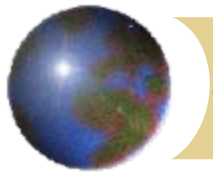


Opening Remarks

Tatsuya Kondo, M.D., Ph.D.

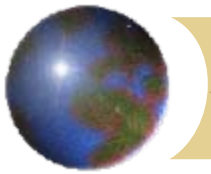
Chief Executive, PMDA (Japan)



PMDA's New Goals

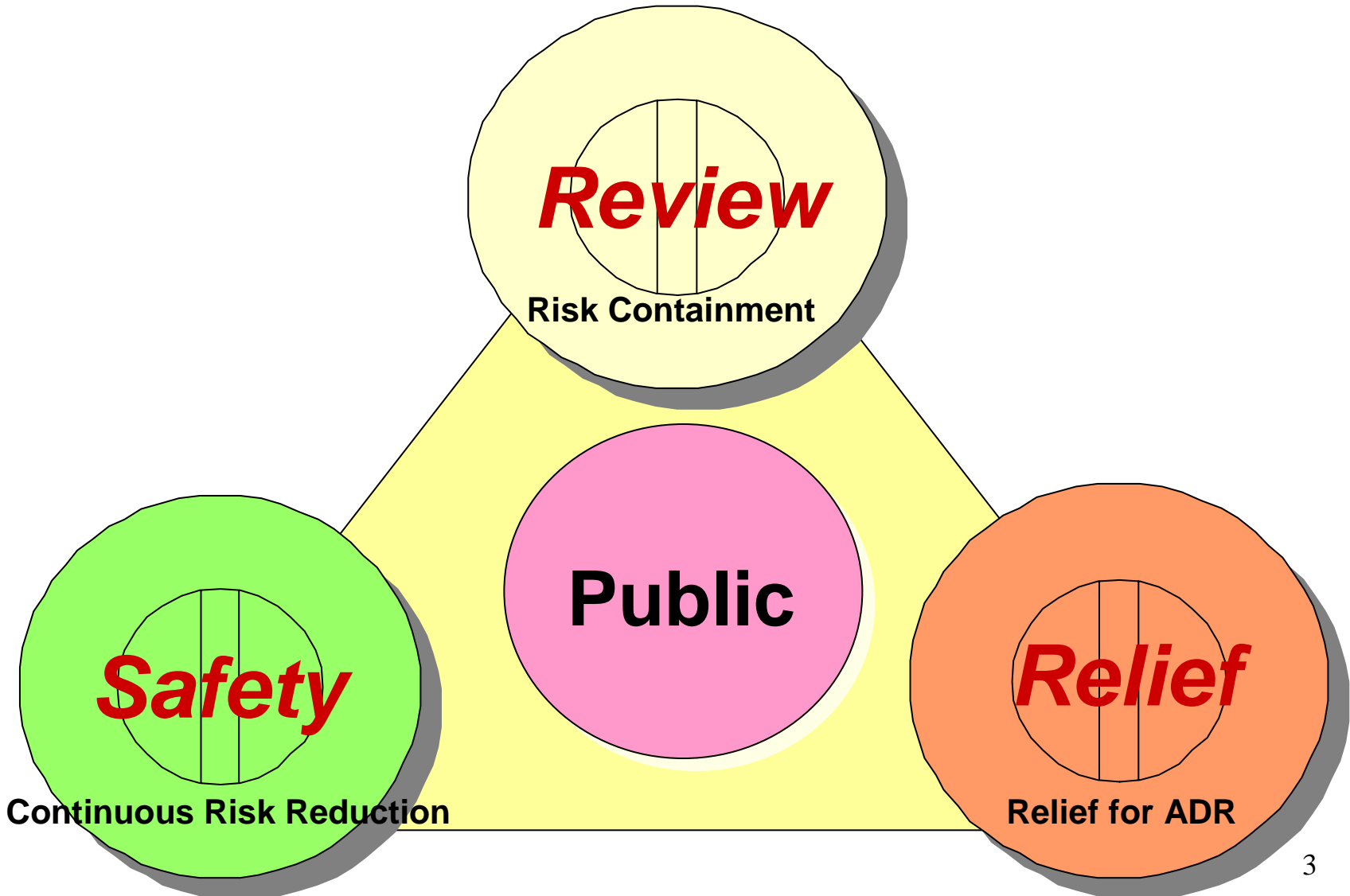
Second mid-term plan (FY2009~2013)

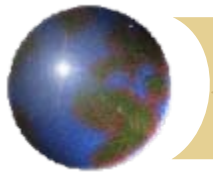
- 1. Eliminate the issue of “Drug Lag /Device Lag” to a level comparable to that in EU and the U.S.**
- 2. Improve Post-marketing safety measures for ensuring public safety and reassurance**
- 3. Advance Regulatory Science (promote Joint Graduate Education Program)**
- 4. Improve and strengthen International Programs**



Safety Triangle

Total Risk Management through three work areas





Our philosophy 行動理念

PMDA continues to improve the public health and safety of our nation by reviewing applications for marketing approval of pharmaceuticals and medical devices, conducting safety measures, and providing relief to people who have suffered from adverse drug reactions.

We conduct our mission in accordance with the following principles:

わたしたちは、以下の行動理念のもと、医薬品、医療機器等の審査及び安全対策、並びに健康被害救済の三業務を公正に遂行し、国民の健康・安全の向上に積極的に貢献します。



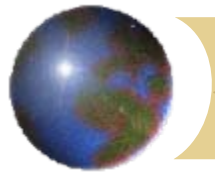
Our philosophy

- **We pursue the development of medical science while performing our duty with greater transparency based on our mission to protect public health and the lives of our citizens.**

国民の命と健康を守るという絶対的な使命感に基づき、医療の進歩を目指して、判断の遅滞なく、高い透明性の下で業務を遂行します。

- **We will be the bridge between the patients and their wishes for faster access to safer and more effective drugs and medical devices.**

より有効で、より安全な医薬品・医療機器をより早く医療現場に届けることにより、患者にとっての希望の架け橋となるよう努めます。



Our philosophy

- We make science-based judgments on quality, safety, and efficacy of medical products by training personnel to have the latest technical knowledge and wisdom in their field of expertise.

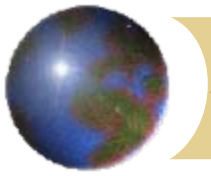
最新の専門知識と叡智をもった人材を育みながら、その力を結集して、有効性、安全性について科学的視点での的確な判断を行います。

- We play an active role within the international community by promoting international harmonization.

国際調和を推進し、積極的に世界に向かって期待される役割を果たします。

- We conduct services in a way that is trusted by the public based on our experiences from the past. ⁶

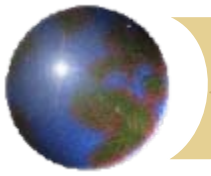
過去の多くの教訓を生かし、社会に信頼される事業運営を行います。



**In pursuit of this philosophy,
PMDA promotes many kind of
international programs**

PMDA理念に基づき

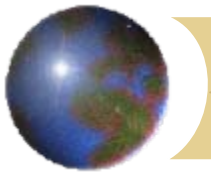
世界のPMDAへ



PMDA 3rd International Symposium on Biologics

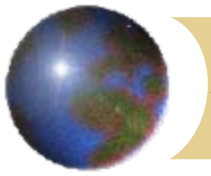
The Theme of the Symposium

**“Follow-on biologics”
(Biosimilar)**



The Purpose of this Symposium

- Form an international platform for quality, efficacy and safety of biological products.
- Offer an opportunity to exchange opinions on biological products and to think a direction for the future among representatives from regulatory authorities and industry.
- Promote and advance the R&D activities and approval review on biological Products



Let's exchange the knowledge and experience through earnest discussion.

熱心な議論により 叡智の交換をしたい

