EUROPEAN BUSINESS COUNCIL IN JAPAN
THE EUROPEAN (EU) CHAMBER OF COMMERCE IN JAPAN

MEDICAL EQUIPMENT

ISSUES AND RECOMMENDATIONS

REVISION OF THE FUNCTIONAL CLASSIFICATION OF MATERIALS COVERED BY INSURANCE

Revision of the Functional Classification of Materials Covered by Insurance

YEARLY STATUS REPORT: Slight Progress

- In the 2016 medical reimbursement price revision, the functional classifications of medical materials covered by insurance were revised and eight classifications were added as a result.
- The regulations associated with exceptional rules still remain an issue.

RECOMMENDATIONS

- The Government of Japan should introduce appropriate reimbursement for innovative technologies through further subdivision of the functional classifications.
- Japan should improve the insurance reimbursement price system based on product characteristics.

DEPLOYMENT OF HTA
(HEALTH TECHNOLOGY ASSESSMENT)
FOR MEDICAL EQUIPMENT

Deployment of HTA (Health Technology Assessment) for Medical Equipment

YEARLY STATUS REPORT: Some Progress

- A trial to evaluate cost effectiveness started in April 2016 targeting five pieces of equipment.
- Details of how to utilise the results are under discussion with *Chuikyo* (the Central Social Insurance Medical Council).

RECOMMENDATION

- Japan should introduce HTA carefully, taking into account the unsuitability of applying QALY (Quality-Adjusted Life Years), the unreliability of the results depending on the level of skill of the testers and the techniques applied, and the short improvement cycle for medical equipment.

MUTUAL RECOGNITION OF CLINICAL EVALUATION AND INTERNATIONAL ALIGNMENT

Mutual Recognition of Clinical Evaluation and International Alignment

YEARLY STATUS REPORT: Some Progress

- The Government encourages companies applying for equipment approval to use the PMDA's prior consultation service to promote utilisation of clinical evaluation results obtained overseas.

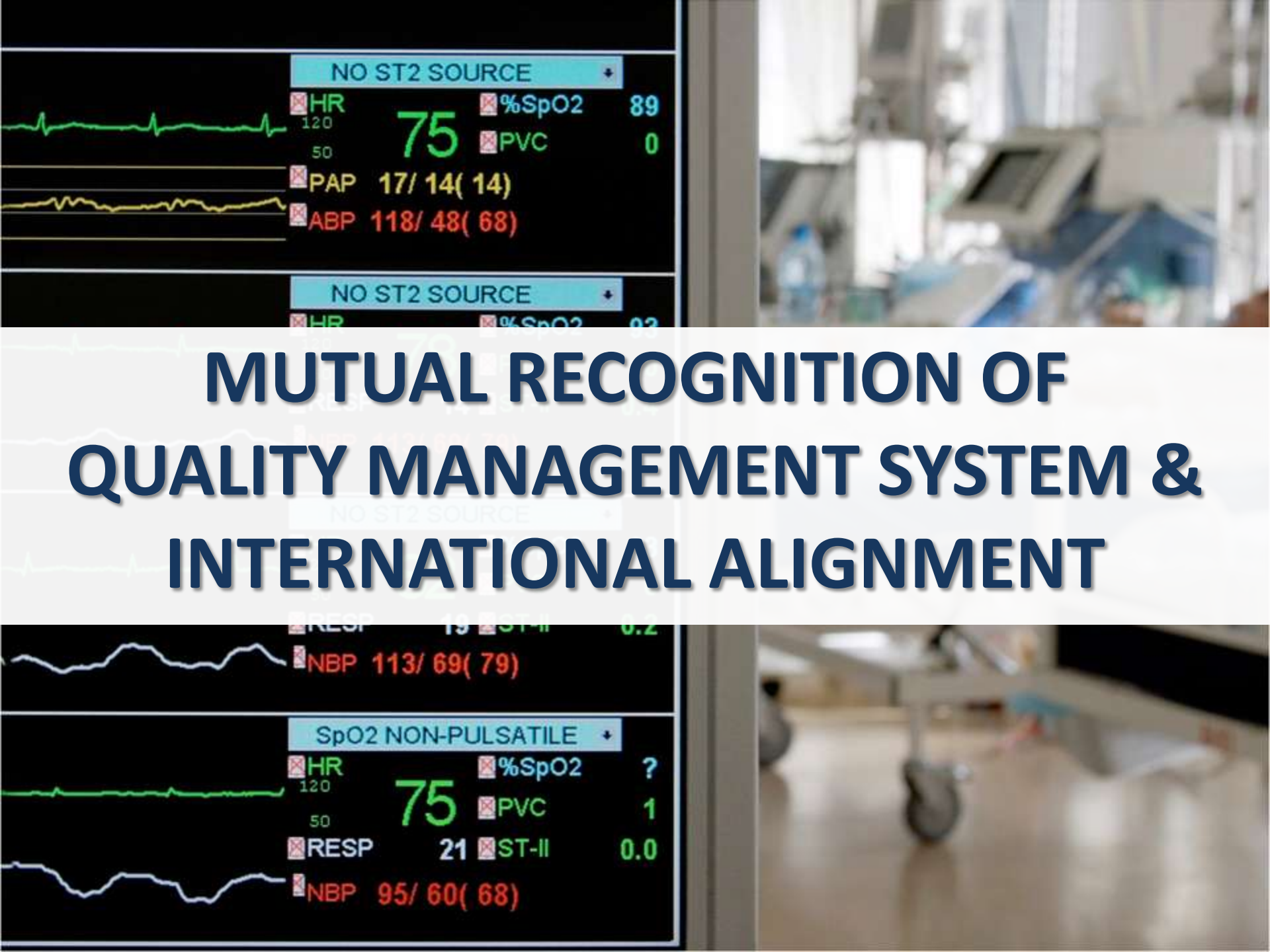
Mutual Recognition of Clinical Evaluation and International Alignment

RECOMMENDATIONS

- Both the EU and Japan should work on promoting mutual recognition of clinical trial results by increasing the number of overseas clinical evaluation results utilised in their approval processes as well as ensuring that those carrying out clinical trials are aware of and understand the guidelines.

- Japanese Good Clinical Practice (GCP) is consistent with ISO14155. However, Japan should improve the actual operation of GCP by accepting clinical trial results from Europe that comply with ISO14155. Where a decision is made not to accept clinical trial results from Europe, the scientific grounds for this decision should be made clear.

- MHLW should issue “early disclosure of clinical trial guidance”.



MUTUAL RECOGNITION OF QUALITY MANAGEMENT SYSTEM & INTERNATIONAL ALIGNMENT

Mutual Recognition of Quality Management System and International Alignment

YEARLY STATUS REPORT: Some Progress

- Some progress has been made in aligning Japan's Quality Management System (QMS) with international standards.
- Furthermore, Japan has formally agreed to participate in the MDSAP (Medical Device Single Audit Program) and moved forward with international alignment in this area.

Mutual Recognition of Quality Management System and International Alignment

RECOMMENDATIONS

- Japan should remove the remaining differences in application formats and standards.
- Japan and the EU should promote mutual recognition of medical equipment in low-risk classifications at an early stage.
- Japan should synchronise its timetable for introducing new ISO standards with other countries in order to avoid variations among countries.
- The authorities should make an effort to provide information on QMS ministerial ordinances in English with a view to participation in the MDSAP.

MUTUAL RECOGNITION OF MEDICAL EQUIPMENT LICENCES & INTERNATIONAL ALIGNMENT

Mutual Recognition of Medical Equipment Licences and International Alignment

YEARLY STATUS REPORT: Some Progress

- Japan has decided to accept examination results from other countries that comply with ISO13485.
- The examination period for PMDA approval has been shortened and performance has improved.
- However, issues still remain with the recognition of equipment licences.

RECOMMENDATION

- The PMDA and MHLW should work with the EU authorities to mutually recognise each other's medical equipment licences, with PMDA giving priority to low-risk class 2 products.