



INTERNATIONAL MEDICAL DEVICE CONSULTANTS



EMERGO  GROUP

Japan Medical Device Market and Business Opportunities

at BIS Conference Center
October 3rd, 2013

Emergo Japan K.K



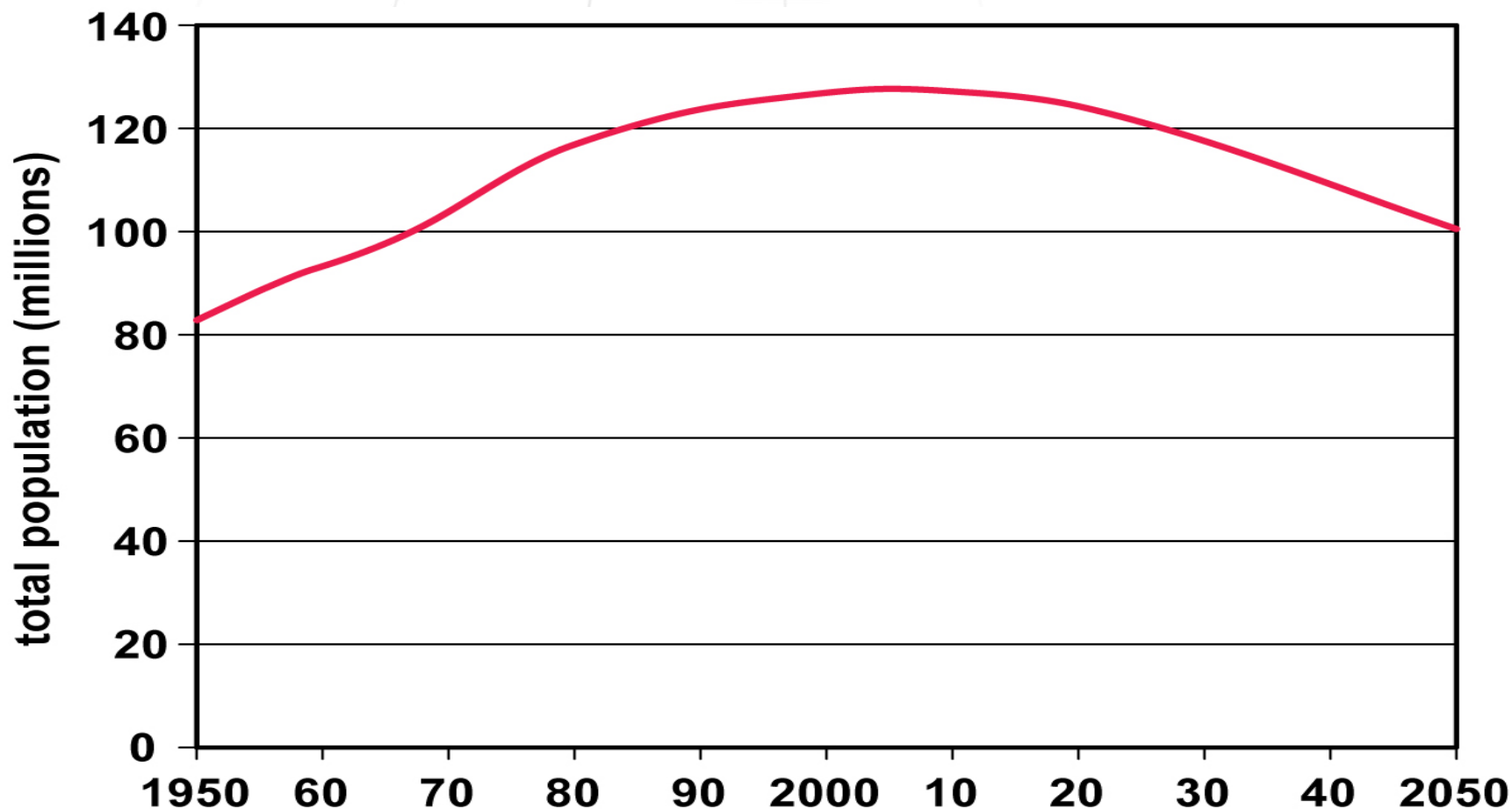
Why export to the Japanese market?

- Population of 127 million, 3rd largest global economy
- Japan's medical device market totals JPY2,386 billion (USD24 billion, GBP15 billion, Euro18 billion) in 2012
- 44.4% of medial devices were imported (JPY1,584 billion)
- Medical device for treatment (pacemaker, implants, catheter etc.) had 52.7% of market share
- Expected to reach \$39 billion by 2015
- Japan's population is aging at a faster rate than any other developed nation, spurring more demand for healthcare

Sources: "Vision for the medical devices industry 2013" of MHLW, JETRO



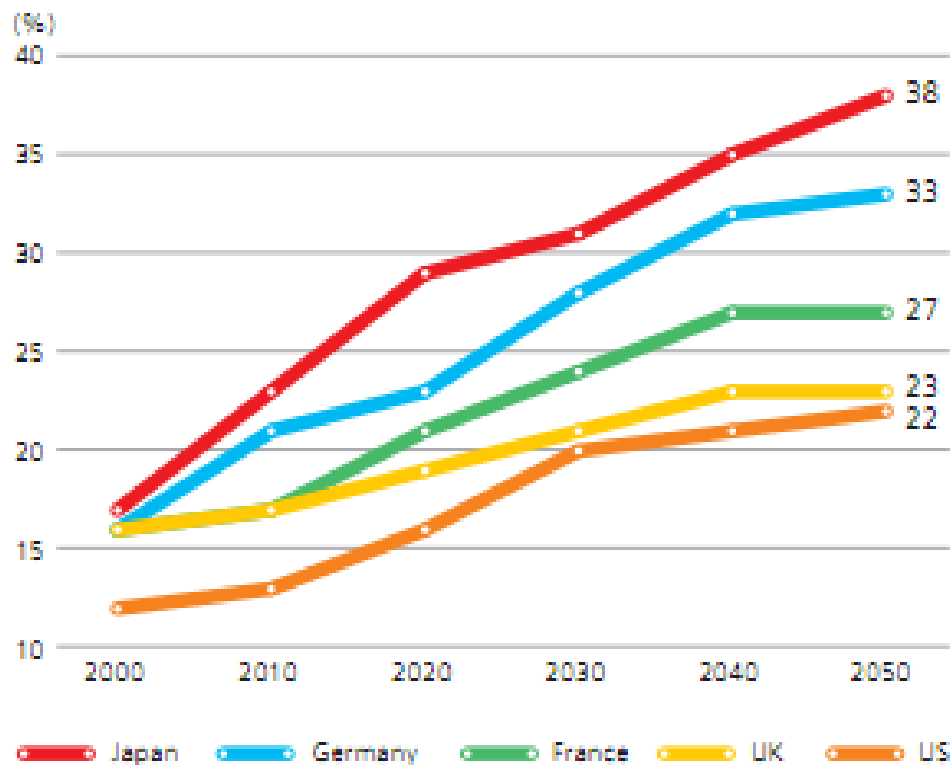
Japan's population is shrinking, but...





Market Overview

Percentage of population aged 65 or older



Source: "World Population Prospects: The 2008 Revision Population Database," United Nation

Demand for medical devices will grow because the median age is rising quickly, and older people utilize healthcare much more intensively.

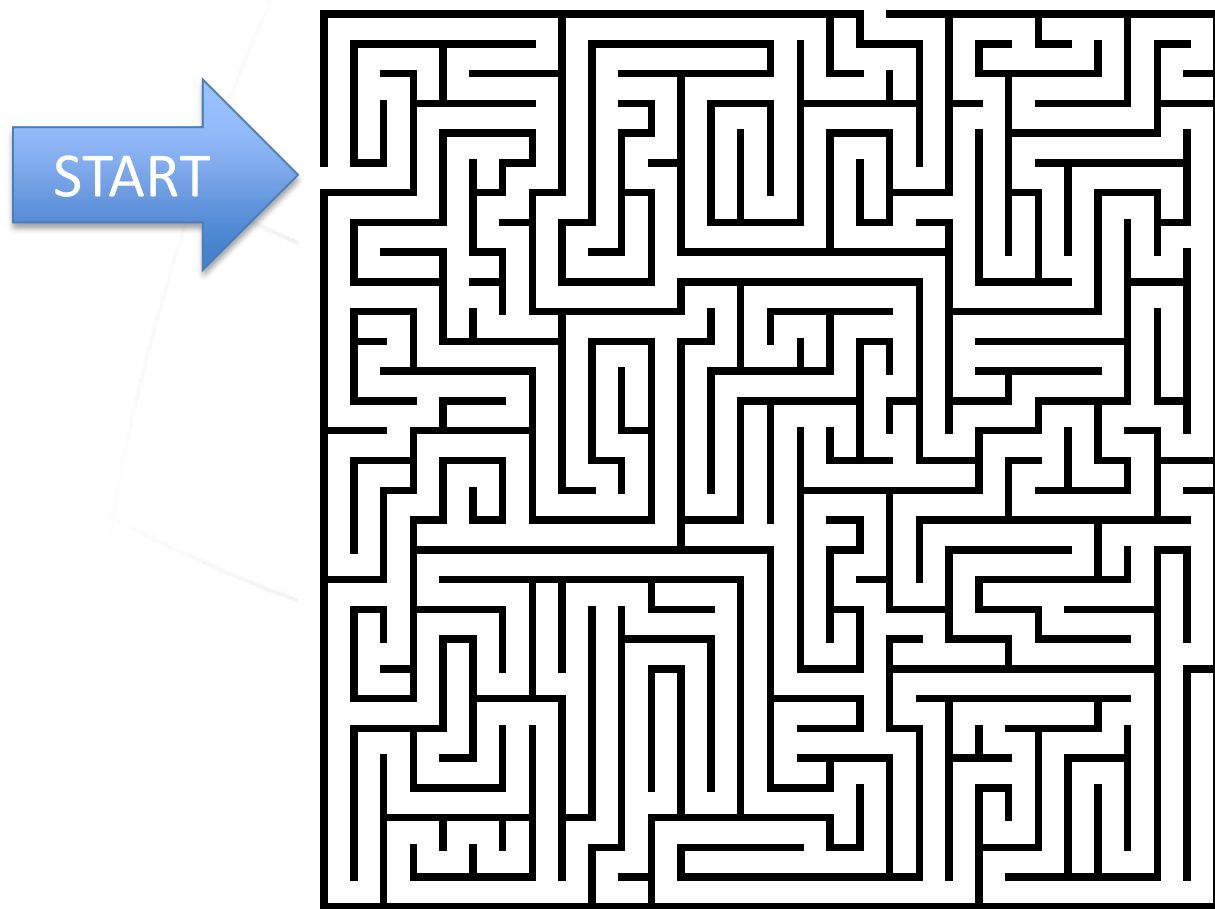


Japanese market characteristics

- Large, mature economy and medical device market
- Large target universe
- Daimyo System
- Complex, expensive distribution system
- Relationship based sales
- Socialized healthcare system
- Heavy regulatory requirements



The Japanese regulatory process



Device-lag!!

But Japan
government
try to change...



Vision for the Medical Device Industry 2013

- MHLW had issued the vision every 5 years (First in 2003, Second in 2003)
- Japanese Population over 65 years of age in 2013
 - Expected to exceed 30,000,000
- High expectation for disease prevention, early diagnosis, early treatment
- Show the future vision of medical device industry, how related industries evolve, how medical devices should realize for practical use and marketed against industry, academia and government.



Vision for the Medical Device Industry 2013 – Action Plan

- | | |
|--|---|
| <ol style="list-style-type: none">1. Promotion and prioritization of research and development2. Promotion of joint research under medical –engineering Collaboration3. Prepare core clinical study hospital4. Promotion of Global Clinical Trial, Clinical Study5. Expand PMDA Regulatory Strategy Consultation6. Reform PAL based on medical device characteristics | <ol style="list-style-type: none">7. Enhance PMDA's review system to expedite medical device approval8. Prepare evaluation of innovation for insurance reimbursement9. Promotion development of guidelines for use of medical devices10. Ensure implementation of actual training for doctor11. Strengthen of relationship with overseas regulatory authorities12. Promotion of exports |
|--|---|



PAL Reform Act

- Draft of PAL(Pharmaceuticals Affairs Law) Reform Act was submitted to the Diet on May 24th, 2013
- Summary of Changes
 1. Strengthening safety measures for drugs and medical devices etc.
 2. **Establishment of regulation based on medical device characteristics**
 3. Establishment of regulation based on regenerative medicine products
 4. Title of PAL (change to “Law for ensuring quality, effectiveness and safety of drugs and medical devices etc.”)



Summary of Proposed Regulation for Medical Devices

1. Establish a chapter for medical device MAH(Marketing Authorization Holder) and manufacturer separate from drugs
2. Expand application of the third party review system (“*Ninsho*”) to specified highly controlled medical devices
3. Apply standalone software used for diagnostics to Pre-market Approval (“*Shonin*”), Pre-market Certification (“*Ninsho*”) and Pre-market Submission (“*Todokede*”)
4. Change to registration system from license system for establishment of manufacturing
5. Rationalize QMS conformity assessment