独立行政法人 医薬品医療機器総合機構

For more and closer communication with Patients - PMDA's efforts for patient satisfaction –

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One of the PMDA's priorities is to communicate with patients. In particular, patient satisfaction is tremendously important to pursue PMDA's fundamental role. In general, needs and feedbacks from patients have already been utilized in the area of post-market safety through Adverse Drug Reaction report, and they are also expected to contribute to streamlining medical products research and development. PMDA has been actively working to listen to their voices and to reflect them to improve PMDA's services further and effectively.

In addition, as the spread of unreliable public health information through social media during the COVID-19 pandemic has become a pressing urgent issue, it is growing importance that reliable and accurate information with plane language is to be conveyed to patient and public in a timely manner. We, PMDA, as a national regulatory authority, are working a wide range of efforts to deliver significant information to patients based on scientific evidence.

Here, I would like to introduce our current efforts on communication with patients.

1. Enhancement of the PMDA website contents for patients and consumers

To promote appropriate use of drugs and other medical products, PMDA provides general Q&A on drugs and a free consultation service on drugs and medical devices for patients. The "Guide for People Receiving Vaccinations" is also available on the PMDA

website to promote proper understanding of various vaccines among persons who receive vaccinations and their families. We are reviewing our website to provide more valuable information with plane language for patients along with their voices.

PMDA has also been providing information on adverse reactions and raising awareness to Patient Reporting of Adverse Drug Reactions for further enhancement of post marketing safety measures for drugs.

2. Relief Services for Adverse Drug Reactions

Relief services for adverse drug reactions are another activities that can allow us to listen to patient's voices. For recipients of the relief services and their families, PMDA conducts consultation services that address issues including mental matters. PMDA also conducts a study activity concerning QOLs for those who suffer from serious and rare adverse health reactions associated with drug products.

Furthermore, we conduct a wide range of activities to raise awareness on relief services such as through brochures, YouTube and TV broadcasts.

3. Patient Centricity Working Group

In order to incorporate patients' voices in PMDA's activities such as drug review and post-marketing safety measures, PMDA has been working to raise awareness for Patient and Public Involvement. The basic concept is to collect opinion and knowledge from patients actively and systematically, and to enhance the provision of information for patients.

For this purpose, PMDA established the "Patient Centricity Working Group", and its splendid first draft guidance will be released soon.

Regulators often use the word 'Communication'. I recognize this means two ways, as they should be reciprocal exchanges of information and thoughts. Regulatory authorities provide lots of information to patients and the public in their own country. But they are not subject to reviews by citizen as usual manner. Such one way provision

is not true 'communication' with public. We, PMDA, would like to promote communication with patients and to improve our services for more patient satisfactions in order to achieve PMDA's ultimate goal for people's sound health.

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