Pharmaceuticals and Medical Devices Agency (PMDA)
独立行政法人　医薬品医療機器総合機構

PMDA facing towards “Drug-induced Suffering”

- Exhibition Room for Remembrance of History of Drug-induced Suffering in PMDA -

24th August, 2021

1. Adverse drug reactions and “drug-induced suffering”

As is well known, drugs can generate therapeutic actions (efficacy) as well as unfavorable ones (adverse reactions).[1]

We have seen cases of health damage following the use of pharmaceutical products, known as “YAKUGAI” (drug-induced suffering), which have caused social problems with tragic sufferers. Drug-induced suffering differs from sole adverse reactions being experienced by individual patients who have taken particular drugs.

For example, thalidomide, which was marketed as a hypnotic or gastrointestinal drug around 1960, caused birth defects of limbs (“phocomelia”), ears (hearing), internal organs, and so on in children born to women who had taken the drug in the early stages of their pregnancy. Chinoform, which people in the 1960s took as an antiflatulent, caused subacute myelo-optico-neuropathy (SMON). SMON involved generalized numbness, pain, and visual impairment, and was initially suspected to be associated with an unclear infectious disease. Thus, it resulted in delayed investigation to identify its cause, which increased the number of victims.

Various pharmaceutical regulations have been introduced and updated so far based on latest science and knowledge in order to prevent the recurrence of such devastating drug-induced sufferings. This has improved assessment of drug safety, including the requirement of animal testing to check fetal effects before approval and the establishment of a post-marketing system to monitor onsets of adverse reactions (adverse drug reaction reporting system), which cannot be achieved only by one country. Today, the regulations introduced to ensure the quality, efficacy and safety of pharmaceutical products have been meticulously implemented for the development, review, and post-marketing stages; many regulations have mandated globally harmonized, stringent requirements.

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[1] https://www.mhlw.go.jp/bunya/iyakuhin/yakugai/data/yakugai_print.pdf (Japanese)

To prevent the recurrence of devastating drug-induced suffering, it is also important to implement and comply with these regulations thoroughly, to understand its history and the lessons learned from it, and to make conscious efforts continuously to prevent it while carrying out pharmaceutical regulatory affairs.

2. Opening of the Exhibition Room for Remembrance of History of Drug-induced Suffering

On 30th March, 2020, the Pharmaceuticals and Medical Devices Agency (PMDA) opened the "Exhibition Room for Remembrance of History of Drug-induced Suffering."[2]

The room exhibits documents and facts on its history and the lessons learned, in order to raise public awareness. Visitors can find visual panels that summarize the history of drug-induced suffering in Japan there; the causes, adverse health effects, lessons learned, and other relevant information. In addition, the "sashes" used during the lawsuits, drug bottles, related books, educational films, and video testimonies of the sufferers are included in the exhibition.

Around one year and five months have passed since the room's opening, and 284 people have visited it so far (as of the end of July 2021), even under the COVID-19 pandemic. This demonstrates a high level of public interest in the history of drug-induced suffering.

3. Monument of Oath and the efforts to eradicate drug-induced suffering

In front of the main entrance of the Ministry of Health, Labour and Welfare, the "Monument of Oath" (established on 24th August, 1999) is located, which has an inscription encouraging continued efforts to ensure the safety and efficacy of pharmaceutical products and prevent the recurrence of devastating drug-induced suffering.[3]

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[2] https://www.pmda.go.jp/about-pmda/exhibition-room/0001.html (Japanese)
[3] https://www.mhlw.go.jp/seisakunitsuite/bunya/kenkou_iryou/iyakuhin/chikainohi/ (Japanese)

With this determination, the PMDA has been contributing to the assurance of quality, efficacy, and safety of the products including drugs and medical devices through reviews of approval applications based on the latest scientific knowledge, as well as timely and appropriate safety measures based on the post-marketing safety data collected. 24th August, the date the monument was erected, is recognized as the Day for the Eradication of Drug-induced Suffering in Japan. Every year on this day, I, as a leader of PMDA, remind all PMDA employees drug-induced suffering, and we renew our determination to ensure that this tragedy is never repeated.

The PMDA is continuing to fulfill its responsibility to promptly deliver safe and effective pharmaceutical products to the patients while never forgetting the drug-induced suffering of the past.

4. My last words

To prevent drug-induced suffering, it is essential that those involved with pharmaceutical products understand its history and the lessons learned. I, as a responsible to PMDA, sincerely look forward to having many of you visit the PMDA's Exhibition Room for Remembrance of History of Drug-induced Suffering.[4]

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[4] Business days/hours: Monday through Friday/11 am to 4 pm (except for national, year-end, and New Year's holidays); Admission fee: free; Location: 14th floor, Shin-Kasumigaseki Building, 3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100 -0013, Japan (Due to the COVID-19 pandemic, entry to the exhibition room is currently allowed through advance reservation only. Please check the exhibition room website before visiting for any change or update regarding the business days, etc.)