARTG inclusion.
- TGA's current register lists 14 determinations in total, including one granted in 2026. [3]

DEVELOPMENTS

TGA is considering options to strengthen regulatory pathways for innovative medical devices. Areas under consideration include expanding eligibility or support under the Priority Review pathway, improving pre-submission regulatory engagement, and a potential new provisional approval pathway providing time-limited approval for innovative devices addressing unmet need based on preliminary data, with subsequent evidence obligations. TGA is also seeking feedback on how existing mechanisms, including reliance pathways, the Special Access Scheme, clinical trials and conditions of approval, could support innovative devices.

FUNDING PATHWAY

General funding landscape

TGA Priority Applicant Determination provides regulatory prioritisation but does not itself confer a higher Prescribed List benefit, MBS funding, or an accelerated HTA pathway. Funding remains subject to the applicable Prescribed List, Medical Services Advisory Committee (MSAC)/ Medicare Benefits Schedule (MBS), or other funding process. [1][4][5]

For innovative devices, faster regulatory review therefore does not necessarily translate into faster funding or patient access.

Part C of the Prescribed List provides a funding route for specified devices that do not meet the Part A criteria, including certain non-implantable technologies. However, uncertainty remains around the process and criteria for adding new product groups to Part C. This can create challenges for novel non-implantable technologies that do not fit existing reimbursement categories, particularly where access also depends on a new or amended MBS-funded service and coordination between MSAC and Prescribed List assessment. [6]

For certain devices, separate funding evidence requirements may also affect timing. For example, joint replacement products seeking Prescribed List access are subject to minimum clinical evidence requirements, including at least two years of follow-up for specified patient cohorts. [7]

Diagnostics-specific funding considerations

For innovative diagnostics, Priority Applicant Determination does not automatically accelerate public funding. Diagnostic tests seeking Australian Government funding may require assessment by the MSAC, most commonly for listing on the MBS. [1][4]

MSAC assesses clinical effectiveness together with economic and financial evidence. For innovative diagnostics, generating this evidence can be challenging where clinical utility and downstream outcomes are still developing at the time of regulatory approval. [4] [8]

Australia also provides a codependent assessment pathway where a diagnostic test and a medicine are linked, allowing coordination between MSAC for the test and the Pharmaceutical Benefits Advisory Committee (PBAC) for the medicine. This provides an example of closer coordination between HTA and reimbursement processes for certain innovative diagnostics. [9]

SOURCES

[1] Therapeutic Goods Administration (TGA). Understanding priority applicant determination rules for medical devices, including IVDs. https://www.tga.gov.au/resources/guidance/understanding-priority-applicant-determination-rules-medical-devices-including-vitro-diagnostics-ivds

[2] Therapeutic Goods Administration (TGA). Fees and charges summary – 1 July 2026. https://www.tga.gov.au/sites/default/files/2026-06/fees-charges-summary-1-july-2026.pdf

[3] Therapeutic Goods Administration (TGA). Medical devices including IVDs – Priority Applicant Determination notices. https://www.tga.gov.au/products/medical-devices/application-and-market-authorisation/supply-medical-device/medical-devices-including-ivds-priority-applicant-determination-notices

[4] Medical Services Advisory Committee (MSAC). MSAC process. https://www.msac.gov.au/how-msac-works/process

[5] Australian Government Department of Health, Disability and Ageing. Final Evaluation of the Prescribed List Reforms, 10 August 2026. https://www.health.gov.au/resources/publications/final-evaluation-of-the-prescribed-list-reforms?language=en

[6] Australian Government Department of Health, Disability and Ageing. Prescribed List of Medical Devices and Human Tissue Products Guide – Part C listing criteria. https://www.health.gov.au/sites/default/files/2023-12/prescribed-list-of-medical-devices-and-human-tissue-products-guide-draft.pdf

[7] Australian Government Department of Health, Disability and Ageing. Prescribed List of Medical Devices and Human Tissue Products Guide. https://www.health.gov.au/sites/default/files/2023-12/prescribed-list-of-medical-devices-and-human-tissue-products-guide-draft.pdf

[8] Evaluating genetic and genomic tests for heritable conditions in Australia: lessons learnt from health technology assessments. Journal of Community Genetics, 2021. https://link.springer.com/article/10.1007/s12687-021-00551-2

[9] Australian Government Department of Health, Disability and Ageing. Health Technology Assessment Policy and Methods Review – Final report. https://www.health.gov.au/resources/publications/health-technology-assessment-policy-and-methods-review-final-report?language=en

Canada

REGULATORY PATHWAY

Priority Review for Medical Devices

BACKGROUND

- **Regulator**: Health Canada.
- **Applies to**: Class III and IV medical device licence applications and amendments, including eligible IVDs. [1]
- **Purpose**: Provides priority review for eligible devices intended for the diagnosis or treatment of serious, life-threatening or severely debilitating diseases or conditions. [1]

WHAT DOES THE PATHWAY DO?

Priority Review is not a separate market-authorisation pathway and does not change the applicable evidence requirements. Eligible applications are reviewed in priority within Health Canada's medical device licence process. Depending on the complexity and novelty of the device, this may result in a shorter time to market. The existing service standards still apply: 60 days for Class III and 75 days for Class IV applications, from screening acceptance to first decision. [1]

ELIGIBILITY CRITERIA

The application must be for a Class III or IV device intended for the diagnosis or treatment of a serious, life-threatening or severely debilitating disease or condition, and there must be substantial clinical evidence demonstrating at least one of the following: [1]

1. The device provides effective treatment or diagnosis of a disease or condition for which no medical device is currently licensed in Canada; or
2. The device provides a significant risk-benefit improvement over existing therapeutic or diagnostic devices for a disease or condition that is not adequately managed by products currently marketed in Canada; or
3. The device responds to an unforeseen or unmet urgent health need.

PROCESS

1. The manufacturer requests Priority Review as part of the Class III or IV medical device licence or amendment application.
2. The application undergoes the standard 15-day screening process.
3. At screening acceptance, Health Canada informs the applicant whether Priority Review has been accepted. If accepted, the application is reviewed in priority. The standard Class III and IV service standards remain applicable. [1]

REGISTRATION FEE

Priority Review does not carry a separate priority-review fee. Standard medical device licence application fees apply. [2]

PATHWAY UPTAKE

Health Canada does not appear to publish a current cumulative total of medical devices reviewed through Priority Review. Historical annual reporting confirms use of the pathway; for example, 3 of 80 new Class IV devices approved in 2018 were reviewed through Priority Review. [3]

Advanced Therapeutic Products (ATP) Framework

BACKGROUND

- **Regulator**: Health Canada.
- **Legal basis**: Food and Drugs Act, sections 21.9–21.96.
- **Purpose**: Provides a legal framework to develop tailored regulatory requirements for therapeutic products that are sufficiently novel, complex or distinct that existing regulatory frameworks may not adequately accommodate them. [4]

CURRENT STATUS

The ATP framework is not currently an operational regulatory pathway for medical devices. For a tailored ATP pathway to operate, a product or class of products must first be added by the Minister to Schedule G of the Food and Drugs Act. As of 2026, Schedule G contains no listed products or product classes. [5]

Manufacturers and other stakeholders may suggest potential ATP candidates to Health Canada. Health Canada has assessed adaptive machine learning-enabled medical devices as a potential ATP candidate, but subsequently determined that updates within the existing medical device regulatory framework were sufficient rather than establishing an ATP pathway for these devices. [6]

FUNDING PATHWAY

Health Canada Priority Review does not itself confer any reimbursement, pricing or funding advantage. Health Canada regulates market authorisation, while the provinces and territories are responsible for health care delivery and determine which services are publicly funded. [7]

For IVDs, diagnostic tests fall within CDA-AMC's health technology remit, but Priority Review of an IVD does not provide a dedicated or accelerated downstream funding pathway. [8][9]

One area of closer coordination is companion diagnostics, where CDA-AMC evaluates diagnostic considerations alongside the associated drug reimbursement review. In 2026, CDA-AMC strengthened this process to collect additional clinical, economic and health-system information related to companion diagnostics and other testing requirements. [10]

SOURCES

[1] Health Canada. Guidance on how to complete the application for a new or amended medical device licence – Priority review. https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents/application-new-amended-licence/implementation.html

[2] Health Canada. Fees for examining a medical device licence application – effective 1 April 2026. https://www.canada.ca/en/health-canada/services/drugs-health-products/funding-fees/fees-respect-human-drugs-medical-devices/medical-device-licence-application-review-funding-fees-drugs-health-products.html

[3] Health Canada. Drug and Medical Device Highlights 2018. https://www.canada.ca/content/dam/hc-sc/documents/services/publications/drugs-health-products/drug-medical-device-highlights-2018/drug-medical-device-highlights-2018.pdf

[4] Health Canada. A framework for regulating and authorizing advanced therapeutic products. https://www.canada.ca/en/health-canada/services/drug-health-product-review-approval/advanced-therapeutic-products/framework-regulating-authorizing.html

[5] Government of Canada. Food and Drugs Act – Schedule G. https://laws-lois.justice.gc.ca/eng/acts/f-27/page-16.html

[6] Health Canada. ATP candidates. https://www.canada.ca/en/health-canada/services/drug-health-product-review-approval/advanced-therapeutic-products/candidates.html

[7] Health Canada. About Canada's health care system. https://www.canada.ca/en/health-canada/services/canada-health-care-system.html

[8] Canada's Drug Agency (CDA-AMC). Health Technology Review. https://www.cda-amc.ca/health-technology-review

[9] Canada's Drug Agency (CDA-AMC). Submit a Request. https://www.cda-amc.ca/submit-request

[10] Canada's Drug Agency (CDA-AMC). Improving Our Assessments of Drugs With Companion Diagnostic Tests. https://www.cda-amc.ca/news/improving-our-assessments-drugs-companion-diagnostic-tests

China

REGULATORY PATHWAY

Special Review Procedure for Innovative Medical Devices ("Green Channel")

BACKGROUND

- **Regulator**: National Medical Products Administration (NMPA), with review conducted through the Center for Medical Device Evaluation (CMDE). [1][3]
- Introduced: 2014; the current Special Review Procedure was issued in 2018 and took effect on 1 December 2018. [3]
- **Applies to**: Class II and III medical devices, including IVDs, where the applicable innovation criteria are met. [1][2]
- **Purpose**: Supports the development and registration of innovative medical devices through priority handling, early regulatory engagement and enhanced communication, without lowering regulatory standards or removing required procedures. [3]

WHAT DOES THE PATHWAY DO?

The Special Review Procedure is not a separate market-authorisation route. Once accepted, the device remains subject to the applicable registration requirements, but receives priority handling, including dedicated regulatory contacts, enhanced communication and guidance, and priority technical review and administrative approval. [1][3]

ELIGIBILITY CRITERIA

The applicant must meet all three criteria: [1][2]

1. Core technology intellectual property: the applicant holds, or has legally obtained, a Chinese invention patent or right of use covering the product's core technology, with the application for innovative review made within five years of patent authorisation; alternatively, the relevant patent application has been published and a CNIPA search report confirms novelty and inventiveness.
2. Product development maturity: preliminary research has been completed, the product is basically finalised, and the research process and supporting data are complete, controlled and traceable.
3. Innovation and clinical value: the product's main working principle or mechanism is first of its kind in China; its performance or safety is substantially improved compared with equivalent products; the technology reaches an internationally advanced level; and it has significant clinical application value.

For IVDs, the NMPA's IVD Registration and Filing Provisions expressly provide the same innovative-product registration pathway and criteria. [2]

PROCESS

Special Review determination

1. The applicant submits the Special Review application before the initial Class II or III registration application, once the product is basically finalised.
2. Domestic applicants submit through the relevant provincial authority, which conducts a preliminary review; overseas applicants submit directly to NMPA.
3. CMDE conducts a formal review and expert assessment. Proposed designations are publicly notified before a final decision is made.

Subsequent registration

4. Once accepted into the Special Review Procedure, the device must still complete the applicable registration review and approval process. Special Review status provides priority handling and regulatory support but does not replace the applicable registration requirements [1][3]

REGISTRATION FEE

The Special Review application itself does not carry a separate fee. Standard registration fees apply to the subsequent medical device registration application. [3]

PATHWAY UPTAKE

By September 2026, 442 innovative medical devices had been approved cumulatively, based on NMPA's reported total of 391 through the end of 2025 and 51 additional approvals in 2026. [4]

National Priority Registration Procedure

BACKGROUND

- Regulator: NMPA / CMDE. [1]
- Introduced: 2016, under CFDA Announcement No. 168, effective 1 January 2017. [5]
- Applies to: Domestic Class III and imported Class II/III medical devices, including eligible IVDs. [2][5]
- Purpose: Provides priority review for devices addressing defined clinical needs or national science and technology priorities. Unlike the Special Review Procedure, eligibility is driven primarily by clinical need rather than technological innovation itself. [1][5]
- Separate provincial priority-review mechanisms also exist for certain domestic Class II devices; these are outside the scope of the national pathway described here.

WHAT DOES THE PATHWAY DO?

Priority Registration does not create a separate approval standard. Eligible applications receive priority technical review and approval, priority scheduling of relevant quality management system inspections and enhanced communication with CMDE. [1][5]

ELIGIBILITY CRITERIA

A device may qualify where it meets one of the following conditions: [1][2]

1. It is:
   - used to diagnose or treat a rare disease and has a significant clinical advantage;
   - used to diagnose or treat a malignant tumour and has a significant clinical advantage;
   - used to diagnose or treat diseases specific to or prevalent among older people where no effective diagnostic or treatment method exists;
   - intended for children and has a significant clinical advantage; or
   - urgently needed clinically and no predicate device is currently approved in China.
2. It is included in a National Science and Technology Major Project or National Key Research and Development Project.
3. It falls within another circumstance specified by NMPA as eligible for priority registration.

PROCESS

1. The applicant submits the Priority Registration request at the same time as the medical device registration application. [1][5]
2. NMPA/CMDE reviews eligibility according to the applicable category. [1][5]
3. Proposed priority projects are publicly notified; under the published procedure, the notice period is at least 5 working days. [5]
4. Once accepted, the application is placed in the priority review queue, with priority technical review, QMS inspection and administrative approval. [1][5]

REGISTRATION FEE

The Priority Registration procedure does not carry a separate priority-review fee. Standard medical device registration fees apply.

PATHWAY UPTAKE

NMPA reported 77 medical devices handled through priority approval in 2022. [6]

FUNDING PATHWAYS

General funding landscape

NMPA Special Review or Priority Registration does not itself confer reimbursement, premium pricing, procurement priority or a dedicated downstream funding pathway. Regulatory approval and downstream pricing, payment and procurement processes operate separately.

However, China is increasingly developing parallel mechanisms intended to support faster clinical adoption of innovative technologies. The National Healthcare Security Administration (NHSA) has been developing national medical service price-item guidelines; by April 2026, it reported 39 batches of guidelines incorporating approximately 180 price items related to new technologies and products. [7]

NHSA is also developing mechanisms such as pre-establishment of medical service price items, compatibility with existing price items, conditional addition of new items and channels for major innovations to reduce the delay between technological development and the ability to charge for clinical use. [8] These developments are relevant to innovative devices, but they are not formally linked to NMPA innovative-device designation.

At the local level, some Diagnosis-Related Groups (DRG) payment systems also provide mechanisms to accommodate new technologies. Beijing, for example, operates an exclusion-payment mechanism for eligible new drugs, medical devices and medical service items that meet defined clinical and cost-impact criteria, allowing additional payment beyond the standard DRG amount. This mechanism operates independently of NMPA innovative-device designation.[9]

Diagnostics-specific funding considerations

For innovative diagnostics, regulatory approval does not itself establish a reimbursable test or service. Diagnostic services are generally charged through medical service price items, with NHSA issuing national price-item guidance and provincial authorities implementing the applicable items and prices. [10]

China has taken specific steps to address emerging diagnostic technologies. For example, NHSA's radiology framework includes AI-assisted diagnosis as an extension of the existing diagnostic service, rather than as a separately billable service; the AI component cannot be charged in addition to the underlying service. [11] For pathology, AI-assisted diagnosis is similarly incorporated into the pricing framework, with relevant resource costs considered within the overall service price rather than through a separate standalone payment. [12]

SOURCES

[1] NMPA. Provisions for Medical Device Registration and Filing. https://english.nmpa.gov.cn/2024-06/05/c_993242.htm

[2] NMPA. Provisions for In-vitro Diagnostic Reagent Registration and Filing. https://english.nmpa.gov.cn/2024-06/05/c_1049322.htm

[3] NMPA. Innovative Medical Device Special Review Application / 2018 Special Review Procedure. https://zwfw.nmpa.gov.cn/web/taskview/11100000MB0341032Y100207202600001

[4] 动脉网 (VBData). 442款创新医疗器械产品，有多少销售额能过亿? 7 September 2026. https://www.vbdata.cn/1519092360

[5] CCFDIE / CFDA. Procedure for Prioritized Review and Approval of Medical Devices (2016 No. 168). https://www.ccfdie.org/zryyxxw/ylqx/cfdztz/webinfo/2016/10/1489837087580000.htm

[6] NMPA. 2022 Medical Device Regulatory Performance Report. https://www.nmpa.gov.cn/xxgk/fgwj/gzwj/gzwjylqx/20260224172356196.html?utm

[7] NHSA. New technology price items support the application of innovative technologies and products. https://www.nhsa.gov.cn/art/2026/4/23/art_14_20296.html

[8] NHSA. Interpretation of the 15th Five-Year Plan for Universal Medical Security. https://www.nhsa.gov.cn/art/2026/8/19/art_105_21829.html

[9] Beijing Healthcare Security Administration. Notice on the Trial Measures for Exclusion Payments for New Drugs and New Technologies under CHS-DRG Payment (2022). https://ybj.beijing.gov.cn/tzgg2022/202207/t20220713_2798069.html & Beijing Healthcare Security Administration. Notice on the First Batch of New Drugs and New Technologies Eligible for CHS-DRG Exclusion Payment (2024). https://ybj.beijing.gov.cn/zwgk/2024zcwj/202412/t20241217_3967640.html

[10] NHSA. Medical Service Price Items. https://www.nhsa.gov.cn/art/2024/11/19/art_109_14761.html

[11] NHSA. Radiology price-item guidance – AI-assisted diagnosis. https://www.nhsa.gov.cn/art/2024/11/20/art_14_14772.html

[12] NHSA. Pathology price-item guidance – AI-assisted diagnosis. https://www.nhsa.gov.cn/art/2025/12/19/art_14_19086.html

Chinese Taipei

REGULATORY PATHWAY

Priority Review

BACKGROUND

- **Regulator**: Taiwan Food and Drug Administration (TFDA).
- **Introduced**: 2017; the current legal basis is Article 9 of the Regulations Governing Issuance of Medical Device License, Listing and Annual Declaration.
- **Applies to**: Medical devices, including IVDs, that meet one of the Priority Review criteria. The Regulations expressly define IVDs as medical devices used to examine human specimens for diagnosis or determination of health status.
- **Purpose**: Encourages development of innovative medical devices and devices in urgent demand by accelerating the approval process. [1][2]

WHAT DOES THE PATHWAY DO?

Priority Review is not a separate market-authorisation route. Once Priority Review status is granted, the designation applies to the subsequent medical device registration application and provides priority regulatory review. [1]

ELIGIBILITY CRITERIA

An application may qualify where any one of the following circumstances applies: [2]

- The device is intended to prevent, diagnose or treat a life-threatening disease or disease causing severe disability, and no appropriate drug, medical device or suitable alternative treatment is available in Taiwan.
- The device is intended to prevent, diagnose or treat a rare disease as defined under the Rare Disease and Orphan Drug Act.
- The device:
  - has received priority support under government policy or public R&D funding and is conducting or will conduct clinical trials in Taiwan to verify safety and effectiveness; or
  - addresses an urgent domestic public-health or medical need.

PROCESS

1. The applicant completes the Priority Review Self-Assessment Form and submits it to TFDA with an inquiry letter and supporting evidence demonstrating that the applicable eligibility criterion is met.
2. TFDA assesses the request and informs the applicant of the Priority Review decision by official letter.
3. If Priority Review is granted, the applicant submits the subsequent registration application together with the official designation letter.
4. The application then undergoes Priority Review while remaining subject to the normal safety, effectiveness and quality requirements. [1]

PATHWAY FEE

The medical device registration fee for Priority Review is NTD 180,000. [3]

PATHWAY UPTAKE

TFDA does not appear to publish cumulative statistics on the number of devices reviewed or approved through Priority Review.

FUNDING PATHWAY

General funding landscape

TFDA Priority Review is a regulatory mechanism and does not itself determine National Health Insurance (NHI) reimbursement or pricing. NHI coverage of medical devices and new medical services follows separate assessment and decision-making processes managed by the National Health Insurance Administration (NHIA). No formal mechanism linking Priority Review designation to accelerated NHI assessment was identified. [1][4]

For new medical devices and medical services, NHIA may commission health technology assessment (HTA) through the Center for Drug Evaluation (CDE). Manufacturers can also access CDE consultation before applying for NHI coverage, including advice on the reimbursement process and evidence preparation. [4][5]

Taiwan also uses balance billing for certain newer or higher-specification medical devices, where NHI pays a defined amount and the patient pays the difference. This provides a downstream access mechanism for newer technologies, but it operates independently of Priority Review. [6]

Diagnostics-specific funding considerations

For innovative diagnostics, Taiwan provides a notable example through NHI reimbursement of next-generation sequencing (NGS) where NHI uses a fixed-amount reimbursement with patient balance billing, with payment levels differentiated according to the type and size of the genomic test. The programme was designed to support more than 20,000 cancer patients annually, with approximately NTD 300 million allocated. [7]

Access is subject to defined clinical and quality conditions, including eligible providers, molecular tumour board arrangements and submission of test results to NHIA. [7]

This provides a notable example of a funding approach designed for an innovative diagnostic technology, but it operates independently of TFDA Priority Review: regulatory designation does not itself determine eligibility for NGS reimbursement.

SOURCES

[1] Taiwan Food and Drug Administration (TFDA). Priority Review Program for Medical Devices. https://www.fda.gov.tw/ENG/siteListContent.aspx?id=28067&sid=10335

[2] Taiwan Food and Drug Administration (TFDA). Regulations Governing Issuance of Medical Device License, Listing and Annual Declaration – Articles 2 and 9. https://www.fda.gov.tw/eng/lawContent.aspx?cid=5063&id=3354

[3] Taiwan Food and Drug Administration (TFDA). Medical Device Administrative Fee-Charging Standards. https://www.fda.gov.tw/tc/includes/GetFile.ashx?id=f638127419401035094

[4] Center for Drug Evaluation (CDE). Health Technology Assessment – Scope of Operation for Special Medical Devices and Medical Services. https://www.cde.org.tw/htaen/26398/26434/26437/26485/normalPost

[5] Center for Drug Evaluation (CDE). General Consultation on NHI-covered New Special Devices and New Healthcare Services. https://www.cde.org.tw/htaen/26398/26471/26476/26482/26828/simpleList

[6] National Health Insurance Administration (NHIA). Medical Devices Covered via Balance Billing. https://www.nhi.gov.tw/en/dl-66546-2d7d3464d48e48a49f3df9c2145d5818-2.pdf

[7] National Health Insurance Administration (NHIA). NHI Coverage of Next-Generation Sequencing for Solid Cancer and Leukemia. https://www.nhi.gov.tw/en/cp-15076-08d24-8-2.html

European Union

REGULATORY PATHWAY

Breakthrough Devices (BtX) – MDCG 2025-9 and EMA Pilot

BACKGROUND

- **Framework**: Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on IVDs (IVDR).
- **Guidance introduced**: MDCG 2025-9, published in December 2025.
- **The guidance applies to**: Medical devices and IVDs across all technologies and risk classifications. Custom-made devices, in-house devices and MDR Annex XVI products without an intended medical purpose are outside scope.
- **Purpose**: Provides a framework to identify breakthrough devices and support a more streamlined pathway towards CE marking and market access, while maintaining applicable MDR/IVDR requirements.
- **Implementation**: EMA launched a pilot on 28 April 2026 to operationalise breakthrough designation and expert-panel support.[1] [2]

WHAT DOES THE PATHWAY DO?

Breakthrough designation is not a separate market-authorisation route. Devices remain subject to the applicable MDR/IVDR conformity assessment requirements.

Designation may provide access to additional support, including:

- priority scientific and regulatory advice;
- early and structured dialogue with notified bodies;
- expert-panel advice on evidence-generation strategies;
- prioritisation and potentially accelerated conformity assessment;
- greater flexibility in how appropriate pre- and post-market evidence is generated, where scientifically justified. [1]

The overall clinical or performance evidence requirements are not reduced, but MDCG 2025-9 allows consideration of whether some confirmatory evidence can appropriately be generated post-market through defined PMS, PMCF or PMPF activities. [1]

ELIGIBILITY CRITERIA

A medical device or IVD must meet both criteria: [1]

1. **Novelty**: the device introduces a high degree of novelty in the device technology, related clinical procedure and/or application in clinical practice.
2. **Positive clinical impact**: the device is expected to provide a significant positive clinical impact on patients or public health for a life-threatening or irreversibly debilitating disease or condition by either:
   i. providing a significant positive clinical impact compared with available alternatives and the state of the art; or
   ii. addressing an unmet medical need where available alternatives are absent or insufficient.

For IVDs, positive clinical impact may include improvements such as earlier diagnosis, greater sensitivity or specificity, or enabling more effective treatment. [1]

PROCESS

1. The manufacturer requests an opinion on breakthrough status from the medical device expert panels. The request can be made during development once sufficient information is available to support the BtX criteria.
2. Expert panels aim to provide an opinion on breakthrough status within 60 days.
3. Once designated, the manufacturer may access relevant support mechanisms depending on the device type and stage of development, including expert-panel advice and structured dialogue with the notified body.
4. The device subsequently follows the applicable MDR or IVDR conformity assessment route. [1][2]

The EMA pilot is being phased in:

- Phase I: Class III devices and active Class IIb devices intended to administer or remove medicinal products;
- Phase II: expected Q1 2027, extending to other medical-device classes;
- Phase III: expected Q3 2027, extending the pilot to IVDs. [2]

PATHWAY FEE

Participation in the EMA breakthrough pilot and expert-panel advice is free of charge. Normal notified-body and conformity-assessment fees remain applicable. [2]

PATHWAY UPTAKE

The pilot was launched in April 2026. Five applications were selected for the initial Phase Ia pilot. As the framework is still being implemented, meaningful cumulative uptake or CE-marking data are not yet available. [2]

FUNDING PATHWAY

General funding landscape

Breakthrough designation does not itself confer reimbursement, pricing or funding approval. Pricing and reimbursement decisions remain the responsibility of individual Member States.

However, the EU framework contains mechanisms intended to improve regulatory–HTA coordination for innovative technologies. MDCG 2025-9 explicitly identifies potential recognition of breakthrough status in HTA assessments, and certain manufacturers may access scientific advice involving both medical-device expert panels and HTA authorities. [1][3]

Under the EU HTA Regulation, selected high-risk medical devices may undergo an EU-level Joint Clinical Assessment (JCA). Eligible devices include Class IIb or III medical devices that have undergone the relevant expert-panel consultation and are subsequently selected for JCA. Selection may take into account factors including unmet medical need, first-in-class status, impact on patients or health systems, AI/ML technologies, cross-border relevance and EU-wide added value. [3]

JCAs provide a common scientific assessment of clinical evidence to support national HTA processes, but do not replace Member State pricing, reimbursement or broader value-assessment decisions. [3][4]

Importantly for innovative devices, health technology developers may also request Joint Scientific Consultation (JSC) while clinical investigations are still being planned, helping align evidence generation with future HTA requirements. For eligible devices, JSC can be conducted in parallel with expert-panel consultation. [3][5]

Diagnostics-specific funding considerations

The same regulatory–funding separation applies to innovative IVDs: breakthrough designation does not itself provide reimbursement.

The EU HTA Regulation nevertheless explicitly includes selected Class D IVDs for Joint Clinical Assessment where the relevant expert panel has provided its views under the IVDR. Class D IVDs may also be eligible for Joint Scientific Consultation while performance studies are still being planned. [3][5]

This creates a potential mechanism for earlier alignment between IVD evidence generation and HTA requirements, although final reimbursement and funding decisions remain national. [3][5]

SOURCES

[1] MDCG. MDCG 2025-9 – Guidance on Breakthrough Devices under Regulations 2017/745 and 2017/746. https://health.ec.europa.eu/document/download/edca94c7-62ab-4dd5-8539-2b347bd14809_en?filename=mdcg_2025-9.pdf

[2] European Medicines Agency. Expert panel support for breakthrough medical devices: pilot programme. https://www.ema.europa.eu/en/human-regulatory-overview/medical-devices/expert-panel-support-breakthrough-medical-devices-pilot-programme

[3] Regulation (EU) 2021/2282 on health technology assessment. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32021R2282

[4] Commission Implementing Regulation (EU) 2025/2086 on JCA of medical devices and IVDs. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32025R2086

[5] European Commission. Guidance for the selection of medical devices and IVDs for Joint Scientific Consultations. https://health.ec.europa.eu/publications/guidance-selection-medical-devices-md-and-vitro-diagnostic-medical-devices-ivd-joint-scientific_en

Japan

REGULATORY PATHWAY

Pioneering Medical Device / Pioneering IVD Designation System (formerly SAKIGAKE pilot)

BACKGROUND

- **Regulator**: Ministry of Health, Labour and Welfare (MHLW), with review and consultation support from the Pharmaceuticals and Medical Devices Agency (PMDA).
- **Introduced**: The SAKIGAKE pilot began in 2015. The scheme was subsequently established in law as the Pioneering Medical Device / Pioneering IVD Designation System, effective from 2020.
- **Applies to**: Medical devices and IVDs.
- **Purpose**: Supports early development and priority review of innovative technologies with the aim of making leading medical technologies available to patients in Japan ahead of, or at the same time as, other countries. [1]

WHAT DOES THE PATHWAY DO?

Designation does not create a separate approval route. Designated products receive:

- priority PMDA consultations;
- enhanced pre-submission assessment;
- priority review, with a target of approximately 6 months for medical devices;
- a designated PMDA concierge to coordinate development and review activities.

To support the shortened review, designated products are generally expected to use PMDA's SAKIGAKE Comprehensive Evaluation Consultation before the marketing authorisation application. [1][2]

ELIGIBILITY CRITERIA

A medical device or IVD must meet all four criteria:

1. **Innovative treatment or diagnostic approach**: for medical devices, generally a new principle, for IVDs, generally a new principle or new measurement item.
2. **Serious disease**: intended for a serious disease that has a major impact on life, or for a condition with no curative treatment where significant symptoms persist.
3. **Very high expected effectiveness or safety**: there is no existing treatment/diagnostic approach, or the product is expected to substantially improve effectiveness or safety compared with existing approaches. Human effectiveness and safety should already be suggested by exploratory clinical studies or equivalent evidence.
4. **Japan-first or simultaneous development and filing**: the sponsor intends and is able to develop and submit in Japan ahead of or at approximately the same time as other major jurisdictions. An application filed within 3 months of the first application in another comparable jurisdiction is regarded as simultaneous. [1]

Where a companion diagnostic is required, the sponsor must also have arrangements allowing the companion diagnostic to be submitted in parallel. [1]

PROCESS

1. The sponsor first requests a designation consultation with MHLW/PMDA.
2. Following consultation, the sponsor submits the formal designation application with supporting clinical, non-clinical and development information.
3. MHLW designates the product after consultation with the relevant Pharmaceutical Affairs and Food Sanitation Council.
4. Following designation, the product receives priority consultations, enhanced pre-submission evaluation, priority review and support from a PMDA concierge.
5. The subsequent marketing authorisation application follows the normal PMD Act approval framework, with a target review period of approximately 6 months for medical devices where adequate pre-submission assessment has been completed. [1]

REGISTRATION FEE

No separate designation fee is specified. However, designated products are generally expected to use PMDA's fee-based SAKIGAKE Comprehensive Evaluation Consultations before filing. [1] [2]

For IVDs, current PMDA consultation fees include: [2]

- Quality: JPY 299,100
- Performance: JPY 999,500
- Clinical performance: JPY 1,599,300
- QMS: JPY 599,000 plus overseas travel expenses, where applicable.

PATHWAY UPTAKE

Under the current statutory system, PMDA lists 2 Pioneering Medical Devices as of 31 March 2026. The former SAKIGAKE pilot, which operated before the statutory system, designated additional medical devices and 2 IVDs. These historical pilot designations are reported separately by PMDA. [3]

FUNDING PATHWAY

General funding landscape

Pioneering designation does not itself constitute an NHI reimbursement decision; medical devices must still follow the applicable insurance listing and pricing process. [4][5]

However, Japan provides a direct pricing incentive for certain designated products. Under the FY2026 medical material pricing framework, a new functional category containing a Pioneering Medical Device may be eligible for a 10% "Pioneering add-on" (先駆加算), subject to the applicable pricing criteria. Other innovation, usefulness or improvement add-ons may also apply where the relevant criteria are met. [4]

Therefore, unlike many markets, Japan provides a formal link between regulatory innovation designation and potential reimbursement pricing, although designation does not itself guarantee listing or patient access.

Diagnostics-specific funding considerations

IVDs follow a separate reimbursement route from medical devices and are generally reimbursed through test fees rather than a product-specific material price. The main categories are:

- E1: existing measurement item and existing method;
- E2: existing measurement item with a new method;
- E3: new measurement item or an existing item with improved clinical significance or convenience. [5][6]

For innovative diagnostics seeking E3 reimbursement, the FY2026 reforms explicitly strengthen the clinical-utility requirement. An E3 application may be classified as non-reimbursable where:

- the clinical positioning of the test is unclear;
- the test does not demonstrate performance appropriate to that clinical position; or
- clinical utility - for example, a change in treatment resulting from the test result - has not been demonstrated. [6]

Japan also provides a Challenge Application mechanism that allows post-listing reassessment based on additional evidence generated after reimbursement. The mechanism applies to medical devices and IVDs, enabling new evidence to inform subsequent reimbursement reassessment. [7]

SOURCES

[1] Ministry of Health, Labour and Welfare (MHLW). Pioneering Medical Devices, IVDs and Regenerative Medical Products Designation System. https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/000013196.html

[2] Pharmaceuticals and Medical Devices Agency (PMDA). SAKIGAKE Comprehensive Evaluation Consultation. https://www.pmda.go.jp/review-services/f2f-pre/consultations/0046.html

[3] PMDA. Lists of products under the Pioneering Designation System and former SAKIGAKE Designation System. https://www.pmda.go.jp/review-services/drug-reviews/0003.html

[4] MHLW. FY2026 Medical Material System Reform – Evaluation of Innovation. https://www.mhlw.go.jp/content/12400000/001667205.pdf

[5] MHLW. Insurance coverage for medical devices and IVDs. https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000176120.html

[6] MHLW. FY2026 reimbursement reform – clarification of evaluation criteria for IVDs. https://www.mhlw.go.jp/content/12400000/001667205.pdf

[7] Ministry of Health, Labour and Welfare (MHLW). Handling of Insurance Coverage for In Vitro Diagnostic Products, 13 February 2026. https://www.mhlw.go.jp/content/12400000/001672637.pdf

Malaysia

REGULATORY PATHWAY

Innovative Medical Device Review (IMDR)

BACKGROUND

- **Regulator**: Medical Device Authority (MDA), Ministry of Health Malaysia.
- **Introduced**: March 2026.
- **Applies to**: Medical devices meeting the definition under Section 2 of the Medical Device Act 2012 (Act 737), including IVDs, and satisfying MDA's innovation and Technology Readiness Level (TRL) criteria.
- **Purpose**: Provides regulatory advisory support to industry and academia during development of innovative medical devices, with a focus on the Essential Principles of Safety and Performance (EPSP) and regulatory readiness. [1][2]

WHAT DOES THE PATHWAY DO?

IMDR is a pre-market regulatory advisory service, not a separate approval or priority-registration route. It allows eligible innovators to engage MDA before market entry and receive regulatory advice according to the maturity of the technology. Participation does not replace the applicable conformity assessment and registration requirements. [1][2]

ELIGIBILITY CRITERIA

The product must meet all three requirements: [2][3]

1. Medical device definition: it falls within Section 2 of Act 737. This expressly includes in vitro reagents, calibrators and products providing diagnostic information through examination of human specimens.
2. Innovation: it demonstrates novel technology or a significant improvement in design, effectiveness or efficiency compared with existing devices, including technologies such as AI or additive manufacturing, and is supported by intellectual property where applicable.
3. Development maturity: it falls within TRL 3–9 and has a well-established proof of concept.

MDA divides eligible products into:

- Early Development Review: TRL 3–5
- Pre-commercial Review: TRL 6–9; a working prototype is required. [2][3]

PROCESS

1. The applicant confirms that the product meets the medical-device definition, innovation criteria and applicable TRL.
2. The applicant submits the IMDR application and supporting documents to MDA.
3. MDA screens the application and confirms whether the innovation criteria and TRL requirements are met.
4. Following payment, MDA arranges an advisory session within 14 working days. The session lasts up to 2 hours.
5. MDA evaluates the application within 30 working days and issues an Early Development Review or Pre-commercial Review report based on the evaluation and advisory session. [2]

REGISTRATION FEE

- Early Development Review (TRL 3–5): RM 1,000 per session.
- Pre-commercial Review (TRL 6–9): RM 1,500 per session. [1][2]

These fees relate to the IMDR advisory service and are separate from the standard fees applicable if the device subsequently proceeds to registration. [1][2]

PATHWAY UPTAKE

MDA has not published quantitative uptake or outcome data for IMDR to date.

FUNDING PATHWAY

General funding landscape

IMDR provides regulatory-development support but does not itself confer public funding, reimbursement or procurement status. Downstream assessment and adoption remain separate from MDA's regulatory advisory and registration processes.

MaHTAS, within the Ministry of Health, assesses health technologies including medical devices, diagnostics and digital technologies to support evidence-based adoption decisions. Importantly, MaHTAS now provides industry-facing mechanisms, including Product Introduction, Early Dialogue and a Health Technology Information Proforma for medical technologies. [4]

There is no automatic mechanism by which IMDR participation or MDA registration triggers or accelerates MaHTAS assessment or subsequent public funding/adoption decisions. Regulatory and market-access planning therefore remain separate, although MaHTAS provides channels for early industry engagement. [1][4]

Diagnostics-specific funding considerations

IVDs are expressly within the scope of IMDR through the Act 737 medical-device definition. On the funding side, diagnostics are also within the scope of MaHTAS health technology assessment and industry-facing submission mechanisms. However, IMDR participation does not itself provide a dedicated or accelerated funding pathway for innovative diagnostics. [2][4]

SOURCES

[1] Medical Device Authority (MDA). Implementation of the Innovative Medical Device Review Pathway. https://portal.mda.gov.my/index.php/announcement/1771-implementation-of-the-innovative-medical-device-review-pathway-by-medical-device-authority-ministry-of-health-malaysia

[2] Medical Device Authority (MDA). Step-by-Step Process for Innovative Medical Device Review (IMDR) Application. https://portal.mda.gov.my/index.php/industry/medical-device-one-stop-centre/innovative-medical-device-review-2

[3] Medical Device Authority (MDA). Appendix 2: Innovative Medical Device Designation Criteria. https://portal.mda.gov.my/index.php/profesional/innovative-medical-device-review?catid=170&id=1769:appendix-2-innovative-medical-device-designation-criteria&view=article

[4] Malaysian Health Technology Assessment Section (MaHTAS), Ministry of Health Malaysia. Services. https://mymahtas.moh.gov.my/index.php/our-services

Singapore

REGULATORY PATHWAY

Priority Review Scheme (PRS)

BACKGROUND

- **Regulator**: Health Sciences Authority (HSA).
- **Applies to**: Class B, C and D medical devices, including eligible IVDs, submitted through the Full Evaluation Route. Class D devices with a registrable drug in a secondary role are excluded.
- **Purpose**: Provides faster registration and market entry for medical devices undergoing Full Evaluation. [1][2]

WHAT DOES THE PATHWAY DO?

PRS is not a separate approval route and does not change the applicable registration requirements. Eligible applications remain under the Full Evaluation Route but receive a 35% shorter target turnaround time compared with standard Full Evaluation. [1][3]

Current target turnaround times are:

- Class B: 104 working days, compared with 160 days for standard Full Evaluation;
- Class C: 143 working days, compared with 220 days;
- Class D: 202 working days, compared with 310 days. [3]

ELIGIBILITY CRITERIA

HSA provides two PRS routes: [1]

Route 1: the device must meet both criteria:

1. It falls within one of the following healthcare focus areas: oncology; diabetes; ophthalmic diseases; cardiovascular diseases; infectious diseases; or skin diseases.
2. It is designed and validated to address an unmet clinical need, meaning either:
   i. there is no existing alternative treatment or means of diagnosis; or
   ii. it represents a breakthrough technology providing a clinically meaningful advantage over existing legally marketed technology.

Route 2: applies to medical devices submitted through Full Evaluation that do not meet the Route 1 criteria. [1]

Route 1 contains the innovation-/unmet-need-related eligibility criteria, while Route 2 is a broader priority-review option for Full Evaluation applications that do not meet the Route 1 criteria.

PROCESS

1. The applicant opts into PRS when submitting the product registration application through HSA's SHARE system.
2. The applicant selects the applicable PRS route and submits the documentation required for Full Evaluation according to device risk class.
3. HSA assesses whether the device meets the qualification criteria for the selected PRS route and may request additional information through an Input Request.
4. The application is evaluated under the applicable PRS turnaround time. [1][3]

REGISTRATION FEE

A SGD 560 application fee applies, together with the applicable PRS evaluation fee. [3]

PATHWAY UPTAKE

HSA does not appear to publish cumulative statistics on applications or registrations completed through PRS.

DEVELOPMENTS

HSA is transitioning towards a more integrated health regulatory model, bringing together regulation across health products, healthcare services and other regulatory domains. HSA has indicated that, for selected high-priority technologies, this could support more coordinated engagement from clinical development and regulatory review through HTA, adoption and access to international markets. Implementation is ongoing, and APACMed will monitor how this develops in practice.

FUNDING PATHWAY

General funding landscape

HSA Priority Review does not itself confer public funding, subsidy or accelerated HTA assessment. Medical technologies are assessed separately by the Agency for Care Effectiveness (ACE), with the Medical Technology Advisory Committee (MTAC) making recommendations to MOH on public subsidy. [4][5]

For most medical technologies, subsidy evaluation topics are selected through an annual call for applications from public healthcare institutions. However, industry now has some direct engagement routes that should be recognised:

- companies may notify ACE of pipeline medical technologies through Horizon Scanning, including devices, diagnostics and digital health technologies, before HSA registration. This provides early visibility for planning and potential adoption but has no immediate funding implications; and
- for specified implant categories, ACE's Model Update Process (MUP) allows companies to directly request evaluation for inclusion on the Implant Subsidy List. [5]

PRS does not automatically trigger or accelerate ACE/MTAC assessment or public funding. Singapore has mechanisms for earlier industry engagement and company-led subsidy applications for certain implant categories, but these operate separately from HSA Priority Review. [1][5]

Diagnostics-specific funding considerations

Diagnostics are explicitly within ACE's medical technology assessment remit.

For innovative diagnostics, companies may notify ACE of pipeline diagnostic technologies through Horizon Scanning before HSA registration, potentially supporting earlier visibility and planning within the public healthcare system. However, ACE expressly states that Horizon Scanning itself has no immediate funding implications, and PRS designation does not provide an accelerated subsidy pathway.

Diagnostic technologies selected for subsidy assessment are evaluated on factors including clinical need, effectiveness and safety, cost-effectiveness, budget impact and organisational feasibility. [4][5]

SOURCES

[1] Health Sciences Authority (HSA). Priority Review Scheme. https://www.hsa.gov.sg/medical-devices/registration-of-medical-devices/register-your-device/priority-review-scheme/

[2] Health Sciences Authority (HSA). GN-15 Guidance on Medical Device Product Registration, March 2026. https://www.hsa.gov.sg/docs/default-source/hprg-mdb/guidance-documents-for-medical-devices/gn-15-r13-guidance-on-medical-device-product-registration-%282026-mar%29-pub.pdf

[3] Health Sciences Authority (HSA). Fees and turnaround time for medical devices. https://www.hsa.gov.sg/medical-devices/fees/

[4] Agency for Care Effectiveness (ACE). Committees we serve – Medical Technology Advisory Committee. https://www.ace-hta.gov.sg/about-us/committees-we-serve/

[5] Agency for Care Effectiveness (ACE). Methods and process – Medical Technologies, Horizon Scanning and Model Update Process. https://www.ace-hta.gov.sg/resources/process-methods/

South Korea

REGULATORY PATHWAY

Innovative Medical Device Designation

BACKGROUND

- **Regulator**: Ministry of Food and Drug Safety (MFDS), with consultation with the Ministry of Health and Welfare (MOHW).
- **Introduced**: The statutory Innovative Medical Device framework took effect in 2020 under the Medical Device Industry Promotion and Innovative Medical Device Support Act.
- **Applies to**: Medical devices falling within designated innovative medical device groups, including eligible IVDs. Korea's IVD Act defines IVDs as medical devices under the Medical Devices Act.
- **Purpose**: Supports development and earlier review of medical devices with technological, clinical or public-health innovation. [1][2]

WHAT DOES THE PATHWAY DO?

Innovative Medical Device designation is not itself a marketing authorisation. Designated devices may benefit from regulatory measures including:

- staged review of development and submission materials;
- priority review ahead of non-designated devices; and
- where existing standards are absent or unsuitable, consideration of product-specific standards proposed by the applicant. [1]

Staged review may cover product design and development, safety and performance, clinical investigation planning, and technical and clinical documentation before the final marketing-authorisation application. [1]

ELIGIBILITY CRITERIA

The device must fall within an Innovative Medical Device Group. Korea currently recognises four groups: [3]

- **Advanced Technology Group**: technologies with high technological intensity and rapid innovation.
- **Medical Innovation Group**: technologies expected to substantially improve safety or effectiveness compared with existing devices.
- **Technology Innovation Group**: areas where development of core medical-device technology is urgently needed.
- **Public Healthcare Group**: devices for rare or intractable diseases where alternatives are unavailable or domestic supply is difficult.

In deciding whether to designate a product, MFDS considers factors including technological innovation, expected improvement in safety or effectiveness, use in rare or intractable diseases, public-health value such as rapid diagnosis of infectious diseases, and other relevant factors agreed with MOHW. [1][3]

PROCESS

1. The applicant submits an Innovative Medical Device designation application to MFDS with information on development history, intended use, operating principle, performance and comparable products. [1][4]
2. MFDS reviews the application in consultation with MOHW and must decide whether to grant designation within 30 days. [1]
3. Once designated, the manufacturer may use the regulatory support mechanisms available to innovative devices, including staged and priority review. [1]
4. For eligible technologies, the applicant may instead use the Integrated Review for Innovative Medical Devices, under which innovative-device designation, HIRA assessment of benefit/non-benefit status and new/innovative health technology assessment are considered in parallel by MFDS and MOHW-related bodies. [5]

PATHWAY FEE

There is no separate fee for Innovative Medical Device designation. [4]

PATHWAY UPTAKE

MFDS publishes individual designation notices and updated designation status lists. The latest official notice identified in this review was published on 29 September 2026 as General Designation No. 140. [6]

FUNDING PATHWAY

General funding landscape

Innovative Medical Device designation does not itself guarantee National Health Insurance (NHI) reimbursement, a premium price or a specific reimbursement level.

However, Korea differs from most markets in this landscape because it has a formal Integrated Review mechanism intended to coordinate regulatory and downstream access processes. For eligible technologies, the review can consider Innovative Medical Device designation, HIRA determination of reimbursed/non-reimbursed status and innovative health technology assessment in parallel, rather than requiring these steps to occur entirely sequentially. [5]

Following successful assessment and authorisation, certain innovative technologies may enter clinical use while additional evidence is generated, including through temporary non-reimbursed or selective-benefit arrangements, with subsequent reassessment. [8][9] This makes Korea one of the clearest examples in the landscape where innovation policy extends beyond regulatory review into earlier clinical access, although designation still does not guarantee premium reimbursement.

Separately, from January 2026, Korea introduced an immediate market-entry route for certain new-technology medical devices that satisfy enhanced clinical-evaluation requirements. MFDS reports that the mechanism can reduce market-entry time from approximately 490 days to 80 days and covers around 199 product categories, including digital medical devices, IVD reagents and medical robots. This mechanism should be distinguished from Innovative Medical Device designation itself. [7]

Diagnostics-specific funding considerations

Innovative diagnostics can benefit from the same integrated approach. For eligible IVDs and diagnostic technologies, the Integrated Review can coordinate regulatory designation with HIRA benefit/non-benefit assessment and health technology assessment, reducing the need for fully sequential regulatory and access reviews. [5][8]

The 2026 immediate market-entry mechanism is also directly relevant to diagnostics because IVD reagents are explicitly included among the eligible technology categories. Where the required enhanced clinical evaluation has been completed, eligible new technologies can enter clinical practice without undergoing the conventional separate nHTA process before use. [7]

Korea has also developed specific temporary funding arrangements for digital and AI-based technologies. MOHW established a mechanism allowing certain innovative technologies to receive temporary health-insurance codes for up to three years, with selective-benefit or non-reimbursed use depending on the technology while further evidence is generated. [9] HIRA continues to publish temporary listings for innovative AI diagnostic technologies. [8][9]

SOURCES

[[1] National Law Information Center. Medical Device Industry Promotion and Innovative Medical Device Support Act – Articles 21-22. https://www.law.go.kr/LSW/lsInfoP.do?lsiSeq=234907

[2] National Law Information Center. In Vitro Diagnostic Medical Devices Act. https://www.law.go.kr/lsInfoP.do?lsId=013481

[3] Ministry of Health and Welfare / National Law Information Center. Regulation on Designation of Innovative Medical Device Groups. https://www.law.go.kr/admRulLsInfoP.do?admRulSeq=2100000196859

[4] Ministry of Food and Drug Safety (MFDS). Guidance on expedited review designation applications – Innovative Medical Devices. https://www.mfds.go.kr/wpge/m_1097/de010410l011.do

[5] Ministry of Food and Drug Safety (MFDS). 2026 Integrated Review for Innovative Medical Device Designation. https://www.mfds.go.kr/brd/m_76/view.do?seq=16171

[6] Ministry of Food and Drug Safety (MFDS). Innovative Medical Device Designation Notice – General No. 140, 29 September 2026. https://www.mfds.go.kr/brd/m_76/view.do?seq=16374&srchFr=&srchTo=&srchWord=&srchTp=&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&page=2

[7] Ministry of Food and Drug Safety (MFDS). New-technology medical device immediate market-entry pathway, 2026. https://www.mfds.go.kr/brd/m_1256/view.do?seq=1

[8] Ministry of Health and Welfare (MOHW). Health insurance approach for digital therapeutics and AI diagnostic medical technologies.https://mohw.go.kr/board.es?act=view&bid=0027&list_no=377470&mid=a10503000000

[9] Health Insurance Review & Assessment Service (HIRA). 2026 Functions and Roles – Temporary Listing of Innovative Medical Technologies. https://www.hira.or.kr/ebooksc/2025/12/BZ202512232703963.pdf

United States

REGULATORY PATHWAY

Breakthrough Devices Program

BACKGROUND

- **Regulator**: U.S. Food and Drug Administration (FDA).
- **Established**: 2016 under the 21st Century Cures Act, replacing the earlier Expedited Access Pathway.
- **Applies to**: Medical devices, including eligible IVDs, reviewed through PMA, 510(k) or De Novo pathways.
- **Purpose**: Expedites development, assessment and review of devices providing more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. [1]

WHAT DOES THE PATHWAY DO?

Breakthrough designation is not a separate marketing-authorisation route and does not lower the applicable safety and effectiveness standards. Designated devices receive priority review and enhanced FDA interaction during development, including opportunities for sprint discussions and early agreement on evidence-generation plans.

Where appropriate, FDA may also allow greater uncertainty at the time of marketing authorisation to be addressed through post-market evidence generation. [1]

ELIGIBILITY CRITERIA

The device must: [1]

1. provide for more effective treatment or diagnosis of a life-threatening or irreversibly debilitating disease or condition; and
2. meet at least one of the following:
   i. represent a breakthrough technology;
   ii. have no approved or cleared alternatives;
   iii. offer significant advantages over existing approved or cleared alternatives; or
   iv. its availability is in the best interest of patients.

PROCESS

1. Sponsor submits a Breakthrough Device designation request through the Q-Submission process before the marketing submission.
2. FDA intends to issue a designation decision within 60 calendar days.
3. If designated, subsequent regulatory submissions receive priority review and the sponsor can access enhanced FDA interaction. [1]

PATHWAY FEE

No separate Breakthrough designation fee applies. Standard FDA user fees apply to subsequent marketing submissions, where applicable. [1][5]

PATHWAY UPTAKE

As of 30 June 2026, FDA had granted 1,320 Breakthrough Device designations, with 210 devices receiving marketing authorisation for an indication consistent with the designation. [1]

Safer Technologies Program (STeP)

STeP is a voluntary FDA programme introduced in 2021 for devices expected to significantly improve the safety of existing treatments or diagnostics for conditions less serious than those eligible for the Breakthrough Devices Program. [2]

Eligible devices receive enhanced FDA interaction and expedited development and review while remaining subject to the normal PMA, 510(k) or De Novo standards. Sponsors apply through the Q-Submission process, with an intended 60-day inclusion decision. [2]

FDA reported 10 devices entering STeP and 4 receiving marketing authorisation in 2025. [6]

Total Product Life Cycle Advisory Program (TAP)

TAP is an FDA pilot launched in 2023 for eligible Breakthrough-designated and STeP devices. It supplements the regulatory pathway with early engagement on the broader route to patient access. [3]

A dedicated TAP advisor supports interaction with FDA and facilitates engagement with payers, providers, professional societies and patient groups, helping developers anticipate evidence needs relevant to regulatory approval, reimbursement and adoption. [3]

As of 1 July 2026, 133 devices were enrolled in TAP, which now accepts eligible devices across all CDRH Offices of Health Technologies. [3][4]

FUNDING PATHWAY

General funding landscape

Breakthrough designation, STeP participation and TAP enrolment do not themselves guarantee payer coverage or reimbursement.

TAP nevertheless provides a mechanism for earlier payer engagement during development, allowing manufacturers to consider coverage and evidence requirements alongside regulatory planning. [3]

In August 2026, the Centers for Medicare & Medicaid Services (CMS) proposed the Regulatory Alignment for Predictable and Immediate Device (RAPID) Coverage Pathway. RAPID is intended to align FDA and Medicare evidence requirements during development and facilitate earlier national Medicare coverage for certain eligible Breakthrough Devices. The public comment period closed on 13 October 2026, and the pathway is not yet operational pending publication of the final notice. [4]

Diagnostics-specific funding considerations

IVDs can qualify for FDA Breakthrough designation and benefit from regulatory acceleration. [1]

However, under the current RAPID proposal, IVDs, including diagnostic laboratory tests, are excluded. CMS states that coverage for most Breakthrough-designated IVDs should continue through existing Medicare Administrative Contractor pathways. [4]

SOURCES

[1] U.S. Food and Drug Administration (FDA). Breakthrough Devices Program. https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program?utm

[2] U.S. Food and Drug Administration (FDA). Safer Technologies Program (STeP) for Medical Devices. https://www.fda.gov/medical-devices/how-study-and-market-your-device/safer-technologies-program-step-medical-devices

[3] U.S. Food and Drug Administration (FDA). Total Product Life Cycle Advisory Program (TAP). https://www.fda.gov/medical-devices/how-study-and-market-your-device/total-product-life-cycle-advisory-program-tap

[4] Centers for Medicare & Medicaid Services (CMS). Regulatory Alignment for Predictable and Immediate Device (RAPID) Coverage Pathway – Proposed Procedural Notice. https://www.cms.gov/newsroom/fact-sheets/regulatory-alignment-predictable-immediate-device-coverage-pathway-cms-3487-nc-procedural-notice

[5] U.S. Food and Drug Administration (FDA). Medical Device User Fees. https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/medical-device-user-fees

[6] U.S. Food and Drug Administration (FDA). CDRH Annual Report 2025. https://www.fda.gov/media/190779/download

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