Trade in Pharmaceuticals and Medical Devices between the EU and Singapore - Opportunities under the EUSFTA and Beyond
Webinar

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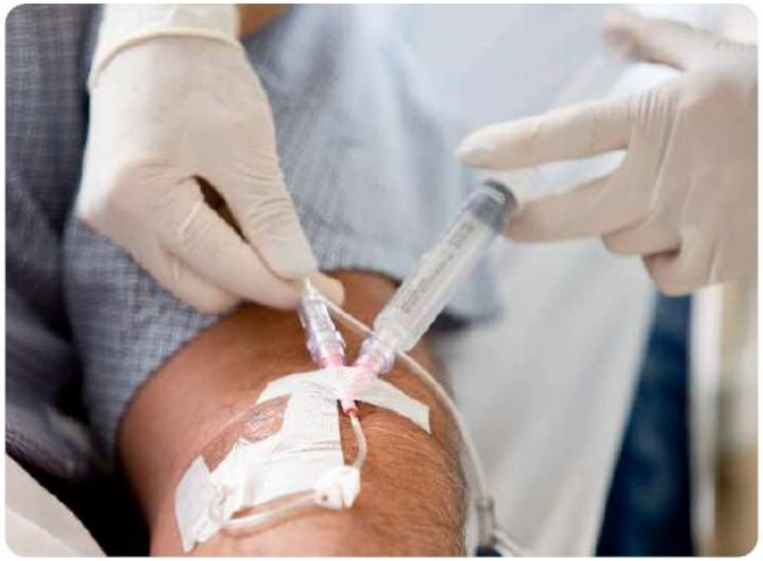
Vice President of Regulatory Affairs,
Greater Asia at BD

BD is helping reinvent healthcare, driven by our purpose of advancing the world of health™ to improve:

Discovery and Diagnosis



Medication Delivery

Interventional Treatment

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BD is an innovative med tech leader

Unmatched scale and global reach to address healthcare's most pressing challenges

45B +
devices made annually

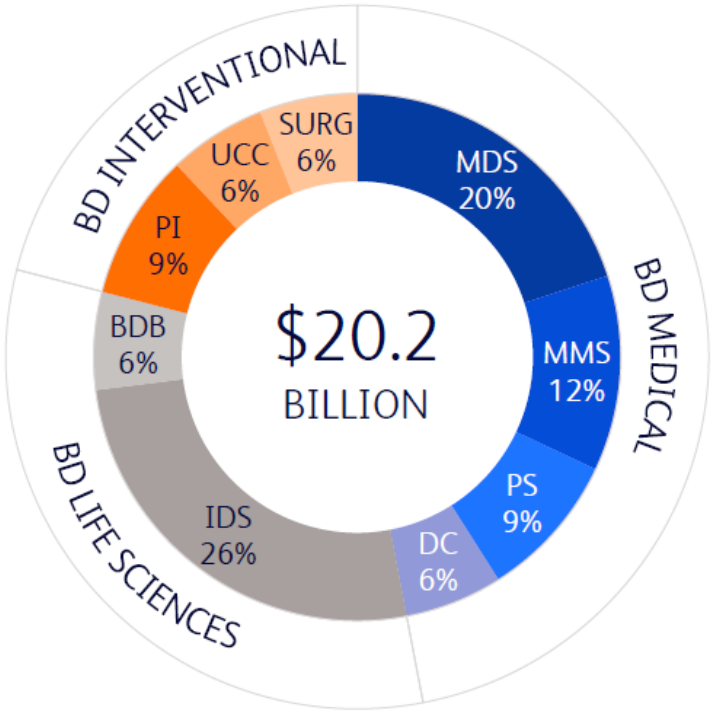
190 +
countries served

29,000 +
active patents

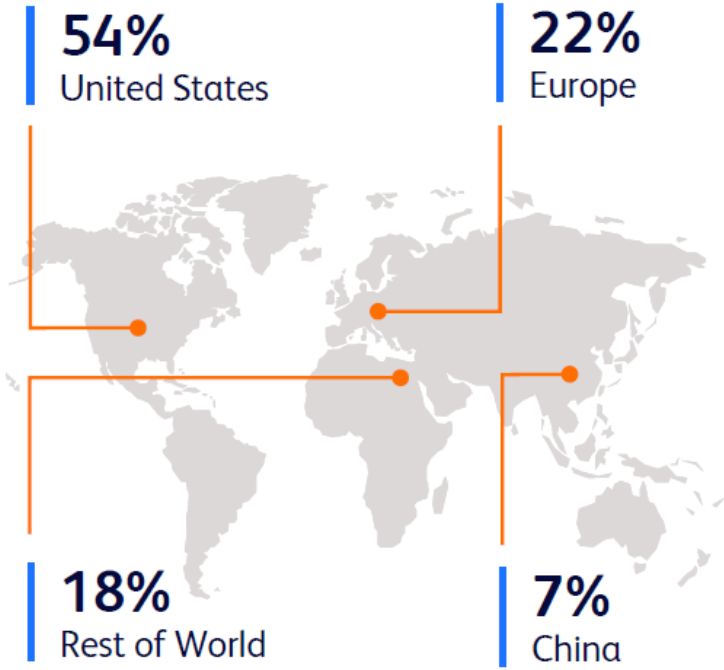
$1B +
annual R&D spending

70,000 +
BD associates

REVENUE BY SEGMENT



FY21 REVENUE BY REGION



Our vision, objective & strategy

TO BE THE VOICE OF THE INDUSTRY PARTNERING WITH REGULATORS

IMPROVE PATIENT ACCESS TO MEDICAL DEVICES

- **Advocate for more effective alternative approval pathways**
- **Promote Regulatory Convergence**
- **Build Future Ready Regulatory Workforce**

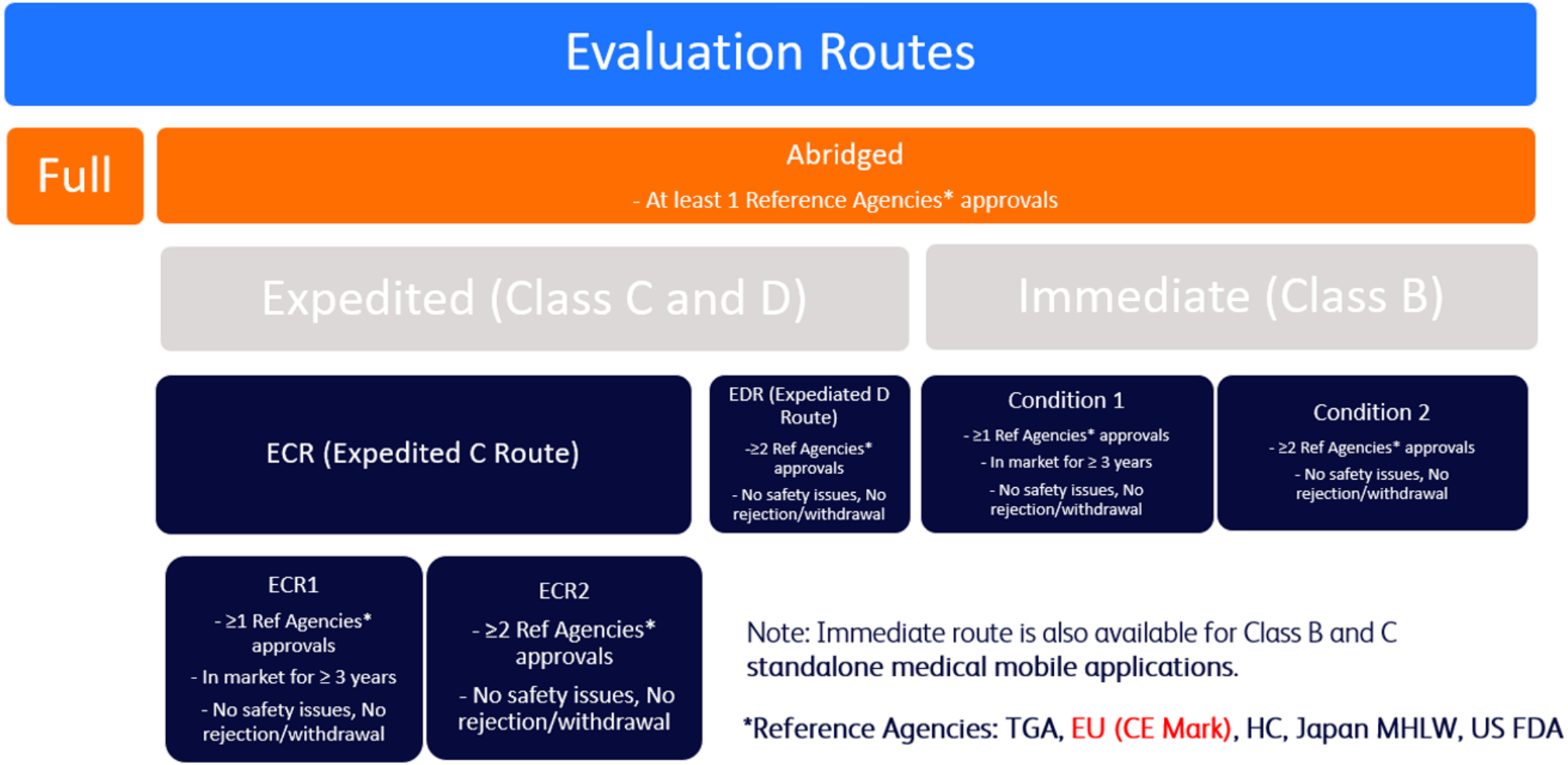
Regulatory Convergence – Current State

- CE-mark is one of reference approvals recognized by Singapore Health Sciences Authority (HSA)
  - Immediate approval for class B
  - Expedited review for class C and D
- HSA is a leading regulatory agency in the region
  - IMDRF member
  - Reference regulator for Regulatory Reliance initiative with Thailand FDA; discussions with others ongoing
- HSA published change notification guidelines related to EU MDR/IVDR

Regulatory Convergence – Opportunities

- HSA to expand the scope of *immediate approval* for class C & D devices with MDR/IVDR CE-mark
- HSA to recognize EU member state derogation particularly for emergency use approval
- Regulatory reliance expansion to EU
- Health Technology Assessment harmonization

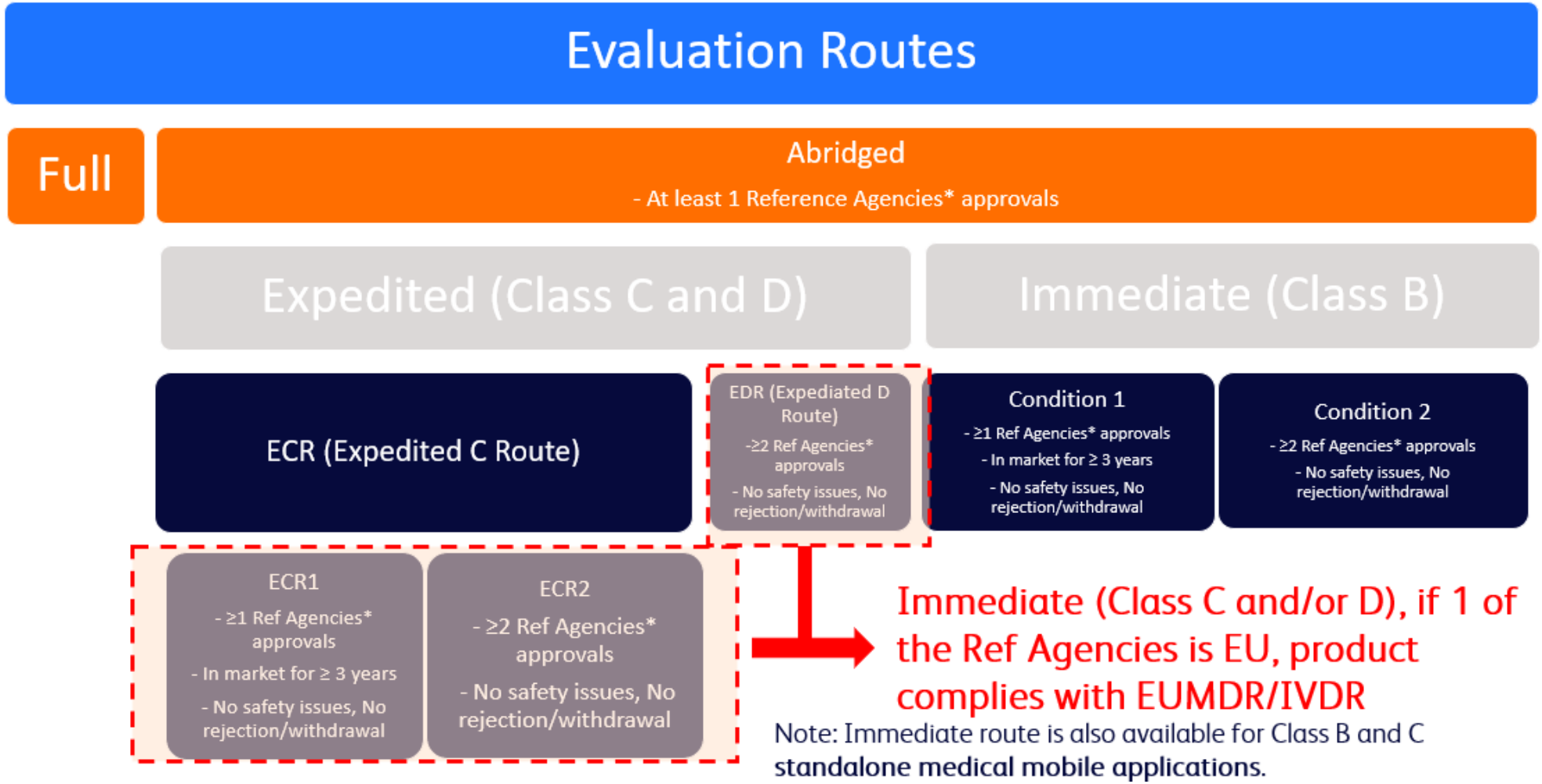
Current HSA Evaluation Routes



Note: Immediate route is also available for Class B and C standalone medical mobile applications.

*Reference Agencies: TGA, EU (CE Mark), HC, Japan MHLW, US FDA

Proposed HSA Evaluation Routes



Appendix

About APACMed

01 WHO

APACMed represents manufacturers and suppliers of medical equipment, devices and in-vitro diagnostics, industry associations and other key stakeholders in the medical technology industry in Asia Pacific.

02 WHAT

We aim to improve the standards of care for patients through innovative collaborations among stakeholders to jointly shape the future of healthcare in the Asia Pacific region.

03 WHY

We provide a unifying voice for the medical devices, in-vitro diagnostics and digital health industry in Asia Pacific, and strive to promote innovation and impact policy that advances healthcare access for patients.

04 HOW

Our functional committees include:

- Regulatory Affairs
- Government Affairs & Market Access
- Legal, Ethics & Compliance
- Digital Health
- Start-ups & SMEs

APACMed Strategic Pillars



ACCESS

We strive to improve access to high quality healthcare for patients through close collaborations with our members and the wider ecosystem stakeholders to help shape policies that truly impact the lives of patients.

INNOVATION

We support innovative new technologies and start-ups that improve quality of care and healthcare outcomes.

HARMONISATION

We drive common approaches aligned with international best practises and standards to promote speed to access in a safe, secure and ethical manner through the adherence of the Code of Conduct.

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Current HSA Medical Device Evaluation Routes: Fees and TAT

Fees for product registration

Fees	Class B	Class C	Class D	Class D with a registrable drug
Application fee	$515	$515	$515	$515
Immediate route fee	$925	$3,090	N.A.	N.A.
Expedited route fee	N.A.	$3,090	$5,560	N.A.
Abridged route fee	$1,850	$3,605	$5,870	$10,200
Full route fee	$3,605	$5,870	$11,600	$75,200
Full route (Priority Review Scheme Route 1)	$4,100	$6,600	$13,200	N.A.
Full route (Priority Review Scheme Route 2)	$5,300	$8,600	$17,100	N.A.
Annual retention fee for SMDR listing	$36	$62	$124	$124

Turnaround time (in working days)

Registration route	Class B	Class C	Class D	Class D with a registrable drug
Immediate route	Immediate upon submission	Immediate upon submission	N.A.	N.A.
Expedited route	N.A.	120	180	N.A.
Abridged route	100	160	220	220
Full route	160	220	310	310
Full route (Priority Review Scheme Route 1)	120	165	235	N.A.
Full route (Priority Review Scheme Route 2)	120	165	235	N.A.

Source: https://www.hsa.gov.sg/medical-devices/fees