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Employing the concept of techno-governance to analyse the field of biomedical engineering in Japan

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Abstract

Brucksch approaches the field of biomedical engineering in Japan, which is hallmarked by several contradictions. Medical devices are one of the leading technologies. Surprisingly, most devices are imported to Japan, despite being one of the largest markets for medical products and its fast demographic change. More precisely, there has been a decline in innovation activities in biomedical engineering over the past two decades. Rather recently the government under Prime Minister Abe took the lead and launched various innovation strategies. For instance, the Comprehensive STI Strategy and Japan's Growth Strategy integrate the field in the Abenomics scheme as a focus area to achieve a "healthy and active ageing society as a top-runner in the world", and to reinforce "industrial competitiveness in the areas of pharmaceuticals and medical devices". Therefore, this article suggests analysing innovation activities in biomedical engineering from a techno-governance perspective broadened by STS in order to allow the analysis of formal and informal structures, norms and values, relevant actor, power balance and its consequences. Thus, particularly, the term of techno-governance needs to be specified and reflected against the Japanese context. To approach the field, this paper draws mainly on findings from research literature, official statistical data, and preliminary results from an ongoing interview study conducted 2016 in Japan.

Keywords: Japan, techno-governance, STS, innovation, biomedical engineering and devices

"The boundaries between the different fields are very big, medical field and the manufacturing field. They are isolated."

"Who would have thought that Japanese patients have fewer chances to benefit from medical innovation than Americans and Europeans?"

(Telling quotes from my interview study 2016 and Altenstetter 2014: 169)

Background

Japan is widely known as rapidly aging society due to a low fertility and mortality rate (2012: 1.41, respectively 10.0) as well as high life expectancy (2012: male 79.9 years/female 86.4 years). In 2012, the proportion of the population 65 years and older amounted to 24.1% (MHLW 2012: 6, 9, 15). As a result, the need for medical and health care steadily rises, and so does the need for medical care and relating equipment. Against the backdrop of demographic change, several authors underline the market potential for medical devices (e.g. Kikuchi 2007: 1; Numata *et al.* 2010: 332). Therefore, the aging society brings various incentives for development of medical products innovation. In addition, hospitals and clinics experience a dramatic change of digitalisation, technical automation and algorithmising at present concerning their institutional organisation, working environment, clinical workflow, daily practices in diagnosing and treatment as well as production of medical knowledge.

While technical solutions are frequently welcomed in Japan, the field of biomedical engineering remains hallmarked by several contradictions though. The country is one of the leading markets for high-end products and cutting-edge technologies. Most devices are imported to Japan despite being one of the largest markets worldwide. Lost shares in the domestic market and abroad as well as the allegedly low intensity in R&D suggest

that other factors are at play beyond pure market potential. Surprisingly, some authors report even on a critical "medical device lag" (delayed access to advanced technology or treatment) or a "medical device gap" (limited access to medical devices) in Japan (e.g. Altenstetter 2014: 172; Ikeno, Ikeda and Uchida 2014: 1; Tanabe 2009: 87). Rather recently the government under Prime Minister Abe took the lead and launched various innovation strategies, which put the field of biomedical engineering under the frame of a "healthy and active ageing society", "as a top-runner in the world" and "industrial competitiveness", what will be addressed below more intensively.

Defining Medical Devices

According to the Japanese *Pharmaceutical Affairs and Medical Device Law* (PMDL Art. 2 § 4, *iyakuhin iryō kiki tō hō*), medical devices (*iryō kiki*) are defined as such machinery and appliances (*kikai kigu nado)*, which are either used for diagnosis, medical treatment or prevention of human and animal injuries and diseases, or which aim at influencing the structure or function of the human or animal body as well as at correcting physical disabilities (see also Numata *et al.* 2010: 330; PMDA 2014a). Under the PMDL, ten categories specify which product is accepted as medical device: (1) devices for surgical procedures, (2) diagnostic imaging devices, (3) biological function assisting, or substituting devices, (4) bio-phenomena measuring, or monitoring apparatus, (5) medical specimen testers, (6) dental materials, (7) medical devices for home-use, (8) diagnostic imaging X-ray related units, or instruments, (9) ophthalmologic appliances and (10) others (MHLW 2013: 96).

Research Interest

Focusing on demographic change, plenty of research is done on the welfare system, gender aspects and the silver market.

However, the field of biomedical engineering is rather seldom examined. In a great deal of studies of medical devices, market and industry perspectives are prevailing. For instance, Gelijns and Rosenberg (1999: 351) have provided in their article on "Diagnostic Devices: An Analysis of Comparative Advantages" valuable insights comparing the EU, Japanese industrial leadership and the USA. Their study mainly draws on technology development and determinants of business success from a long-term evolutionary perspective. Moreover, they attributed the rapid spread of diagnostic devices in Japan to "certain religious and cultural traditions as well as by the organization of the Japanese health care system". Here, they merely refer to the fee-for-service reimbursement and mass screening programmes initiated in 1961 but refrain from specifying "religious and cultural traditions" further on. What is meant by cultural and religious tradition in the Japanese context? Furthermore, what can be reasoned from the circumstance that conventional narratives of Japan's industrial policy such as techno-nationalism, state interventionism, leadership by METI (Ministry of Economy, Trade, and Industry, *keizai sangyō-shō*) or dominance of the economy does not provide sufficient explanatory power? To conclude, these and similar reductions prevailing in the study of innovation in biomedical engineering in Japan underline the necessity to broaden theoretical and methodological approaches to a wider and more interdisciplinary perspective.

Basically, the sociologist Werner Rammert (2007: 484-486) defines technology as the "collectivity of all creatively and artificially cause-effect relationships instituted in society that produce reliably and permanently intended effects due to their shape, functionality, and fixation in various carrier media". He draws further attention to the three dimensions of (a) processes and techniques, (b) technical artefacts (machines, devices), and (c) technology of codes, software and algorithms. Similarly, Okada (2006: 9) supports this definition by directing attention to

technology as a "collection of theoretical and practical knowledge, know-how, skills, and artefacts that individuals and organizations use to develop, produce and deliver their products and services" from an economy point of view. Accordingly, the OECD (2013 [2001]) defines technical or technological innovations as "new products and processes and significant technological changes of products and processes. An innovation has been implemented if it has been introduced on the market (product innovation)." To call an innovation successful, not only the invention matters but also its successful diffusion and wide acceptance. Everett M. Rogers (2003: 5), founder of the diffusion theory, understands by diffusion "the process in which an innovation is communicated through certain channels over time among the members of a social system." However, diffusion processes in varying societal systems are shaped by formal and informal structures, norms and values, constellation of players and opinion leaders, power balance and its consequences (Rogers 2003: 24-27). The abovementioned gap of medical devices diffusion illustrates the need to shed more light on diffusion and implementation of medical devices to and within Japan.

Inspired by the OECD definition and Rogers' findings, this article suggests approaching innovation activities in biomedical engineering from a governance perspective in order to allow the analysis of abovementioned factors. This leads to the question how techno-governance can be defined and employed in the field of biomedical engineering. To add, in which way is it possible to specify these in the Japanese context. More precisely, the article aims at presenting reflections for the analysis of innovation in biomedical engineering and the diffusion of medical devices in Japan from a different angle by taking a stance as political scientist but also by suggestions from Science & Technology Studies (STS). This paper draws mainly on findings from research literature, official statistical data, and preliminary results from an ongoing interview study conductedin Feb-Apr and Oct-Dec 2016

focussing central actors on the national level in Japan (med-tech associations, manufacturers, administrative bodies, med-tech informants, research centres, and medical institutions).

To proceed, the paper begins with specifying the concept of techno-governance from a Science & Technology Studies (STS) background to provide a basis for examining the Japanese context. Then, the paper sheds light on decisive domains and actors with their context in Japan, namely hospitals, patients and clinicians, manufacturers and academia. Particular attention will be paid to the industry-university linkage due to the highly complex and interdisciplinary nature of medical devices nowadays. This step is followed by an examination of institutional boundaries and governance within the regulatory framework and technology policy on the national level. Finally, the paper draws a preliminary conclusion on boundary work and framing processes regarding techno-governance in biomedical engineering in Japan. Because this research project is work in progress (early stage), this article provides merely a very rough picture of employing the governance concept for the study of medical devices in Japan.

Techno-Governance

This article refers to the argumentation of Irwin (2008: 583-584) that the term "scientific governance is preferable to the more conventional formulation of science and technology policy" because it broadens the view to the "very manner in which decisions are represented and 'framed'", to "implicit sociocultural assumptions that operate within these representations and framings", to "organizational mechanisms, operational assumptions, modes of thought, and consequential activities involved in governing a particular area of social action". What is more, according to Irwin (2008: 585), it is important to pay attention to the circumstance that categories such as "science and technology" and "political decision-making" themselves are often interwoven with "cultural

framings and interpretations" that can refer to the notion of nation, democracy, techno-nationalism, beliefs in modernity and rationality as well as uncertainty and struggles of credibility in institutions as stressed by Ulrich Beck.

Governance and STS alike inhere the methodological preference of "follow the actors" (Irwin 2008: 584). However, the reader gets the impression that there is an overemphasis of the scientific aspects at the cost of the governing momentum of technology, respectively socio-technical infrastructures. This article alternatively suggests the term *techno-governance* in order to relate the spheres of "technology-making" and "policy-making" by language while following Irwin's argumentation though.

Basically, the term *governance* instead of *government* implies that the analysis of the development, implementation and management of technical artefacts and infrastructures will not be limited to the domain of the nation-state and governmental authorities (centralised). In contrast, the term offers a multi-actor perspective (decentralised) covering industry and business operators, academic organisations and medical institutions, patients' groups and other stakeholder, governmental authorities and legal institutions as well as the agency of the socio-technical infrastructure and distributed action between human and non-human actors (Cramer and Weyer 2008: 268; Langer and Hüther 2009: 470-473). More precisely, Langer (2009: 494-495, 527) refers to three forms of coordination of governance: That is hierarchy, exchange and competition (market) as well as solidarity and collaboration. To continue, Irwin (2008: 599) specifies the term by shedding light on several approaches well-known in STS such as (a) boundary work, (b) co-production, (b) framing, (d) networks and assemblages as well as (e) situated knowledge as a way to integrate vague sociocultural suppositions, tacit knowledge or implicit assumptions and related structure of interest and power.

a) Boundary Work

The concept of boundary work assumes that institutions and other entities defend actively their margins to preserve their integrity and autonomy in the face of external challenges, e.g. regarding their legitimacy, working priorities and practices, ways of knowledge production and property rights, funding and power, particular regarding the relationship between political actors and bureaucracy, expertise or scientific disciplines and industry states (Irwin 2008: 588).

b) Co-Production

Several STS scholars suggest the concept of co-production to encompass the "contemporaneous generation and mutual embeddedness" of Science & Technology and political order. According to Irwin (2008: 589), in every vision of the natural and social order, the state authority and political identity are reinforced as part of scientific and technological governance.

c) Framing Processes

Framing processes are part of the political agenda-setting, which encompass selection mechanisms of critical issues, decision on "relevant" evidences, and, therefore, limitations in alternative solutions, according to Irwin (2008: 590-592). Moreover, because framing processes become embedded and "disciplined" infrastructure against the backdrop of a particular socio-technical order, there exist no neutral technical system.

d) Networks and Assemblages

The actor-network theory (ANT) contributes here with the finding that agency is distributed among human and non-human actors. Similarly, the concept of "ethno-epistemic assemblage" takes the emergence of hybrid entities and new alliances into consideration, which resemble border guard organisations in

the concept of boundary work (Irwin 2008: 592-593).

e) Situated Knowledge

In a pluralistic democracy, the question arouses who is a legitimate source to produce and to provide knowledge and interpretations regarding Science & Technology. There are varying domains where citizens and public participation are welcomed (ethics, values) and where they are not accepted (specialist expertise). On the contrary, policy- and technology making are interlinked and shaped by processes of power and not limited to expert communities (Irwin 2008: 594-595). Again, the contested lines between expert and citizen science refer to the boundary work.

To summarise, STS perspectives on techno-governance comprise complementary perspectives to established approaches of industry-university relationship, innovation studies, political economy, and institution theories. Thus, the concept of techno-governance contributes to examining the field of biomedical engineering among its manifold disciplinary and institutional boundaries in Japan.[1]

Biomedical Engineering in Japan

After defining and specifying the term techno-governance, this chapter explores in which way this approach can be specified for the field of biomedical engineering in the Japanese context. Basically, the mentioned methodological preference of governance and STS implies a multi-actor-network approach. Accordingly, this article sheds light on relevant players and their

[1] This can be broadened to bio-political and bio-economic thoughts based on Michel Foucault's concept of biopower (van den Daele 2009). Also other STS scholars provide a variety of approaches such as Donna Haraway, Annemarie Mol, Nikolas Rose to mention a few (see a more detailed overview in Lengersdorf & Wieser 2014: 156, 296-272, 312-313, 331-332).

context in politics, industry, academia, as well as public health in Japan.

Hospitals and Clinics, Physicians and Patients

Medical centres and experts play a central role in the development and implementation of advanced medical technology (medicine/engineering). Owing to their immediate manipulation of the human body, medical products have to fulfil high-quality standards and long-term reliability. Therefore, mainly hospitals, clinics, as well as medical corporations purchase and utilise highly specialised and expensive engineering products. However, there seem to be differences in quality standards, product variety and prevalence of technical equipment.

In 2011, 8,605 hospitals (more than 20 beds), 99,547 general clinics (less than 20 beds) as well as 68,156 dental clinics could be found in Japan. The vast majority of these medical centres fall under the "National Health Insurance fee list" (*shinryō hōshū seido*), which is released by the Central Social Insurance Medical Council (*chūō shakai hoken iryō kyōgikai, short: chūikyō*) and controlled by the MHLW. Accordingly, medical engineering products are purchased by medical institutions through public tender (MHLW 2012: 40; Rodwin 2011: 184). Afterwards, the national health insurance reimburses barely expenditures on a fee-for-service basis (*dekidaka-barai hōshiki*) that are enlisted in the national fee schedule (Mori *et al*. 2014: 105; Lui *et al.* 2009: 12). After several reforms, patients need to pay a 30 % excess on-site to strengthen their cost effectiveness and self-responsibility, particular in the light of a rapidly aging society and fast rising health care costs (Liu *et* al. 2009: 12-13; Sakurai 2006: 41). Consequently, there is little room left for negotiation between medical institutions and manufacturers regarding the purchase of advanced medical devices. Therefore, it comes as no surprise that the demand for cheaper foreign medical devices have surged over the past years.

Paying closer attention to medical institutions, actually, four groups of persons are of significance: these are patients, physicians, medical caregivers, and the hospital management. One group that is often neglected though is the group of clinical technicians. They may grow in importance against the backdrop of a further surge for high-tech devices within clinics and hospitals in near future. Nonetheless, the scholarship predominantly reports on the hybrid role of medical experts in Japan shaped by professional duties and patient care, time pressure and limited reimbursement, social status and high reputation, commercial incentives and conflict of interest. Besides, the relationship between physicians and patients is sometimes characterised by trust and suspicion, medical expertise and lack of transparency as well as need for clinical trials but reluctance to medical trials (see in-depth Rodwin 2011). On the other hand, there seem to be public expectation in Japan to clinicians, caregivers and medical institutions to ensure a high quality in medical treatment as well as cutting-edge equipment. Surprisingly, several authors criticised that cutting-edge devices are implemented quite late in Japan in comparison to the EU and US (e.g. Altenstetter 2014: 169; Kikuchi 2007: 3). During their explanation, they refer to the neglect of the patient's right of the best treatment available, or respectively to impediments for biomedical engineering companies to earn return of investment.

Also a scheme is missing, which could provide systematic feedback from hospitals and clinical laboratories to the manufacturer, regarding reports of unintentional medical errors where devices were applied. More precisely, some authors claimed (e.g. Goydke 2007: 130) sufficient adverse event reporting (ADRs) beyond PMDA/MHLW and disclosure of these datasets is not implemented yet. Leflar (2009: 6-9, 12-14, 26) reports on several cases of fatal clinical errors and malfunctioning machines which resulted in arrestment by the police because of a "weakness of other institutional mechanism for medical quality control"

(hospital peer review committee) and a substantial smaller number of autopsies. This practice turns hospital staff into crime suspects and raise through the "intensive coverage in mass media" confrontational lines between caregivers and patients due to a search for individuals to blame (last point supported by informant, 01.04.2016). As a first step to tackle this problem, mandated standards of good clinical practice (GCP), adverse drug/device event reporting (ADRs) in the post-marketing phase have been implemented in 2013 as well as three model projects of systematic peer-review monitored by MHLW but with mixed outcomes and responses by the various stakeholders (Altenstetter 2014: 171; Leflar 2009: 31-48; Mori *et al*. 2014: 106-107). Nevertheless, the prominent role of criminal law for the regulation of medical practices and investigation with their very side effects remain prevalent for the time being.

According to Altenstetter (2014: 171), the main lobby organisation of medical experts in Japan, JMA (Japan Medical Association, *Nihon ishi-kai*) exerts enormous control by entitling experts to the Central Social Insurance Medical Council (*chūikyō*) and its subcommittees at MHLW (Altenstetter 2014: 172). This is the main reason why JMA has developed strong authority, to control standards and to influence what is recognised as legitimate scientific knowledge. Although the device gap is regularly framed as legitimate patient right for adequate healthcare in an "advanced country" like Japan, patients groups allegedly hardly have voice in the central advisory body of MHLW or other administrative bodies (Altenstetter 2014: 171). Hence, the argumentation of patient right is more of an academic nature. The figure of the "patient" is utilised more often for the purpose of "quality and safety" than in terms of "access and availability" in Japan.

Developer and Manufacturer of Medical Devices

Japan is not only one of the largest markets but has been one of the largest manufacturing countries of biomedical equipment

next to the US and Europe (Numata *et al*. 2010: 330). In 2014, the global market for medical devices amounted almost to 340.3 billion US dollar, while the Japanese market amounted to ca. 2.8 trillion Yen with an annual growth rate of 4.8 % on average since 2010 (JFMDA 2016, Internet). Japanese manufacturers perform comparatively well in market segments like diagnostic devices but the proportion of therapeutic and surgical equipment remains rather small (METI 2015: 3). What is more, in 2014, the import volume of 1.368 trillion Yen (ca. 48.8 %) outnumbers by far the export volume of 0.572 trillion Yen (JFMDA 2016). In other words, Japanese corporations provide merely half of the domestic sales.

In addition, competition became fierce in the domestic market due to the growing number of foreign enterprises after intensive liberalisation during the same period. As a result, Japanese makers began to relocate production lines to Asian countries (local/global) because of rising costs in Japan, shrinking profit margins, and the resulting preference for cheaper foreign devices (Collins 2008: 115; Himpel and Krütten 2007: 184). On the contrary, foreign companies widely benefit from lower production- and R&D costs abroad in their export strategy to the Japanese market (MEDIC 2014). Among the top 30 ranking on medical devices enterprises worldwide three Japanese companies are listed, namely Terumo, Olympus Medical and Toshiba Medical (MPO 2014). Most companies, however, are of small or medium size and functioned often as subsidiaries of large corporations or trading company for foreign manufactures (Collins 2008: 117; METI 2015: 3). Overall, Japanese manufacturers operate in an environment that is shaped by an increasingly sharp competition, and the global dominance of US and European manufacturers in biomedical engineering pose a huge challenge to Japanese companies at home and abroad.

In highly competitive and saturated markets, manufacturers

may maintain a competitive edge only by investing in R&D and developing advanced-technology products. Japan had been responsible for one tenth of the world production but faced a distinctive decline of innovation in medical engineering over the past few years (MEDIC 2014; Numata *et al.* 2010: 331). Currently, the US, Japan and EU are dominating by far fundamental research in the field of medical engineering. However, when it comes to applied R&D and the commercialisation of biomedical findings, threshold countries such as China and South Korea pose additional challenges to the competitiveness of Japanese manufactures. Japanese companies spend on average about 7.6 % of their revenues on R&D in 2011 (MEDIC 2014). This implies that Japanese manufactures need to obtain robust profits abroad because, in Japan, the return of investment will remain low and production costs high. Owing to the fact that investing in R&D causes high fixed costs, primarily large Japanese manufacturers are able to achieve economies of scales. Although some large firm like Fuji Film, Canon, or Sony have substantially increased their R&D investment in biomedical engineering (e.g. CT, diagnostic devices and endoscopes), promising R&D projects are conducted by SME (e.g. in the field of machine- and material science) (MEDIC 2014). Similarly, there are voices that large manufacturers limit their investment in R&D to such technology promising large-scale profit margins and do not contribute to the commercialisation of a wide range of medical technologies developed in research institution or medical institutions in Japan. This problem becomes intensified by the scarcity of venture capital available in Japan (Interview with med-tech associations, 25.03., 04.04.2016), which pose a huge challenge to SME, start-ups, and university spin-off in particular.

However, Numata *et al.* (2010: 331) underline that several institutional hurdles have contributed to the distinctive decline in R&D activities. Owing to the highly regulated approval and reimbursement mechanism, medical engineering companies

seem to be heavily reliant on official approval of their products and integration under the reimbursement scheme of the national health insurance. Low profit margins caused by the price-setting mechanism leaves little room for substantial return of investment and necessary R&D investment particularly against the backdrop of fierce competition from foreign corporations (Interview with med-tech association, 25.03.2016). Moreover, cost reduction policy by MHLW was not counterbalanced by strong administrative guidance in favour of economic support and innovation by METI (cost reduction/economic growth) in very contrast to other industrial sectors (Altenstetter 2014: 173). Generally speaking, the argumentation of med-tech advancement is widely accepted among developers and manufacturers but lacks sufficient political support on national level.

Linkages between Academia and Industry

Innovation activities in biomedical engineering consist of several processes and realms covering basic research, applied R&D, market analysis and conceptualisation, clinical testing as well as approval and certification, production, commercialisation and marketing within the national health insurance scheme (METI 2015: 8-9). More precisely, these processes are borne by different institutions, disciplines and organisations such as universities, research centres, manufacturers, hospitals and clinics, financing bodies and insurers. A smooth communication between them is the key to enable meaningful knowledge transfer, synergies, interdisciplinary training and sharing of expertise. Besides, Numata *et al.* (2010: 331) stress the necessity for more interdisciplinary research in academia in Japan (medicine/engineering). Particularly, joint research between clinicians and engineers were rare over the past few years and resulted accordingly in a lower level of product development. In addition, collaboration between academia and industry is essential to translate research findings into successful medical products. In

Japan, however, the OECD (2006: 75) issued prevailing "in-house R&D activities", low mobility of researcher between companies and universities, the focus on basic research at universities, lack of interdisciplinary education at universities until recently as well as the negligence of strategic applied research with biomedical engineering companies (academia/industry).

What is more, one decisive factor in biomedical engineering is the divergent innovation mode of *ikō renkei* (med-tech partnership) of "clinical needs driven development of technology seeds" compared to conventional modes of "technology seeds driven evolution of market needs" of university-industry linkages (*sangaku renkei*). Despite missing a joint definition of *ikō renkei*, the phrase points to boundaries existent between medical & engineering science, clinical workplace & manufacturing sites, technology seeds by manufacturing companies & medical needs in hospitals and alike (e.g. METI 2015: 6-7). Several reasons that seem to contribute to this situation are (Interview with med-tech association, 04.04.2016):

- research results are published in scientific journals but do not result in product development and commercial viability (missing reward in academic career path),
- manufacturing R&D activities often do no match with requirements of medical sites (*iryō genba*),
- business people have almost no access to clinical sites (*rinsho genba*) to inquire which technology is needed (lack of communication), or gain medical expertise (esp. SME),
- lack of capacities for clinical testing and clinical trials,
- effective support is missing for the development of medical devices in the various regions in Japan.

The Japanese government recently launched the concept of "special zones" (*tokui*) with facilitated condition of R&D and

commercialisation like in Kawasaki or Fukushima to encourage research collaboration (local/global) (Interview with med-tech association, 25.03.2016). However, in the past, funding was obviously provided predominantly towards prestigious universities and large companies, while most patents stem from small universities and local incubators (Collins 2008: 111, 119, Numata *et al.* 2010: 331). The situation has change to a certain extent with the establishment of AMED as governmental funding body for medical device research (see below), but several voices expressed the necessity for further improvement regarding the scope of financial resources and service available (Interview with med-tech associations, 25.03., 04.04., 08.11.2016). Particularly, the promotion of R&D activities by local authorities steadily broadens. For instance, local governments and municipalities offer grants and subsidies especially to small and medium-size manufacturers (SME) like in Tokyo, Yokohama or Saitama that seem to exceed funding on national level by far (MEDIC 2014; Interview with med-tech associations, 04.04. and 08.11.2016).

Regulating Medical Devices

At present, medical devices are regulated under the Pharmaceutical and Medical Device Law (PMDL, *iyakuhin iryō kiki tō hō*), which was revised in 2013 and renamed from Pharmaceutical Affairs Law (PAL, *yakuji-hō*) (Mori *et al.* 2014: 104). The Pharmaceutical and Medical Devices Agency (PMDA, *iyakuhin iryō kiki sōgō kikō*)established in 2004 (Mori et al. 2014: 104-106; PMDA 2014b: 7), as subordinated administrative body of MHLW, conducts approval procedures by controlling quality, efficiency and safety regarding medical equipment, drugs and tissue-engineered medical products. Basically, the legal revision led to a clarification on definition, criteria and procedures regarding medical devices that were missing until 2014 in the preceding legal act.

The approval of new medical devices depends on four

safety categories. For general devices (Class I), no further approval or certification is required. Controlled products of low risk (Class II) will be reviewed by third-party certification, which grant certifications. Devices of medium and high risk (Class III & IV) need a special approval by the Council for Highly Advanced Medical Technology (MHWL), which consists of experts for medical technology and healthcare services. After provisional approval, the new product can be deployed at designated authorised medical institutions. These institutions, which are hospitals with a high level of medical infrastructure approved by the MHLW, are obliged to report regularly to the PMDA about the quality, safety and efficacy (adverse events) of the new devices during this early post-marketing phase (Lui *et al.* 2009: 12; Mori *et al.* 2014: 104; Sakurai 2006: 42-43). Later on, the manufacturing company is responsible to report to PMDA about any adverse event. In serious cases, re-evaluation and re-examination would be conducted by PMDA, which is obliged to continuously collect such data and redistribute them among healthcare professionals. Overall, the intensive approval provides a high standard of safety and reliability but causes additional expenditures and economic risk for developers and manufacturers of disapproved devices.

Principally, the approval and clinical evaluation of pharmaceuticals follows a different logic in clinical testing than medical devices (drug/device). For instance, medical appliance testing usually does not need placebo group testing. However, pharmaceutical expertise within Japan's governmental and approval bodies as well as the content of the previous regulatory framework PAL seem to have led to a lopsided drug focus in these institutions over the past decades at the costs of medical appliances. Additionally, lengthy approval procedures contradict the rapid innovation cycles in biomedical engineering of 3-5 years. Unsurprisingly, various criticisms aroused regarding the high level of regulation for medical devices in Japan. For instance,

Sakurai (2006: 41) levelled criticism particularly at the lack of trained reviewers and the lengthy approval period until medical devices become enlisted in the national fee schedule. Moreover, Goydke (2007: 137) stressed that one fifth of all tests allegedly lead to disapproval of medical devices from abroad as well as planning uncertainty caused by continuing legal amendments. Consequently, this raised the discussion about possible non-tariff trade barriers against foreign manufacturers; an argument that was not supported anymore (Interview with large foreign manufacturers, 06.12.2016 and 10.11.2016).

Accordingly, the medical journalist Tanabe (2009: 87-88) stated that this approval practice have been sometimes called *senryoku no ijime* (bullying by authorities). MHLW and PMDA, on the contrary, justified their practices as their *kuni no seki'nin* (governmental responsibility) or emphasised their practices as "*sekai ni rei wo minai sēfuti toraianguru*" (a safety triangle without precedence in the world) by pointing to the three elements of *shinsa* (review procedures), *anzen taisaku* (safety measures) and *kenkō higai kyūsai* (rescue from damage to health). Nevertheless, the focus on drug safety can continuously be observed to some extent. The author argues that this logic might stem from the previous fatal incidences caused by pharmaceutical scandals such as SMON disease (1979), Sorivudine (1993) or aids scandal (1980s and later) (safety/risk).

As response, the Japanese government adopted a 5-Year-Plan in 2007 to reduce the lengthy approval procedure. Thereafter, the PMDA have obviously increased the number of their review staff from 256 people to 700 experts (2004-2014). Among them, 50 medical experts and, at present, around 14 experts on biomedical engineering were newly employed (drug/device) (Mori *et al.* 2014: 104; Interview with informant, 01.04.2016). Consequently, the approval time dropped slightly from 14.4 to 12.7 months (standard), resp. 28.8 to 9.3 months (priority reviews) between 2008 until 2012 (Kondo 2013). Moreover,

Ikeno, Ikeda and Uchida (2014: 1-2) argue that approval time has been dropped over the past few years. Nonetheless, they still criticise PMDA for the lengthy "pre-submission delay" caused by uncertainty of required data, "under-recognition of clinical trials for industries", "slower accomplishment of clinical trials", asynchronous trials between the US and Japan, and lower priority of the Japanese market. On the other hand, the approval practices between FDA (Food and Drug Agency, US) and PMDA seem to resemble already largely. The acceptance of remaining risks by Japanese patients stays at a very low level compared to EU and US. More precisely, in cases where the benefit from new devices reach around 90 per cent for patients in need, (acceptable) risks of 10 per cent will allegedly not be accepted though. This circumstance is further intensified by the ambiguity about to what extent manufacturers have exclusion of liability (*menseki*). However, the dominant feature of "*shippai wo yurusanai*" (unforgiving of unintended errors, often referred to as "culture of blaming"), obviously prohibits a constructive dealing with unintended malfunctioning of medical devices and undermines strictly any political discussion on that issue (Interview with informant, 01.04.2016).

Besides, MHLW uses the reimbursement scheme to exert control to strengthen cost efficiency in healthcare spending (cost reduction/economic growth). Due to the universal coverage (above 90%) of the Japanese national health insurance, engineering enterprises need to get their medical products enlisted under the national fee-list in order to receive reimbursement and earn profits. Since 1994, MHLW have been able to cap healthcare expenditures substantially. Consequently, spending grows very moderate in Japan at present (10.2 % of GDP that almost equals OECD average, 2014). In other words, Japan performs well by slowing down its healthcare spending, and MHLW expects only a moderate increase in near future (MEDIC 2014). On the other hand, official statistical data supports the finding that medical

devices can be neglected as driver for growing healthcare costs in Japan, in contrast to physicians' fees, elderly care and drug dispensing (Ikegami and Campbell 2004: 26-29; Lui *et al.* 2009: 16; MHLW 2012: 33-34).

Medical Device Policy

Although there are manifold incentives for technological advancement, innovation-friendly policy are essential. However, METI and MEXT (Ministry of Education, Research and Technology, *monbu kagaku-shō*) did not perceive biomedical engineering as key industrial sector until recently despite having known about declining innovation activities. This finding surprises because it contradicts technology policy in other segments such as automotive, robotics, or semiconductor, where administrative guidance and leadership by METI were found more common. Even though MHLW collaborates with METI and MEXT regarding science, technology and innovation (STI) policies, both ministries hardly took a lead over decades in counterbalancing declining innovation activities in the biomedical engineering sector. Due to this reason, the sector has been left to the working priority of MHLW and its focus on cost reduction and strict safety. Various authors (Kikuchi 2007: 3; Numata *et al.* 2010: 331, 336) have stressed the bureaucratic sectionalism, the incoherent national R&D strategy and inconsistent research funding as major causes for the current situation. According to them, these were the major causes why little integration between fundamental- and applied R&D has been achieved, and less joint research between academia and industry have taken place so far.

In contrast, in the US, the government has encouraged innovation activities in medical engineering over the past 30 years. In the EU, medical engineering has been established as key sector and supported at least 10-20 years ago. In Japan, however, not before a consortium of industry, medical experts and academia came together and formulated their very own

national strategy. More precisely, the consortium initiated the Medical Engineering Technology Industrial Strategy (METIS, *iryō gijutsu sangyō senryaku*) in 2000 to foster R&D and production in medical engineering in Japan (METIS 2014; Numata *et al.* 2010: 331). Although there have been several action plans by MHLW, METI and MEXT, a substantial shift has taken place rather recently with the distinctive leadership of Prime Minister Abe Shinzō by integrating biomedical engineering in Japan's Growth Strategy (Abenomics). In 2007, for instance, the Japanese government included the medical engineering sector in its national strategy ("Innovation 25") and moved the lead to the Cabinet Office in an effort to reduce institutional sectionalism and lacking collaboration among the various administrative bodies. The Cabinet Office forced METI and MEXT to offer more funding for basic and applied research and work closer with MHLW (Altenstetter 2014: 123, 127). Similarly, medical devices became part of the focus area "healthy and active ageing society as a top-runner in the world" regarding the Comprehensive STI Strategy and Japan Revitalisation Strategy in 2013 (CAO 2007; METI 2016). More precisely, in both documents the following points are listed among others:

- reinforcing industrial competitiveness in the areas of pharmaceuticals and medical devices,
- establishing a control centre for R&D in medical field (see AMED)
- to reform regulation for accelerating development of drugs, medical devices, and regenerative medicine as well as for strengthening the Pharmaceuticals and Medical Device Agency (see PMDA above),
- "developing future health care", "expansion of advanced medical care" and "global expansion of medical care"
- realisation of "robot revolution: medicine and nursing care (including ICT and robot solutions", and "developing

> BMI [brain machine interface] and devices for medical care and nursing at home".

Most recently, in line with the Japan Revitalisation Strategy, the government established the Japan Agency for Medical Research and Development (AMED, *Nihon iryō kenkyū kaihatsu kikō*) in April 2015 (AMED 2015, Internet), which operates under the authority of Headquarters of Healthcare Policy (*kenkō iryō senryaku suishin honbu*) at the Cabinet Office. This administrative body allocates budget from MEXT, MHLW, and METI, which exemplifies the intention to launch a coherent scheme for the biomedical engineering sector and medical research in general (Interview with governmental body, 23.03.2016). Among others, one major goal reads as follows: *"renkei" ni yoru "jitsuyōka" no suishin* (practical utilisation through fostering partnerships) to overcome institutional and disciplinary boundaries among medical centres, academia and manufacturing companies as well as among medical and engineering science by providing funding, matching schemes, training, consultancy on regulatory and business affairs. The continuing emphasis by interest groups stressing the divergent mode of innovation as well as the growing complexity of medical technology supported the reorganisation. Even though several associations appreciating the recent organisational changes, voices remain that the scope of measures needs further increase in terms of financial resources but also platforms for exchange between manufacturers and clinicians (Interview with med-tech associations, 25.03., 04.04.2016).

Foreign Pressure for Market Access and Harmonisation of Standards

Japan has been identified as one of the largest market worldwide for medical devices by foreign corporations as well as exports have grown in importance for Japanese manufacturers. Furthermore, the varying approval practices in target markets abroad provide additional constraints for Japanese manufacturers. One

prominent example is the strategy to seek the EU CE mark[2] first in order to deal with lengthy approval by PMDA in Japan. In other words, lengthy approval together with expensive clinical trial can easily result in financial pressure up to bankruptcy particularly for SME.

On the contrary, the Japanese government and ministerial bureaucracy were pressured by a strong US lobby and by the EU for international harmonisation (Altenstetter 2014: 91, 130). Consequently, Japan implemented the ICH's Good Clinical Practice Consolidated Guidelines in 1996 for drugs, and applied them for medical devices in 2004. In 2007, MHLW started to acknowledge foreign clinical data for medical devices in the case the evaluation standards conform or are even stricter than Japanese ones. The Japanese Global Harmonization Task Force (GHTF) was broken up in 2011. Since then, the International Medical Device Regulatory Forum has took its place, wherein the EU und US are continuously pushing Japan to harmonise its regulatory framework, approval processes, evaluation standards, criteria of good clinical practice, adverse event reporting and reimbursement scheme to achieve similar access to the Japanese market. More precisely, Japan did adapt various med-tech standards, implemented by the European Union as the CE-marking, while being pressured mostly by US med-tech lobby towards fair competition and market access. One result of harmonised clinical standards may be that medical centres within Japan are allegedly more frequently involved in clinical trials and applied R&D with foreign corporations than domestic

[2] The CE mark for medical devices is based on harmonised standards within the EU member states, which are specified in the Medical Device Directive (MDD of EU Council Directive 93/42/ECC from 1993 and consolidated in the Directive 2007/47/EC), https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/medical-devices_en (accessed on 28. Dec 2016). The faster mechanism contains declaration of conformity regarding safety and efficacy of medical products, which distinctively differ from procedures in Japan and in the US. However, the hurdle to be accepted under the reimbursement scheme remains though.

firms (Goydke 2007: 130; MEDIC 2014).

As Altenstetter (2014: 176) puts it, Japanese actors already moved in the direction of US and European standards. And elsewhere, the author (Altenstetter 2014: 149-151) argues, acceptance of "clinical evidence for drugs and medical devices is not necessarily the same to Japanese, American, or European pharmaceutical or medical device experts". This argumentation is supported by findings on the divergent concept of safety and accepted risk-benefit balance by the Japanese patient (Interview with informant, 01.04.2016). Apparently, processes of boundary work and framing can be observed among international actors with different belief systems and working priorities. Notwithstanding, the PMDA (2015: 4) underlines in its International Strategic Plan 2015-2023 its eagerness to intensively cooperate with "overseas regulatory authorities for expansion of harmonization activities and […] work sharing" such as International Medical Device Regulators Forum (IMDRF), Quality Management Systems (QMS), Good Manufacturing Practice (GMP) as well as ISO/IEC (International Standard Organisation/International Electrotechnical Commission) "so that such standards reflect the ideas from Japan, which may result in rationalized/expedited review".

Concluding Remarks

Altogether, the article casted light on relevant actors who shape innovation activities in biomedical engineering in Japan. Altenstetter (2014: 111, 176), for instance, concludes in her book on regulation policy of medical technologies "MHLW has been and ultimately remains in control of how these and other scientific and technical issues are framed, debated, and finally settled." Moreover, later, "what works in the EU and the United States, […], does not necessarily work in Japan, because of substantial differences in institutional arrangements and

traditions of public management and law". While already paying attention to the mechanism of framing, norms and values and alike, these remarks shall explicate these processes in order to enhance a systematic analysis integrating aspects of boundary, co-production, framing, network & assemblage, and situated knowledge as well.

Contested domains in the field biomedical engineering in Japan	
Contested margins	Affected domains or features
cost reduction/ economic growth	price-setting mechanism, reimbursement, national funding, leadership by MHLW, METI, MEXT or Cabinet Office
drug/device	regulatory environment, approval practices
patient/physician	clinical trials, acceptance of risk, transparency, informed consent, ethics
industry/academia	research collaboration, intellectual property, collaboration among academia, hospitals & manufacturers
safety/risk	regulation, risk-benefit balance, hospital practices, public/patient's acceptance
medicine/engineering	interdisciplinary research, training, academic education, funding scheme among administrative body
local/global	international harmonisation of regulation and standards (e.g. good clinical practice, clinical trials), global competition and regional revitalisation

Accordingly, the table provides a short listing of the contested margins in various domains. They arouse an assemblage of manifold factors influencing development and diffusion of medical devices in Japan. The readers stumble upon bio-economic arguments of cost efficiency in healthcare spending, negotiation of safety-risk balance, framing of access to advance technology and medical treatment as patient rights in contrast to

the non-acceptance of acceptable risk for new devices ("culture of blaming"). On the other hand, one can observe the frequent absence of patient interest in central committees and the struggle of bureaucratic sectionalism, which partially explains the device gap. Only recently, has biomedical engineering moved from the cost reduction frame to stronger innovation emphasis under the lead of Prime Minister Abe (economic growth). However, the framing as patient rights, however, did not emerge. In addition, foreign players adapting different working practices in product approval and clinical trials contest regulatory practices and standards. To conclude, the aspect of boundary work, coproduced governance practices, framing, and legitimate knowledge seem to provide the most explanatory power to enhance the study of innovation activities from a governance perspective regarding biomedical engineering in Japan.

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