PMAC 2025 Background paper

In response to the rapid development of AI (Artificial Intelligence), the Japanese government has been reviewing the current status and issues of AI policy. Japan has been working on a set of issues based on the vision and goals agreed upon at the 49th G7 Summit (Hiroshima Summit) in 2023. To date the "AI Strategy 2022[[1]](#footnote-1)" and "Social Principles of Human-Centric AI[[2]](#footnote-2)" have been established and these documents are published on the Japan Government website. In addition, the "Tentative summary of AI issue (Provisional Translation)" was released in May 2023, summarizing the issues and directions with a focus on generative AI, after the production and discussion of the issues to date.

While Japan's technological capabilities, changing social structure, and needs for digitalization have affinity with the advancement of AI technologies, it is necessary to address risks of these technologies so that people can feel sense of security and predictability in the rapidly changing society. In addition, infrastructure should be developed to facilitate the activities of industries and researchers who will actually drive AI technology.

AI respects no national borders, and it can be easily distributed across borders, which means AI can exert its influence all around the world. Therefore, addressing its risks is not just a matter of one country or one region responding to them, but also requires international cooperation and coordination. The Japanese government emphasizes the need to play a leading role in international rulemaking and to lead discussions to enhance international common understanding and interoperability. This includes appropriate addresses for risks to the development, provision, and promotion of AI technologies, as well as rapid and agile responses involving multiple stakeholders. An interim summary on this point is expected this autumn[[3]](#footnote-3).

In Japan, there have been various discussions about the risks posed by AI. For example, Japanese government released "Social Principles of Human-Centric AI2" in 2019, which describes the risk of social instability and confusion due to disinformation, the risk of sophisticated and facilitation of crimes, political disruption by using image generation and synthetic voices, the disparity in literacies and capabilities between people, such as those who can utilise AI and those who cannot.

“The Provisional summary of AI issues[[4]](#footnote-4)” released in May 2023, enumerates more detailed and specific risks, and encourages stakeholders to take necessary actions by providing directions for responses to them. It emphasizes the importance of AI developers, service providers, and users assessing risks and exercising governance functions themselves. it also emphasizes the importance of considering and implementing frameworks for responding to these risks by various stakeholders, including the government. The report recommends that measures should be considered with reference to legislative frameworks set out in other countries for those risks that may not be adequately addressed by existing legal frameworks in one’s own country. Active participation in international discussions is therefore necessary to this end.

Regarding measures to utilise AI in the healthcare sector in Japan, several discussions have continued to take places and the Ministry of Health, Labour and Welfare (MHLW) established the “Advisory Group for the Promotion of AI Utilisation in the Healthcare Sector” in 2017 and compiled a summary report[[5]](#footnote-5). The report states that AI (deep learning, machine learning and others) will be utilised to create new diagnostic and treatment methods, create an environment where people can receive the latest medical care anywhere in Japan, and reduce the burden on medical and nursing staff. In order to tackle these challenges, six priority areas (genomic medicine, image diagnosis support, diagnosis and treatment support, drug development, nursing care and dementia, and surgical support) were chosen in which AI development should be promoted to demonstrate the strengths of medical technology in Japan and to solve issues in the Japanese health and medical field. Alongside with this, the report also states the necessity for developing an infrastructure to promote the development of AI and rules to ensure the quality and safety of AI and for a system to collect real world data which are necessary for the development of healthcare AI covering the whole country, as well as the need for the development and verification of a cloud environment for AI development.

The MHLW is continuing to discuss the contents of this report in the “Consortium for Accelerating AI Development in the Health and Medical Fields”, which is considering the ways to promote AI development and utilisation in the healthcare sector, taking into account the AI Strategy 2022 and other policies mentioned above. The Pharmaceuticals and Medical Devices Agency (PMDA), which is the regulatory authority for pharmaceuticals and medical devices in Japan, has close link with diagnostic imaging support mainly, so I will talk on this point. Before that, I would like to introduce an overview of the PMDA.

In Japan, the Pharmaceuticals and Medical Devices Agency (PMDA) and the MHLW are responsible for administrative measures for pharmaceuticals and medical devices under the Pharmaceuticals and Medical Devices Law. The PMDA is responsible for analysing and providing important scientific evidence, whilst the MHLW, on the other hand, is responsible for taking final administrative measures based on these scientific bases.

PMDA plays three key roles- relief services for person injured by adverse reactions to drugs and regenerative medical products, product reviews, and safety measures, which we call as “Safety Triangle”. PMDA is engaged in ensuring the quality, efficacy and safety of medical products- drugs, vaccines, biologics, medical devices and regenerative medical products, from development to post-market stages, in order to provide citizens and healthcare professionals with rapid access to safer, more effective medical products, and to ensure their safe use.

In 2024, PMDA is celebrating its 20th anniversary and making its purpose as “Making everyone’s lives brighter together”. Based on this new purpose, I am confident that PMDA is going to contribute to make peoples all over the world live brighter, together.

PMDA's Fifth Mid-Term Plan (FY2024-FY2028) states that "PMDA will further extend its international comparative advantage through the establishment of overseas offices for developing the Safety Triangle mechanism which is three pillar system unique to Japan. PMDA will promote strategic international activities to establish itself as a reliable “reference country” for Asian regulatory authorities. PMDA established PMDA Asia Office in Bangkok, Thailand in July 2024 and PMDA also opened the PMDA Washington, D.C. Office in November 2024. The two offices are expected to strengthen regulatory cooperation and promote the exchange of regulatory information by closely connecting and facilitating dialogue with stakeholders not only in Japan but around the world.

The use of AI technology in health has several aspects, for example, use of AI as medical device that assist in diagnosis in clinical setting and as data analysis in R&D stage allowing the utilization of medical information accumulated in hospitals as valuable data resource. Regulatory challenges will differ depending on how AI is used. When using AI in medical data analysis, informed consent and protection of personal information may be the key challenges. From Japan’s experience, issues surrounding market authorization of Machine learning-enabled Medical Devices (MLMD) will be shared along with regulation in the US and EU.

The points considered during the review process of MLMD are basically the same as conventional MD. However, there are two special properties of MLMD that requires consideration: plasticity and unpredictability. Plasticity is a property that may change (e.g. performance) as AI learns (post-market). Unpredictability is a property that are unknown (e.g., whether the device has bias or not). Pharmaceutical regulations are not compatible with the products’ plasticity since they require re-approval/certification when changes are made after approval. A review scheme (called “IDATEN”) for timely evaluation for review is implemented in Japan to partially deal with the plasticity of MLMD.

Several guidance documents have been developed to facilitate development and appropriate evaluation in medical devices approval/review process.

In US and EU, the medical devices utilizing AI are also regulated basically the same as other MD, no AI-specific regulation but specific notices and guidance documents on AI exists. However, when considering Large Language Modes (LLM)- based health applications, the situation is more preliminary. At present, more than 40 products have been approved for software as a medical device (SaMD), whereas no product have received regulatory approval as LLM-based health application in Japan. Despite the fact that the LLM-base health applications are already marketed, none of the product seems have been approved by any regulatory authorities.

As described above, regulatory authorities are still in the process of exploring the appropriate pharmaceutical regulations for AI-based medical devices, and continued discussions in the global setting are needed. PMDA is going to actively utilise global forums and other opportunities to support the research and development of AI-based medical devices and contribute to the healthier lives of people around the world.

1. AI Strategy 2022 (tentative translation) <https://www8.cao.go.jp/cstp/ai/aistratagy2022en.pdf> [↑](#footnote-ref-1)
2. Social Principles of Human-Centric AI <https://www8.cao.go.jp/cstp/ai/humancentricai.pdf> [↑](#footnote-ref-2)
3. AI strategy <https://www8.cao.go.jp/cstp/ai/> [↑](#footnote-ref-3)
4. TENTATIVE SUMMARY OF AI ISSUES <https://www8.cao.go.jp/cstp/ai/ronten_youshi_yaku.pdf> [↑](#footnote-ref-4)
5. Report by Advisory Group for the Promotion of AI Utilisation in the Healthcare Sector (Japanese only) <https://www.mhlw.go.jp/file/05-Shingikai-10601000-Daijinkanboukouseikagakuka-Kouseikagakuka/0000169230.pdf> [↑](#footnote-ref-5)