



# Entering Japan Knacks and Pitfalls

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# Japan in a snapshot

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## Baseline Positive

- ▶ No. 3 device market
- ▶ No.3 Healthcare spender
- ▶ HE is \$332B and rising
- ▶ HE is 10.3% of GDP
- ▶ 40% of US population
- ▶ 27% is >65 years of age
- ▶ Universal Healthcare System
- ▶ Fair Valued Reimbursement
- ▶ Fast Adapter on New Technology
- ▶ Most westernized in Asia

## Risks & Opportunities

- ▶ Health Expenditure is twice of income
- ▶ 30% copay
- ▶ 22% tobacco smoker
- ▶ Obesity is only 3.5%
- ▶ Deaths are Cancer, Heart and Brain
- ▶ 10 M Hypertensive patients
- ▶ Bed Density is 13.7/1000
- ▶ Regulatory Complexity
- ▶ Language
- ▶ Risk Adverse Society



# Myth on Japan

- ▶ Regulatory hurdle is a trade barrier
- ▶ Reimbursement is twice of USA
- ▶ US companies cannot own the product approval
- ▶ Japan business practice is totally different from USA
- ▶ Better to start with a distributor and then go direct
- ▶ Physicians prefer using domestic devices
- ▶ Patients prefer to be hospitalized longer



# Common Approach: Pay later, much much more

1. Find a distributor
2. Give a copy of the regulatory dossier and have the distributor obtain the approval & reimbursement
3. Send same product as USA or EU
4. Visit once a year and complain that the numbers are not acceptable, with minimal support from USA
5. Look for another distributor or consider going direct
6. Tough negotiation with approval holder on transfer
7. Go through couple GM to find the right guy or gal



# When to think about Japan: Hindsight is 20/20

Situation	Risk	Extra investment or lost of opportunities	Time to market lag
<ul style="list-style-type: none"> <li>• After successful EU &amp; US launch</li> <li>• Meanwhile not preparing for Japan</li> </ul>	<ul style="list-style-type: none"> <li>• Original staff are gone</li> <li>• Test reports are not sufficient</li> <li>• Studies are not GCP compliant</li> <li>• Product generation gap</li> <li>• Can not build legacy product</li> <li>• Unfavorable Reimbursement</li> </ul>	\$\$\$	Min 3 to 5 Years
<ul style="list-style-type: none"> <li>• After successful EU &amp; US launch</li> <li>• Meanwhile prepared for Japan</li> </ul>	<ul style="list-style-type: none"> <li>• Original staff are gone</li> <li>• Test reports are sufficient</li> <li>• Key Studies are GCP compliant</li> <li>• Product generation gap</li> <li>• Need to build legacy product</li> <li>• Acceptable Reimbursement</li> </ul>	\$\$	Min 1.5 to 3 Years
<ul style="list-style-type: none"> <li>• Japan as Priority No 1 international market</li> </ul>	<ul style="list-style-type: none"> <li>• Original staff are still in-house</li> <li>• Test reports are sufficient</li> <li>• Key Studies are GCP compliant</li> <li>• Acceptable Reimbursement</li> </ul>	\$	Min 6 to 18 Months

# Evaluate: Direct, Distributor or Hybrid

- ▶ Does your product fill in an unmet clinical need?
- ▶ Will your product be appropriately valued?
- ▶ Is the growth opportunity large?
- ▶ Is the projected ROI relatively large?
- ▶ Are you direct in USA?
- ▶ Is your product not capital intensive
- ▶ **Are you willing to invest as much as the USA?**

# Hybrid distribution model: Take the best of both worlds

Functions	Distributor	Hybrid	Direct
Sales	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Marketing	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Pre market regulatory	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Post market regulatory	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Reimbursement	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Human Resources	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Finance/Administration	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

# Step 1: Engage w/ Physician customers

- ▶ No user then No business
- ▶ Are they willing to advocate the technology?
- ▶ Request petition as “Unmet Clinical Need Device”
  - ▶ So called “Device Lag”
- ▶ Strengthen advocacy with actual clinical use
  - ▶ Physician own risk use with no insurance coverage
  - ▶ Advance Therapy program with partial coverage
  - ▶ Patient Compassionate Use program with partial coverage





# Unmet Clinical Need Device

- ▶ Physician and/or patient society petition to MHLW
- ▶ Not approved in Japan
  - ▶ FDA and/or CE marked Device
  - ▶ Superb clinical outcome based on published data
  - ▶ Good clinical outcome with AT program
- ▶ Device Lag Committee evaluates technology
  - ▶ Clinical necessity
  - ▶ Severity of the applicable disease
- ▶ Clear regulatory/reimbursement pathway with expedited review by PMDA, if selected

# Past Selected Devices

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- ▶ Optune by Novocure
- ▶ Lifestest by Zoll
- ▶ Bactiseal by JNJ Codman
- ▶ Alair by BSX
- ▶ Aorfix by Lombard Med
- ▶ Freezor Max by MDT
- ▶ Nykanen RF wire by Baylis Med
- ▶ Activa RC by MDT
- ▶ Pipeline Embolization by MDT
- ▶ Surpass NeuroEndo Graft by Stryker
- ▶ VNS system by Cyberonics
- ▶ Precise Stent by Cordis
- ▶ MitraClip by Abbott
- ▶ NRG RF transeptal Needle by Baylis Med
- ▶ Meniett by MDT
- ▶ Trigen Sureshot by S&N
- ▶ PillCam by MDT
- ▶ Advisa MRI by MDT
- ▶ Aero stent by Merit Med
- ▶ Silmet by Novatech
- ▶ Merci retriever by Stryker
- ▶ Wingspan by Stryker
- ▶ Reveal DX by MDT
- ▶ Cyberknife by Accuray

# Special Programs: Partial coverage by Social Insurance

## Advance Therapy Program

- ▶ Hospital apply to MHLW
- ▶ Committee evaluates
- ▶ If selected, standard fees are paid by social insurance system
- ▶ Annual Reporting
- ▶ Data can be supplemented toward regulatory approval
- ▶ Caution: Uncovered cost will be basis for reimbursement

## Patient Compassionate Use

- ▶ New program from April 2016
- ▶ Patient request Designated Hospital
- ▶ Hospital apply to MHLW
- ▶ Committee evaluates within 6wks
- ▶ If selected, standard fees are paid by social insurance system

# Step 2: Think Reimbursement

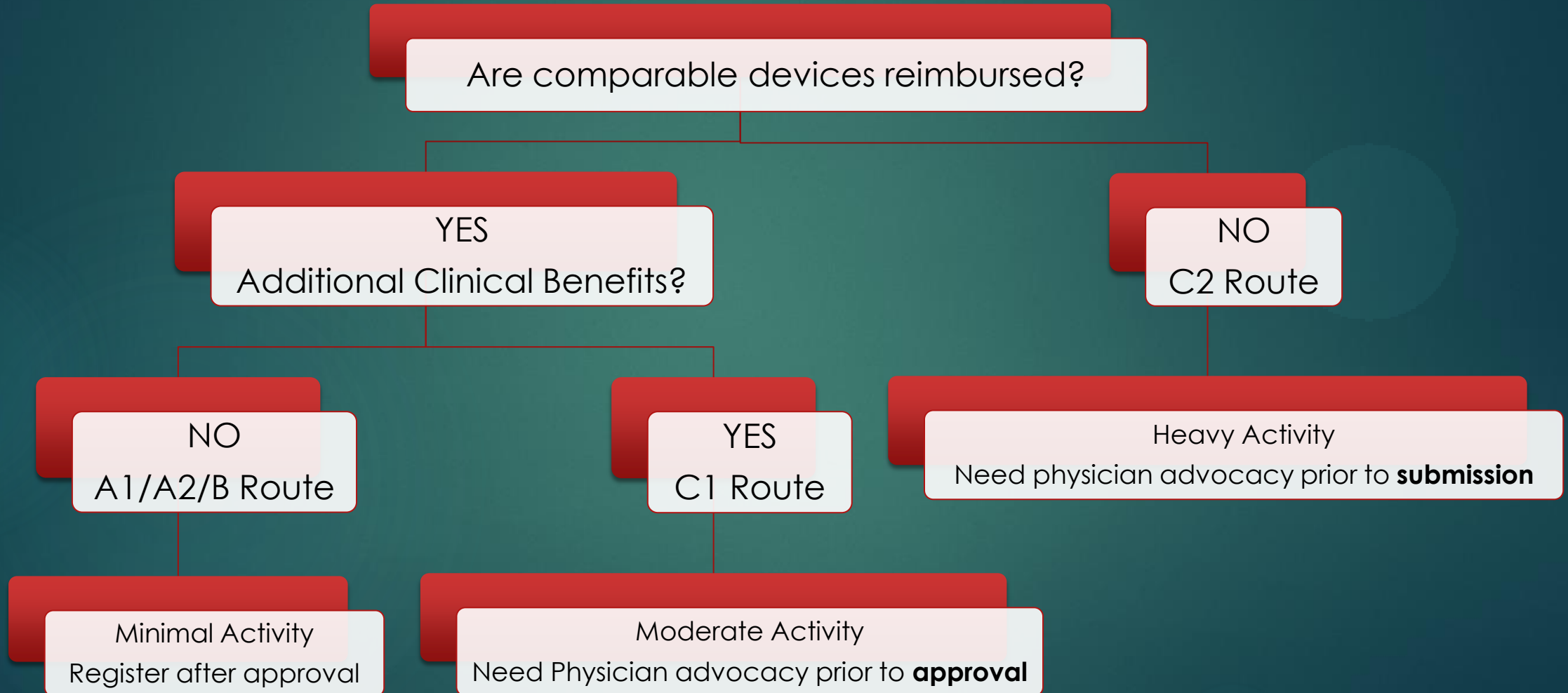
- ▶ No reimbursement then No business
- ▶ What are the present level of reimbursement
  - ▶ Identify the gap
- ▶ Is the medical practices similar?
  - ▶ Obtain hospital data and compare
- ▶ Do you have a cost effectiveness study?
- ▶ What do you need prepare while in regulatory review
  - ▶ Utilize clinical use data in Japan, compare to historical data of those sites?



# Device Reimbursement

Category	Definitions	Examples
A1	Inclusive to any Treatment Code	sutures, disposable syringes, gauges
A2	Medical Device with Specific Treatment Code (included)	X rays, CT-scans, endoscopes
B	Individually Reimbursable Medical Materials based on defined functional categories (separate from Treatment Code)	dialyzers, pacemakers, artificial joints, bare metal stents,
F	Not applicable	Home use thermometer
C1	Treatment Code exist but device improved and/or modified from present A2 or B	DES
C2	Totally new device with no appropriate Treatment Code	implantable artificial hearts, stent grafts

# Decision Tree on Reimbursement



# Reimbursement: Drives Regulatory Options

		Regulatory Categories					
		Class 1	Class 2		Class 3 & 4	ALL	
		Registration	Guidance Certification	No Guidance	Similar	Modified	New
Reimbursement Path	F	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
	A1	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>			
	A2	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
	B		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
	C1					<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
	C2						<input checked="" type="checkbox"/>

# Pitfalls:

## 25 years of Lesson Learned

- ▶ Go with the first distributor knocking the door
- ▶ Agree on pricing not knowing reimbursement price
- ▶ Clinical use at only one hospital with physician license importation
- ▶ Believe the distributor about regulations
- ▶ FDA approval is paramount
- ▶ Good clinical outcome means GCP complied study
- ▶ Published clinical data are all GCP complied
- ▶ PMDA will not read every single attachment
- ▶ Establish local entity early and hope for the best
- ▶ Opportunity will come again
- ▶ Japan will listen to the States,
- ▶ Bureaucrats will bow to politicians without any retaliations
- ▶ Reporting to government is to inform and not full closure
- ▶ Suspension of business by MHLW is a temporary matter
- ▶ Hiring a GM then all is done



# Are you ready for Japan?

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Government	<ul style="list-style-type: none"><li>• Low quality submission will take a long time to gain approval as it represent the quality of the company and its products/services</li><li>• Low quality post marketing activity will shut you down as again, it represent the quality of the company and its processes</li></ul>
Supply Chain	<ul style="list-style-type: none"><li>• # of reject will triple or more</li><li>• All rejected products will be returned</li><li>• Request you to improve your visual inspection or packaging process</li></ul>
Healthcare Provider	<ul style="list-style-type: none"><li>• # of Complaints will triple ore more</li><li>• Most Products will be returned</li><li>• Welcomes and invites you to learn more</li><li>• Wants to know why it happened and how you will fix</li><li>• Will report to the government if safety issues</li></ul>
Patients	<ul style="list-style-type: none"><li>• Silent customers who rely on the above providers to do their very best to prevent incidents on them</li></ul>

# Key takeaways

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- ▶ Think about Japan NOW
  - ▶ Meet your customers
  - ▶ Think reimbursement
  - ▶ Prepare for Japan's expectations
- ▶ Once decided to enter Japan
  - ▶ Have your advocates petition for your technology
  - ▶ Reimbursement drives regulatory
  - ▶ Win the selection as unmet clinical need device
  - ▶ Think direct first and distributor last

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**Satisfy your most demanding customer  
then the rest would love you**

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# Back up