10 THINGS TO DO AND NOT DO TO BE SUCCESSFUL IN ASIA'S MEDTECH MARKETS

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INTRODUCTION TO PBM

PACIFIC BRIDGE MEDICAL (PBM) is a leading medical consulting firm dedicated to assisting medical companies in Asia. Our consultants have helped over 500 medical companies with business development, sales, sourcing, and market research in Asia since our founding in 1988. ***We are very knowledgeable about the Asian healthcare market and have a great team on the ground in Asia with various medical specialties.***

1) WHICH ASIAN MARKETS SHOULD YOU GO TO: WHAT TO DO AND NOT DO

Overview of Asia

Which Asian Markets Should You Go to First/Last?

- Is it a high technology device?
- Is the device very expensive?
- Can the device be easily reverse engineered?
- Which countries in Asia have the best healthcare systems?
- Which strategies should I use?
  - Distributor network, joint venture, subsidiary

Which Asian Markets Should You Go to First/Last?

Asia Economic Statistics (2015)

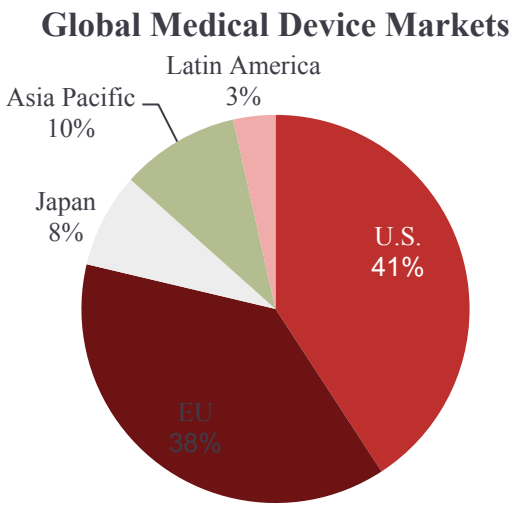
	Per capita GDP	Per capita income growth	GDP (PPP)	Real GDP (PPP) Growth Rate
China	$7,380	9%	$18 trillion	7.4%
Hong Kong	$43,320	4.6%	$381.3 billion	2.5%
India	$1,570	2.6%	$7.4 trillion	7.4%
Indonesia	$3,630	2%	$2.7 trillion	5.3%
Japan	$42,000	-3%	$4.73 trillion	0%
South Korea	$27,000	4.7%	$1.7 trillion	3.3%
Malaysia	$10,750	2.2%	$769 billion	4.7%
Philippines	$3,470	5.2%	$693 billion	6.1%
Singapore	$55,150	2%	$454 billion	2.9%
Taiwan	$22,083	2%	$1.1 trillion	1.5%
Thailand	$5,370	2%	$673.0 billion	1.8%
Vietnam	$1,900	8%	$512 billion	5.3%
United States	$55,200	1.8%	$17.4 trillion	2.1%
European Union	$34,300	1.5%	$18.5 trillion	1.3%

Source: World Bank and other PBM sources

Size of Medical Device Markets

Global Medical Device Markets	
Region	Market Size (US$)
US	$140 billion
EU	$130 billion
Japan	$27 billion
Asia Pacific	$34 billion
Latin America	$12 billion

Asian Medical Device Markets	
Country	Market Size (US$)
China	$22 billion
Hong Kong	$850 million
India	$3.5 billion
Indonesia	$780 million
Korea	$3.9 billion
Malaysia	$1 billion
Philippines	$300 million
Singapore	$530 million
Taiwan	$2.5 billion
Thailand	$850 million
Vietnam	$630 million



2) MARKET RESEARCH: WHAT TO DO AND NOT DO

China: Key Market Research Issues

- Research has to be well thought out
- Secondary research – not normally that accurate; government statistics not reliable or non-existent
- Primary research is the best way to go
- Researcher should have worked for Western medical companies before
- Big research companies send out 20 year olds, may not have experience to get answers you need; maybe a few in-person quality interviews will do
- Determine if there is a market before product registration; many companies do not do this

Japan: Key Market Research Issues

- Has the opportunity been confirmed by good primary research (size of market and growth rate)?
- Have Japanese market research executives talked to KOL's about your product; not just Western executives from a foreign manufacturing company? Are the Japanese KOLs double agents?
- Will the reimbursement justify the investment? Best to know upfront to make sure you can have a profitable business

3) DISTRIBUTOR SEARCH: WHAT TO DO AND NOT DO

China Distributor Search

- Lots of small players; some good regional players
- Are the small distributor companies going to survive? Do they have cash flow problems?
- Conflict of interest – 3 sales teams in same product area
- Do bigger national Chinese distributors really have branch offices? Call and visit to make sure
- Do distributors really do what they say they are doing? Always double check! Don't be "blind" to the market!

China Distributor Search

- US medtech company (about $200 million in sales) sells product to Chinese importer
- Chinese importer buys about $3 million per year from US medtech company
- Re-register similar products
- Undercover find out copycat manufacturer owns Chinese importer
- Copying NOT illegal in China if no patent, exact same copy

Japan Distributor Search

- Takes time to find the right distributor/partner
- Moving registrations can be difficult and costly
- DMAH
- Continual follow-up a MUST to keep the relationship and business moving forward
- Just because there is a market in the West does not mean there is a market in Japan

4) MEDICAL DEVICE REGISTRATION: WHAT TO DO AND NOT DO

Japan: New Regulatory Issues

- November 24, 2014 new regulations
- The Pharmaceutical Affairs Law (PAL) became the Pharmaceutical and Medical Device Act (PMD Act)
- More products approved by third party certification
- QMS inspection has been simplified – conducted according to product groups, not individual products
- FMA simplified – changed from license and accreditation to just registration; key is GM of main manufacturing facility
- Cellular and tissue products – less upfront clinical trials
- Software stand alone now

Chinese Medical Device New Regulations (October 1, 2014)

- 2000 Regulations only 6 chapters and 48 articles. Now 2014 Regulations 8 chapters and 80 articles
- Class 1 – Notification, not registration, but more documentation needed than previous class 1 registration
- Class 2/3 devices – more local clinical trials needed
- Class 3 device clinical trials require CFDA protocol approval
- Registrations now good for 5 years not 4
- More information required on outside labels in Chinese
- Advertising restrictions

Chinese Medical Device Registration

- Getting a lot tougher and longer for approvals (new regulations October 2014)
- New standards released
- Testing delays (only 10 centers)
- More supplementary reviews requested by the CFDA
- Will clinical evaluation reports work?
- Class 2 and 3 medical devices need more local clinical trials; new exempt list too
- Approval in country of origin still required (can you make in EU)

Malaysia Medical Device Registration

- Old days – no device registration required
- Last summer if not on transition list, cannot keep selling
- Registration now means long wait and Malay government is short-staffed

5) CLINICAL TRIALS: WHAT TO DO AND NOT DO

Clinical Trials in China

- Pick CRO and/or sites very carefully
- Local CRO or foreign CRO – check reputation
- CTA – could be 6-18 months
- Records are often not kept well
- Post clinical trial check data

Clinical Trials in Japan

- Have you gone to PMDA clinical trial consultation session(s)?
- Which CRO has done device trials?
- Key investigator/KOL most important
- How do you determine best KOL?

6) REIMBURSEMENT: WHAT TO DO AND NOT DO

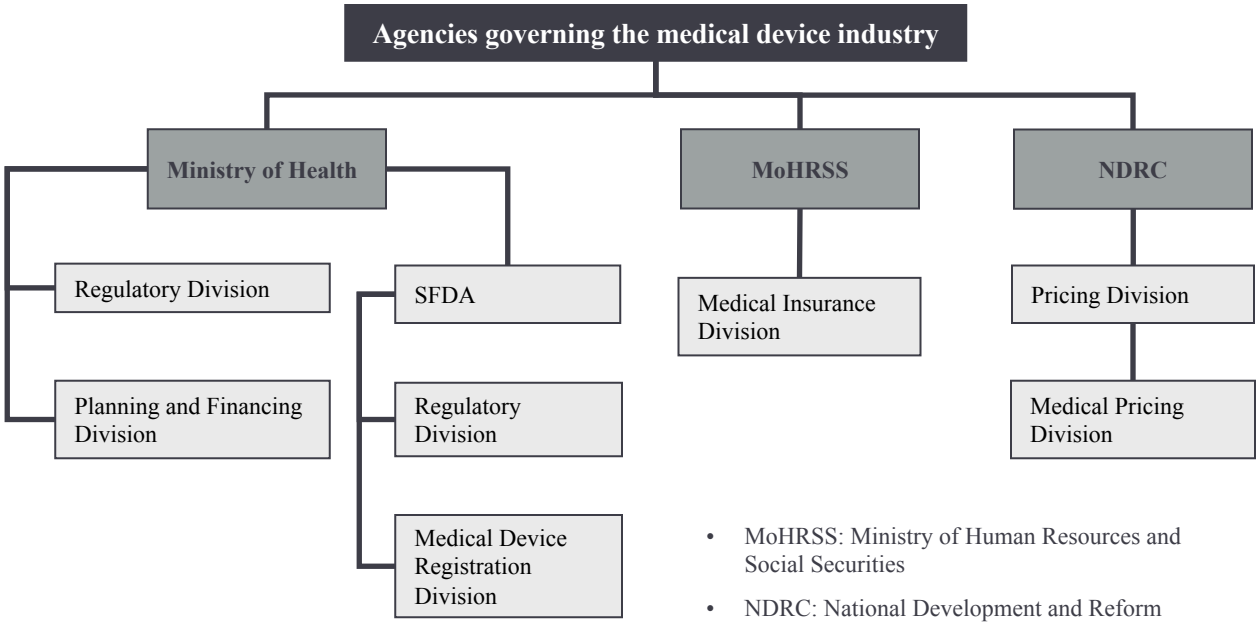
(WHICH ASIAN COUNTRIES OFFER REIMBURSEMENT)

China Pricing and Reimbursement

- Pricing
  - Oftentimes follows the national price list, but now is determined more and more by the provincial pricing bureaus (need to go province by province)
- Reimbursement
  - Mostly for procedures with domestically made products. If patient wants a foreign stent, they must pay out of pocket
  - Adjunct devices are normally not reimbursed

China Pricing and Reimbursement

Multiple government agencies are responsible for policy-making, and for monitoring the medical device industry in China

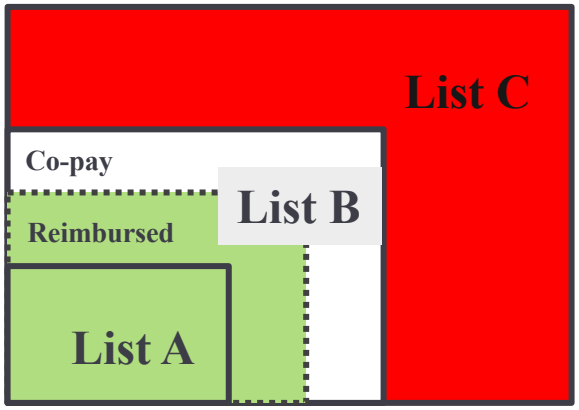


- MoHRSS: Ministry of Human Resources and Social Securities
- NDRC: National Development and Reform Commission
- SFDA: State Food and Drug Administration

* This organization structure is replicated at provincial level

China Pricing and Reimbursement

Matrix reimbursement scheme, set at provincial level



List A
- 100% reimbursed in general
- No co-pay or less than 10% co-pay

List B
- 20% - 60% Co-pay
- Sometimes for imported products, a deductible also applies

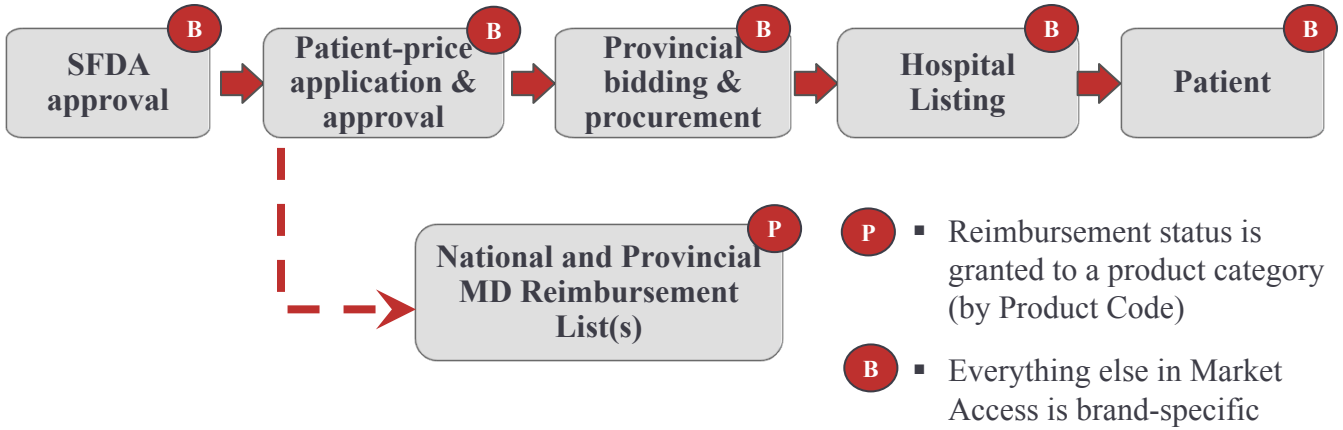
List C
- No reimbursement, 100% Self-pay

Various "Ceilings"
- Annual ceiling per patient
  - Usually, the ceiling is 4-6 times the average annual income in that province/city
- Annual ceiling per patient per diagnosis code
- Ceiling per hospital stay (per hospitalization)

Supplemental Reimbursement
- Insurance policy purchased by the employer/employee from a commercial insurance company
- Local government and commercial health insurance, designed mainly for "catastrophic diseases"
- Supplemental reimbursement helps to reduce co-pay; however, does not apply to List C in general

China Pricing and Reimbursement

The overall market access process in China for imported medical device products



- A complex, lengthy, and uncertain process
- First started in the late 90's, and has been upgraded over the years in an effort to ensure transparency, minimize corruption, and bring down the cost to the payer and to the patient
- Since late 2014, more significant changes and experimentations throughout the country have led to huge uncertainties in the near future

Japan Pricing and Reimbursement

Category	Description
A1	**(Inclusive)** Included within the technical fee. No separate reimbursement is made for the device itself. Product examples: gloves, gauze, sutures
A2	**(Designated inclusive)** Technical fee granted for use of the device or class of devices. No separate reimbursement is made for the device itself. Product examples: MRIs, CTs, and most types of capital equipment
B	**(Individual evaluation)** "Me-too" products that are similar to other products on the market. As a result, these products fit into existing technical fee and STM reimbursement categories. Product example: CoCr hip stem
C1	**(New function)** New products based on existing products/therapies.
C2	**(New function and New technology)** New products that result in a new therapy or procedure. No predicate product or treatment exists.
F	Products that do not match the reimbursement system in place or are not suitable for insurance coverage

Japan Pricing and Reimbursement

- Foreign reference pricing
- R-value
- Product not reimbursed, sales will be limited (except aesthetics)
- New technology – better mousetrap, will reimbursement increase or put in existing category where the prices may or may not meet your expectation and provide company profit
- Must be checked upfront, NOT after registration

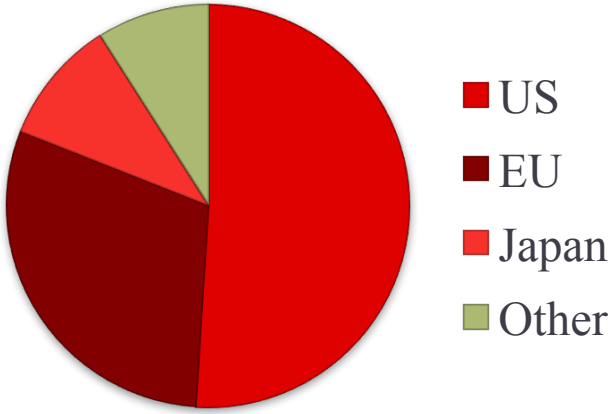
7) SOURCING IN ASIA: WHAT TO DO AND NOT DO

Reasons to Source or Manufacture in Asia

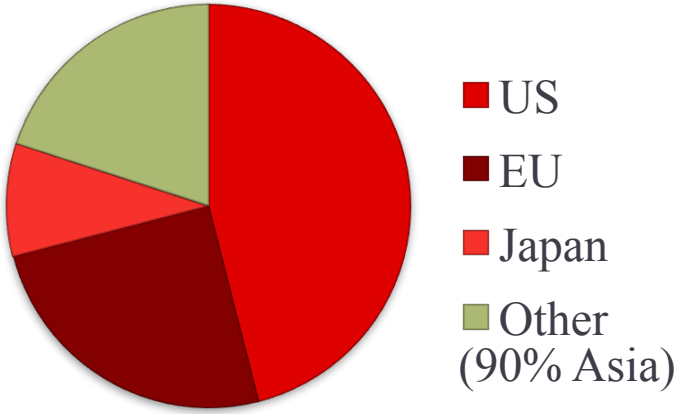
- Some labor costs and manufacturing costs are cheaper – Vietnam, India
- Quality in Asia is quickly getting better
- Able to make high volumes with established device manufacturing bases in China
- More FDA/ISO factories in Asia now
- Device market growth is fastest in Asia; get closer to customers in Asia
  - Per capita income growth and the increasing middle class demand better healthcare
  - Increased number of hospitals/specialty health centers – new hospitals, government investing a lot in healthcare coverage (i.e. Indonesia universal coverage)
  - More device reimbursement
- In some cases, it may not make sense to source or manufacture in Asia if you want to (1) sell in the US/EU or (2) reduce supply chain risks and/or freight costs, etc.
- Make a B-line of your product with less bells and whistles

Medical Device Manufacturing Moving to Asia (to reduce cost in some situations and get closer to growing Asian device markets)

2005



2015



**Sources: Frost and Sullivan, Department of Commerce, and other PBM sources*

Manufacturing and Sourcing in Asia

- China costs have skyrocketed, but quality has also improved.
- It may be cheaper for commodity devices and components to be made in Vietnam and India rather than China.
- Due diligence, close and continuous follow-up, monitoring, audits, and QA will be key.

Sourcing in Asia

Sourcing and transferring manufacturing production of a product from Mexico to China (2010)

- Client wants to reduce cost. Cost per unit in Mexico $10/unit, cost per unit in China $5/unit. Does this cost differential still exist?
- PBM identified and qualified factories in Asia. We then visited best prospects, set up a tech transfer deal and supplier agreement.
- PBM made sure manufacturing site was compliant with Chinese government regulatory requirements, CFDA, ISO, etc. Later we did a mock audit to prepare to meet FDA standards.

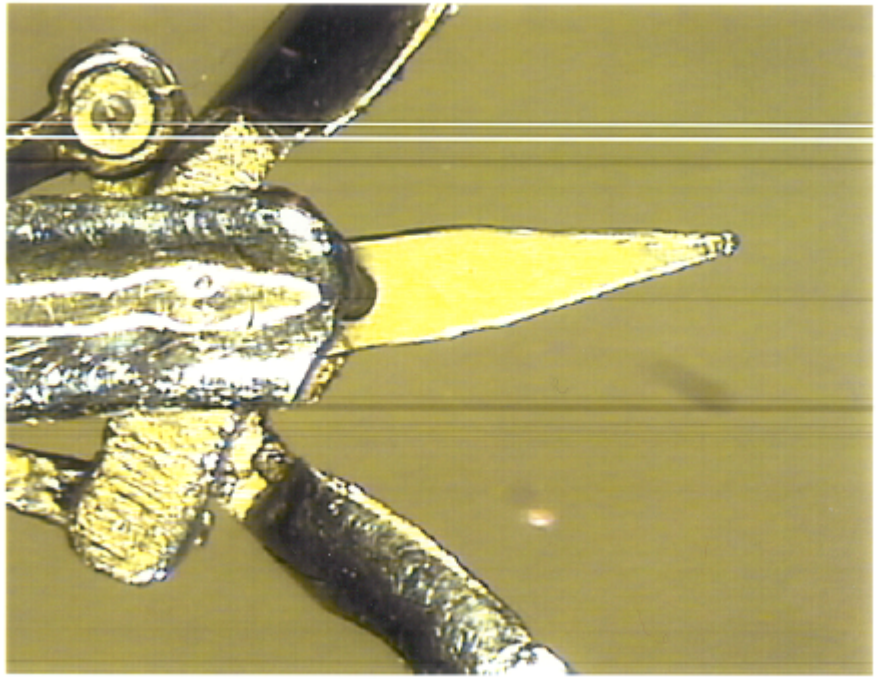
Sourcing in Asia

US Product: “Biopsy Forceps”

Sourcing in Asia

Initial Samples from China

Lot A-2 SIR# 26-11-05-119



Needle bent

- ❑ Does product meet US testing standards?
- ❑ Can China product meet coating and metal injection molding processes?

Sourcing in Asia

- Took 2 years for technology transfer
- Now China factory makes 500,000 units per year
- Total savings cost:
  - $5/unit x 500,000 units = $2.5 million
- Chinese manufacturer now making 7 other SKUs for client with cost savings of about $8 million per year
- Some Western companies now sourcing class 3 products in China

8) QUALITY CONTROL: WHAT TO DO AND NOT DO

Quality issues in China for sourcing and manufacturing

- We were asked by a device manufacturer to audit a Chinese factory supplier (2011)
- Goal: FDA approval for Chinese factory
- Initial inspection – factory quality standards not very good
- New 2014-2015 Chinese regulations show improving manufacturing and quality standards

Quality issues in China for sourcing and manufacturing

- **Initial response from Chinese factory manager**:
- "She has been working with the Chinese factory's process engineers and technical staff to come up with a batch record that contains clear and sufficient operational instruction and detailed records to be used at the time of performance. This is the highest priority. Without executable batch record, no validation can begin. The seriousness of the compliance problem at the Chinese factory cannot be overstated – no executable written procedures, including the batch instruction, or records existed at the plant. They were constantly changing process parameters without records, leading to the loss of important historical data and valuable institutional memory on manufacturing experience. We will try our best to bring them up to speed."

Quality issues in China for sourcing and manufacturing

- **PBM auditor trying to improve quality:**
- "I had a face-to-face discussion with the Chinese factory manager to find solutions for significant problems and to update him on the tasks we finished. After this talk, I can feel he is not 100% committed to address the identified issues in the best way; rather, he looks for second-best solutions or even excuses not to do this. He believes we are doing too many things of which the requirement is not appropriate for them. He even says the overseas purchaser may not establish a certain SOP or qualify an equipment as the Chinese factory is required."

Quality issues in China for sourcing and manufacturing

China Announces New Guidelines on Medical Manufacturing September 1, 2015

- The China Food and Drug Administration (CFDA) issued more comprehensive guidelines for manufacturing three types of medical devices: sterile and implantable devices, and in-vitro diagnosis reagents. These guidelines went into effect on October 1, 2015.
- The guidelines are detailed into three separate appendices.
  - Announcements number 101, 102, & 103 of 2015
- These guidelines aim to improve the administration and quality management of medical devices in China in order to ensure their safety and efficacy.

9) BEST BUSINESS STRATEGY: WHAT TO DO AND NOT DO

Best Business Strategy

- Make sure all internal executives and/or consultants examine all issues upfront before implementation
- Organic vs. inorganic growth
- Start-up usually takes time, could be serious registration hurdles
- JV's, more divorce now
- M&A could work but never enough due diligence done
- Strategy needs to be well thought out to succeed

10) CULTURAL ISSUES: WHAT TO DO AND NOT DO

Asian Ethnic Diversity

- Japan and Korea: very homogenous; small minority populations
- China: 92% Han, Over 50 National Minority Groups for other 8%
- Singapore: 77% Chinese, 14% Malay, 8% Indian
- Malaysia: 50% Malay, 24% Chinese, 7% Indian
- Indonesia: 40% Javanese, over 300 ethnic groups for other 60%
- Thailand: Majority Thai, 14% Chinese
- Philippines: Very diverse population in terms of language, religion and ancestry
  - Tagalog 28%, Cebuano 13%, Ilocano 9%, Bisaya/Binisaya 8%, Hiligaynon Illonggo 8%
- Vietnam: over 50 ethnic groups
  - Almost 90% Vietnamese
  - Chinese (Hoa) around 1%
- India: 3 major groups
  - 72% Indo-Aryan, 25% Dravidian, 3% Mongoloid and other

Relationships of trust is how business is done in Asia

- Relationships take time in Asia, unlike in the West.
- How do you write your emails to the Japanese?
- Do you send holiday cards and do you write hand written messages on the holiday cards?
- Have you made an effort to understand the history and culture in the Asian countries you are working with?
- Good relationships can always deal with difficult problems. Lawyers do not dominate the regulatory and business practices in Asia, and should be used rarely.

Final Comment: TPP

- TPP seems dead, but TPP is crucial for medtech companies to succeed in Asia. Generally, we need to tilt toward Asia for participation in growth. TPP includes 40% of the global economy and includes Japan, Vietnam, Malaysia, Brunei, Singapore, New Zealand, Australia, Canada, Peru, and Mexico. 25% of exported health products were to TPP countries
- Tariffs in Malaysia are 30%, 20% in Vietnam, and 5% in Japan – almost 100% of tariffs eliminated with TPP
- China has offered alternative plan called the Regional Comprehensive Economic Partnership which would be the largest global trade agreement. US is NOT included!

THANK YOU

FOR YOUR PARTICIPATION AND ATTENTION

For more information, visit us at
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