



**MINISTRY OF FOREIGN AFFAIRS
OF DENMARK**



Government Cooperation in Health Through Economic Diplomacy

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Purpose of bilateral DK-JPN cooperation

Economic Diplomacy: Emphasize commercially oriented government cooperation with Japan, while supporting Danish research and commercial interests (National Internationalisation Strategy - Growth Plan for Health and Life Sciences)

“Fundamental to the Danish-Japanese strategic partnership and economic diplomacy in health are efforts to stop the erosion of the ‘social contract’, secure our universal health systems sustainability, and the implementation of engaging campaigns and programs as catalyst for achieving positive societal, economic and health outcomes by the means of access to innovative products and services”



Bilateral Government Partnership in Health

- Danish-Japanese sector cooperation in health and life sciences
- *Drive the health agenda and economic growth through innovation in health (social contract)*



Stakeholder Co-creation of Health Goal

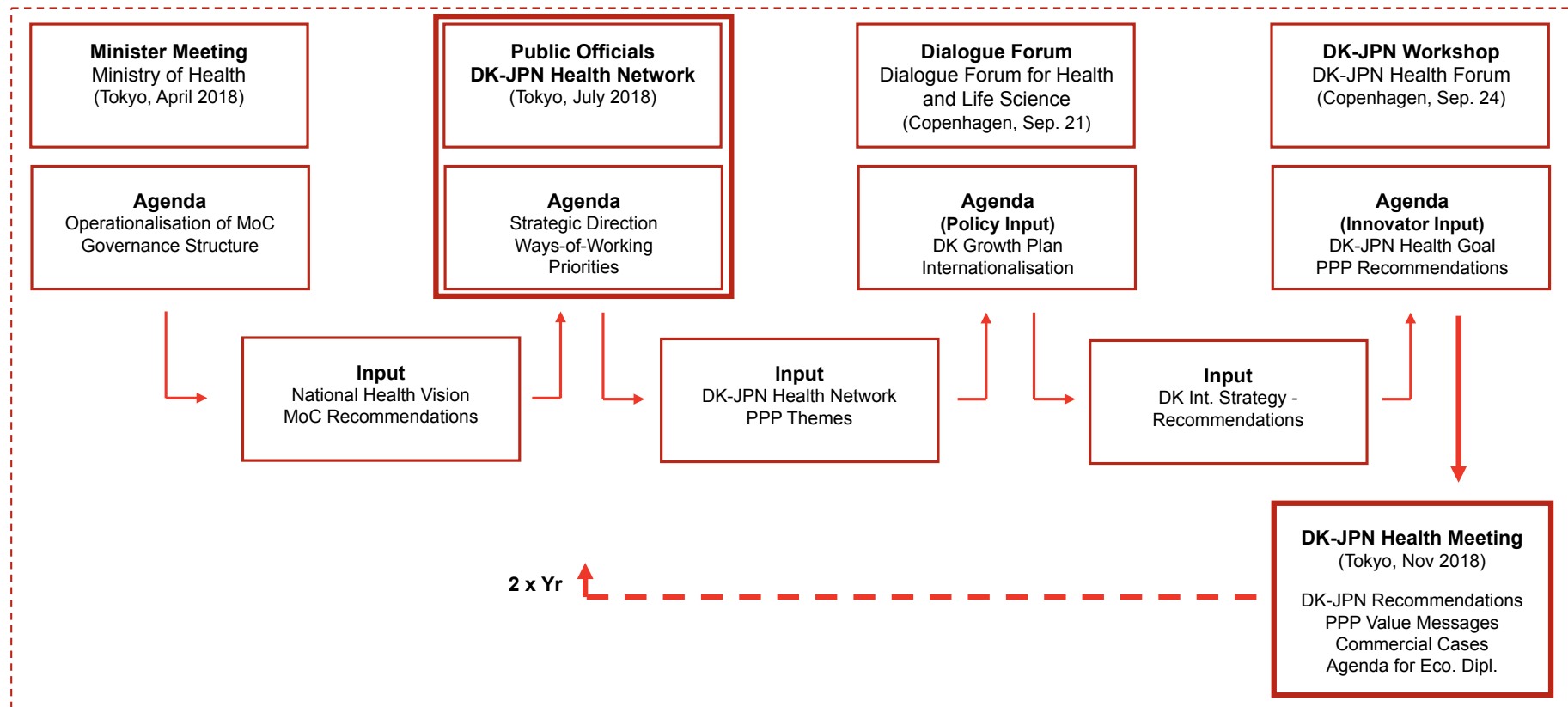
- Operationalisation of Memorandum of Cooperation
- *Create hospitable environments (Establish recognition of benefit / outcomes)*



Policy Development & Implementation

- Industry - Danish Medicines Agency – MHLW-PMDA Cooperation
- *Public-Private Cooperation for Efficiencies in Regulatory Pathway and Good Practice Value Assessment Implementation (Earlier access to innovative products)*

Bilateral Committed to Systematic ways-of-Cooperating



Co-Created Goal For DK-JPN Health Cooperation*

Objective: The DK-JPN Health Network aims to translate the National Growth Plan for Health and Life Sciences into tangible health outcomes and economic growth by advancing internationalisation efforts through collaboration on innovative solutions between Danish and Japanese authorities, academia, clinical societies and businesses.

Guided by the bilateral Strategic Partnership on Growth and Innovation and Memorandum of Cooperation in Health between Denmark and Japan, the DK-JPN Health Network will propose cooperation areas, build coalitions and implement concrete goals for prioritised activities within three collaboration areas in health and life sciences:

1. **Health Collaboration:** Optimise health provider performance and support health vision deliverables
2. **Regulatory Collaboration:** Improve regulatory efficiencies and access to innovative products
3. **Science Collaboration:** Integrate R&D programs in support of health and societal value demonstration

Outcome: Collaboration on initiatives that recognizes the **value of treatment** and care pathway optimization, encouraging better **disease area programs** (incl. awareness), **citizen participation** and health outcomes, through supportive policy frameworks and **regulatory efficiencies** promoting **earlier access** to innovative health solutions:

1. **Health service redesign and solution positioning:** Collaborate on service model and market shaping disease area programs and share experiences to an appropriate audience in the Danish and Japanese healthcare systems, promoting outcome-based care, patient pathway organisation and consumer participation, where Danish and Japanese capabilities, products and solutions are relevant and effective.
2. **Regulatory Framework and Market Access:** Advance agency-industry-science cooperation on regulatory sciences and establish mechanisms through early advice, data and trial requirements for clinical program planning, supporting efficient product development, resource planning and market access through a clear and transparent process for innovative health technologies.
3. **Science and innovation:** Formalise networks between knowledge environments, linking sciences and commercialisation efforts based on research of high quality and relevance for industry, universities and hospitals. Foster capability building across the full health and life sciences value chain, expanding evidence-based practice and serve the overall contribution of scientific production and body of evidence in support of the Danish and Japanese life sciences stronghold, clinical product development and commercialisation.

* The Goal Objective and Outcome emphasize government cooperation with Japan, while supporting Danish research and commercial interests. It is inspired by the Danish government's Growth Plan for Life Science; Japan's Healthcare Vision 2035; Strategic Partnership for Growth and Innovation between Denmark and Japan; Memorandum of Cooperation in Health between Denmark and Japan; Denmark's Internationalisation Strategy for Health and Life Sciences (draft); early stakeholder consultation.

Innovator Platform for Business Objectives



Health Sciences Research and Value Demonstration

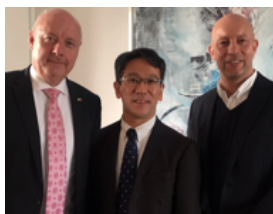
- Prof. Finn Børlum Kristensen, Faculty of Health Sciences, Department of Public Health, Research Unit of User Perspectives, University of Southern Denmark. EUnetHTA Executive Committee Chairman and EUnetHTA Secretariat Director 2006-16

Purpose: Delivering on initiatives to improve health and societal value demonstration for health product evaluation and earlier access



Symposia

- **Increase understanding** of product regulations and value assessment trends in Japan and international harmonization.
- **Share perspectives and bring relevant international results** and discussions into the bilateral context on more comprehensive and systematic approach to the introduction of innovations into the health care system.



Regulatory Sciences and Clinical Development

- Prof. Hisashi Urushihara, Division of Drug Development & Regulatory Science, Faculty of Pharmacy, Keio University

Purpose: Support agency-industry-science cooperation on regulatory sciences, for national capability building, efficient product development and market access



Outcome

Programs supporting a **stakeholder-involved promotion and authority adoption of a clear and transparent process (Good Practice)**, which promotes regulatory efficiencies and captures the value of treatment offered by way of innovative health technologies.

- Authority: Framework & Good Practices
- Academia: Evidence Generation
- Innovators: Sign-Posting Business Objectives

Medical Writers capture symposia recommendations for advocacy briefs

DK-JP Health Value Symposium (November 1st – Copenhagen) - DRAFT

08:30 – 09:00 MORNING COFFEE, TEA & CROISSANT

09:00 – 09:10 DK-JPN Cooperation in Health – Practice Sharing for Public Health & Growth

- Cooperation on introducing innovations into the health care system
- Mr. Joakim Steen Barron-Mikkelsen, Minister Counselor, Economic Diplomacy in Health, Royal Danish Embassy Japan

09:10 – 09:35 Understand the landscape and current practice

- The value of treatment offered by way of innovative products and the need to produce evidence and information on value during development and market introduction
- Professor Finn Børlum Kristensen, Faculty of Health Sciences, Department of Public Health, Research Unit of User Perspectives, University of Southern Denmark

09:35 – 10:00 International perspectives on health economics and value assessment

- Overview of current international health economic trends, cost effectiveness and budget impact analysis, value frameworks
- Professor Michael Drummond, Centre for Health Economics, University of York

10:00 – 10:30 COFFEE BREAK

10:30 – 11:00 Japans approach and future commitment to economic evaluation

- Experiences and good practices in HTA program development
- Professor Isao Kamae, M.D., Dr.P.H., Health Policy and Technology Assessment, Graduate School of Public Policy, The University of Tokyo - TBC

11:00 – 11:30 Denmark's approach to Economic analyses of new medicines and extensions of indications

- In applying economics the Danish payers have deliberately decided to apply cost analysis and budget impact analysis and not cost-effectiveness analysis – what are the implications?
- Professor Dorte Gyrd Hansen, Head of Research Unit, DaCHE - Danish Centre for Health Economics, University of Southern Denmark. - TBC

11:30 – 12:00 The role of regulatory science in value demonstration

- Regulatory authorities as partners in access to innovation
- Dr. Harald Enzmann, Chair of the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) (Federal Institute for Drugs and Medical Devices, Germany)

12:00 – 13:00 LUNCH

13:00 – 14:30 Therapy Area Innovator cases

- What are the assessment, market access and pricing characteristics and challenges experienced within the therapy areas?
- Innovator and pipeline perspectives from diabetes, psychiatry and mental health, skin diseases, allergy and immunotherapy, oncology and paediatric illnesses (examples – TBD)
- Therapy perspectives by innovators

14:00 - 14:15 BREAK

14:15 – 15:00 Panel Consolidation on Good Practice Recommendations

- Message development for good practice cooperation and implementation
- Chair: Japan MHLW Official – Representative TBD
- Danish Academic (SDU, KU, CBS)
- Program Speakers
- ISPOR representative
- DKMA

15:15 – 16:00 Individual Consultations

16:00 – 18:00 Network Reception

DK-JPN Symposium: Converging Regulatory Science beyond the boundary – Cooperation and Harmonization (November 23rd – Tokyo) - DRAFT

Opening Remark: DK-JPN Cooperation in Health

- Honourable Peter Taksoe-Jensen, Danish Ambassador to Japan

Introduction (Moderator): The Role of Regulatory Science in Clinical Development and Commercialisation for Prosperity – Early Stakeholder Consultation and Program Development

- Prof. Hisashi Urushihara, Division of Drug Development & Regulatory Science, Faculty of Pharmacy, Keio University

PMDA – New Leadership Vision and Priorities

- Dr. Yasuhiro Fujiwara, President, The Japan Pharmaceuticals and Medical Devices Agency

Panel Track 1: Authority Aspects: DKMA – MHLW/PMDA Cooperation – Status and Operational Steps

- Dr. Jens Piero Quartarolo, Director of Division for Pharmacovigilance & Medical Devices, Danish Medicines Agency (DKMA)
- Dr. Nikolai Constantin Brun, Director of Division of Medical Evaluation & Biostatistics division, Danish Medicines Agency (DKMA)
- Dr. Daisaku Sato, Chief Management Officer, PMDA (Chairperson)
- Dr. Yoshiaki Uyama, Office of Medical Informatics and Epidemiology, PMDA
RE: Regulatory perspective of RWD and RWE use during medicines life cycle
- Dr. Junjko Sato, Office of International Programs, PMDA
RE: Collaborative leadership for mutual harmonization among EMEA and Japan

Panel Track 2: Academic Aspects: Evidence Generation and Capacity Building (Sharing health and trial data beyond boundary, E-health and value assessment during clinical development and post-marketing, Education for regulatory capability)

- Dr. Hiroyoshi Arai, Director, Centre for Regulatory Science, PMDA
- Prof. Masayuki Amagai, Dean, School of Medicine, Keio University
- Prof. Hiroshi Watanabe, Vice President, Hamamatsu University School of Medicine
- Prof. Hiroshi Yamamoto, Clinical Research Center, Nagasaki University
- Professor Marie Louise (Marieke) De Bruin, Copenhagen Centre for Regulatory Science (CORS)
- Professor Timo Minssen, Managing Director of Centre for Advanced Studies in Biomedical Innovation Law (CeBIL)

Panel Track 3: Innovator Aspects on evidence generation under mutual collaboration and international harmonization

- What are the regulatory characteristics and challenges experienced within therapy areas?
- Innovator perspectives and characteristics on global data and regulatory evaluation within diabetes, psychiatry and mental health, skin diseases, allergy and immunotherapy, oncology and paediatric illnesses
- Therapy perspectives by innovators

Closing Remarks: Commitment to cooperation for patient access to quality medical solutions, efficiencies in health delivery and societal prosperity

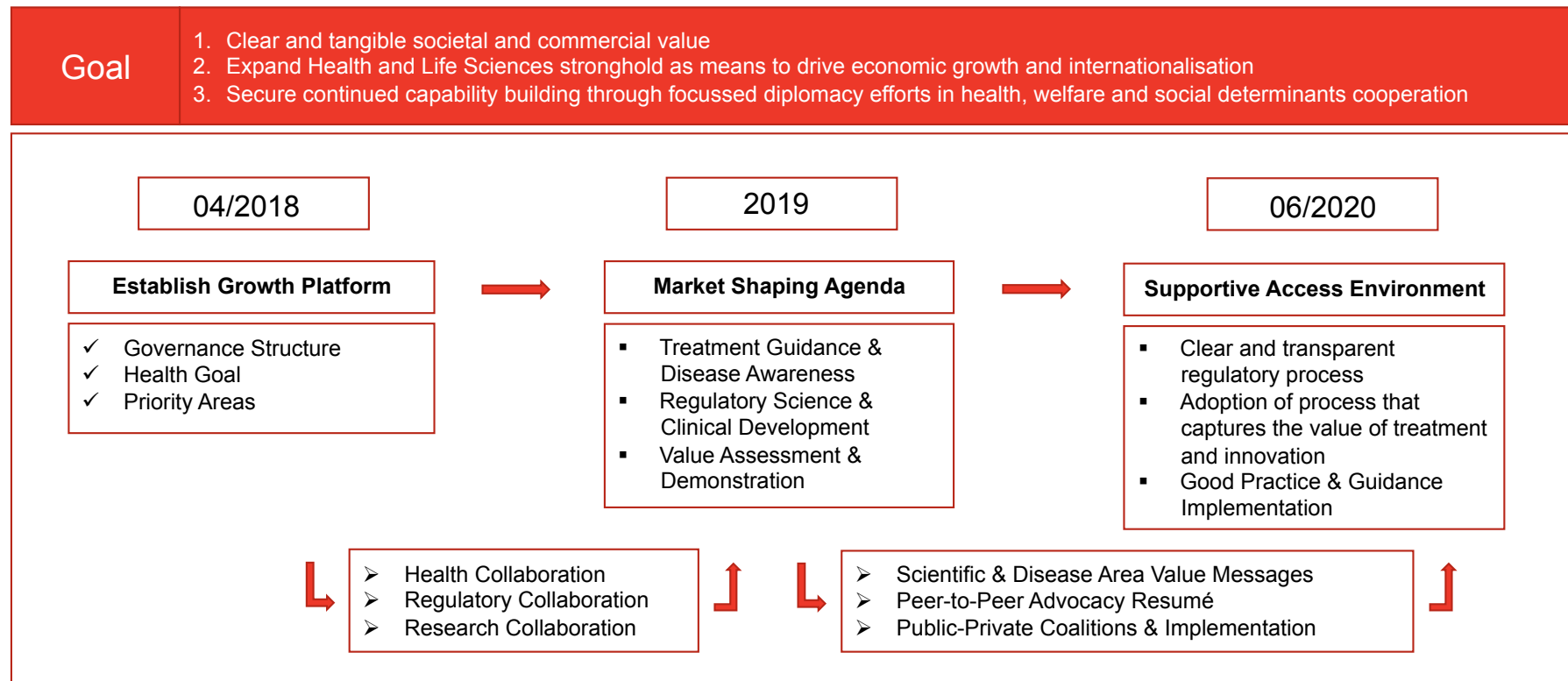
- Dr. Yasuhiro Suzuki, Vice-Minister for Health to Japan

Network Reception

Health Officials Dinner

- Residence (invitation only)

Work Plan For Economic Diplomacy Japan 2018 - 2020





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Inspiration from others?

More Info on DK-JPN Economic Diplomacy in Health

- [Denmark and Japan enter Regulatory Medicines Agency Partnership](#)
- [Danish-Japanese Health Relations](#)
- [Health as a Growth Driver through Economic Diplomacy](#)
- [A Diabetes Expert Session in Japan](#)
- [Denmark and Japan Seeks TeleHealth Solutions](#)
- [A Day of Unity and Partnership in Health](#)
- [Danish and Japanese Life Science Community support the Japan Health Care Vision](#)
- [Life Design for Quality of Life](#)
- [Open Innovation – From Science to Society](#)
- [Danish-Japanese Healthgeneering – What is a hospital?](#)
- [Danish Elderly Care Inspire Japans Social Innovation](#)

- [Japanese Health Officials and Danish Enterprises Share Needs and Expertise](#)
- [Japanese Publication Showcase Danish Quality of Life](#)
- [Keio University Joins Strategic Cooperation in Health](#)
- [Danish-Japanese Health Service Research and Value Assessment](#)
- [Danish-Japanese Health Network Welcomes AMED](#)
- [Student Exchange Program on Economy, Healthcare and Society with Showa Women's University Tokyo](#)
- [Danish Design DNA for a Japan Healthy at Work](#)
- [Danish-Japanese Fertility Planning and Access to Reproductive Technologies](#)
- [Horizons for Personalized Health - New Telehealth and Telerehabilitation Technologies](#)

Hyperlinks accessible in presentation mode