ICH GL Update: M4Q (R2) Expectations from an Industry Point of View

Hiroshi Ohtsuka

(JPMA, Bayer Yakuhin Ltd.)

The views and opinions expressed in this presentation are those of the presenter and should not necessarily represent the views and opinions of the relevant organizations.

Outline

- Missions of Pharmaceutical Industry
- Benefits of Revised M4Q
- Industry Expectations
- Considerations as industry

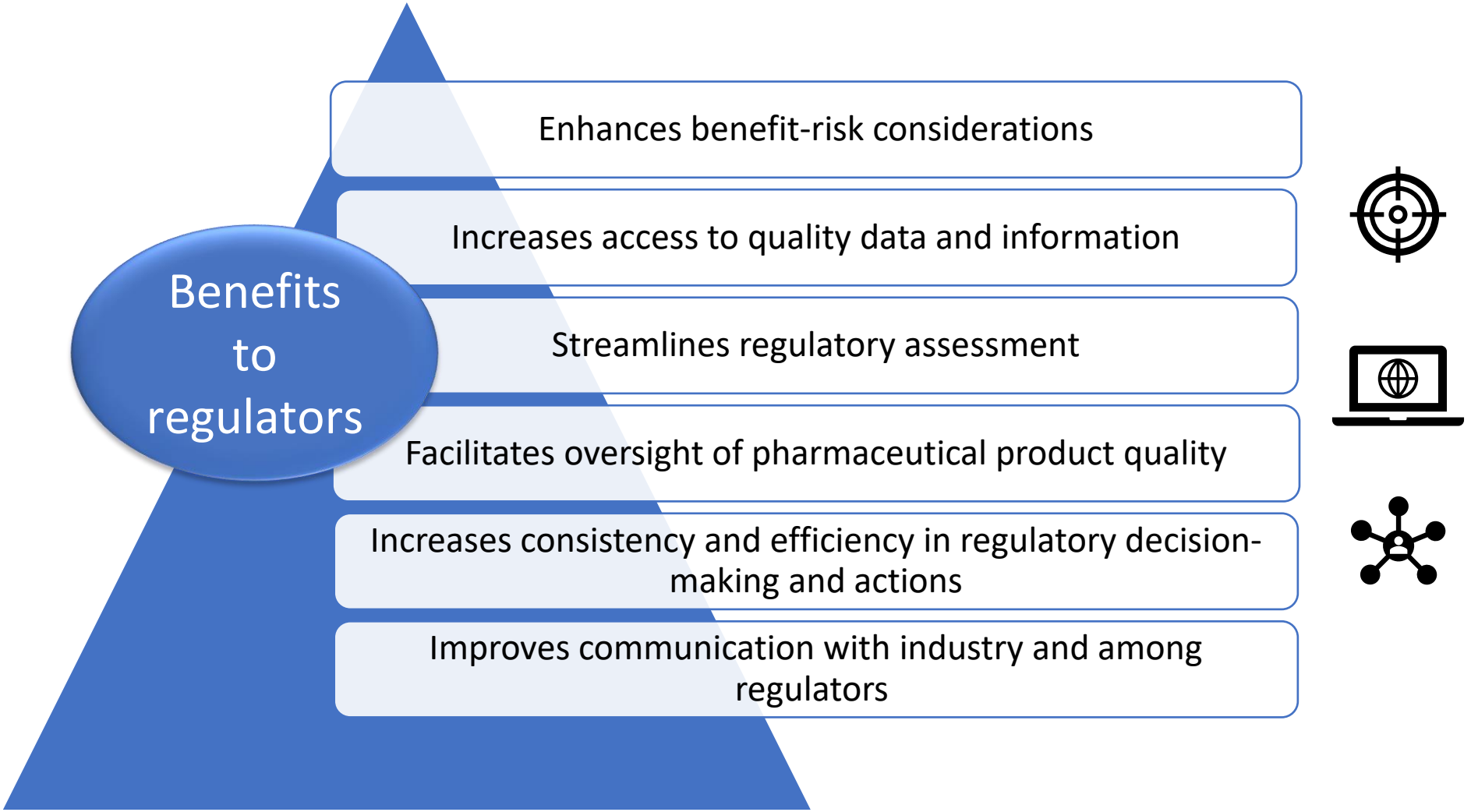
Missions of Pharmaceutical Industry

Five major missions of the pharmaceutical industry (by ChatGPT based AI):

1. **Research and Development (R&D)**: Innovating and developing new drugs and therapies to address unmet medical needs and improve patient outcomes.
2. **Regulatory Compliance**: Ensuring that all products meet safety, efficacy, and quality standards set by regulatory authorities to protect public health.
3. **Access to Medications**: Working to improve access to essential medicines for patients globally, especially in underserved populations.
4. **Sustainability and Ethical Practices**: Committing to ethical practices in drug manufacturing and distribution, as well as promoting environmental sustainability in operations.
5. **Patient Education and Support**: Providing information and resources to help patients understand their medications and manage their health conditions effectively.

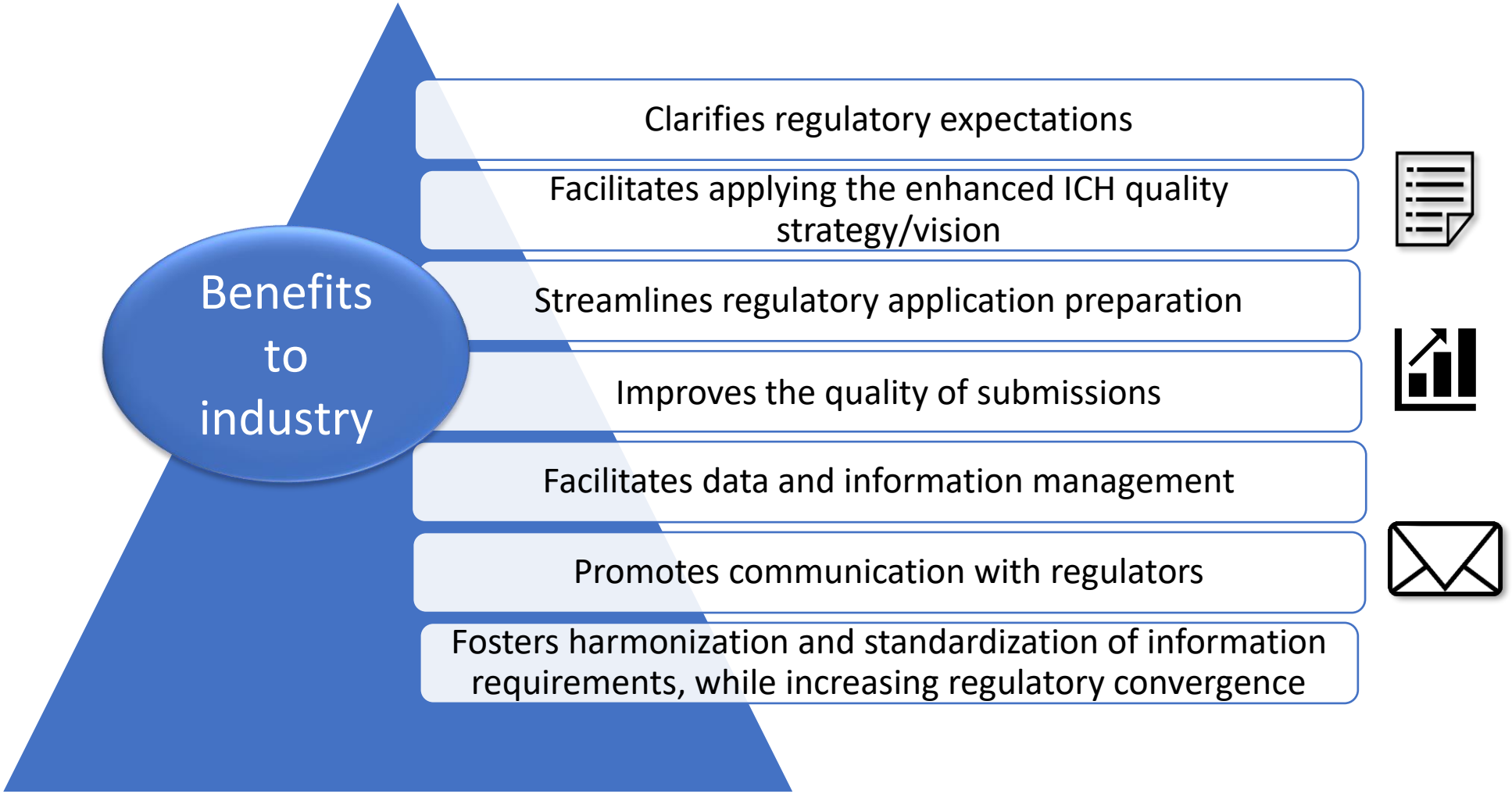
Benefits of Revised M4Q to Regulators

JPMA



Benefits of Revised M4Q to Industry

JPMA



Benefits of Revised M4Q to Patients and Consumers

JPMA

Benefits to Patients and Consumers

M4Q(R2) guideline would speed up patients and consumers' access to pharmaceuticals

Industry Expectations for M4Q (R2)

1. Global harmonisation of CMC documents and submission
2. Risk-based principles focusing on critical quality elements
3. Efficient/Minimum post approval change management
4. Compatible with new product modalities and new technologies

Industry Expectations for M4Q (R2)

1. Global harmonisation of CMC documents and submission

   - One core dossier with minimum regional amendment
   - Facilitates simultaneous submission worldwide

Access

Industry Expectations for M4Q (R2)

2. Risk-based principles focusing on critical quality elements
3. Efficient/Minimum post approval change management

- Benefit from Core Quality Information (CQI) and Development Summary and Justification (DSJ) sections
- Post approval changes can focus on CQI

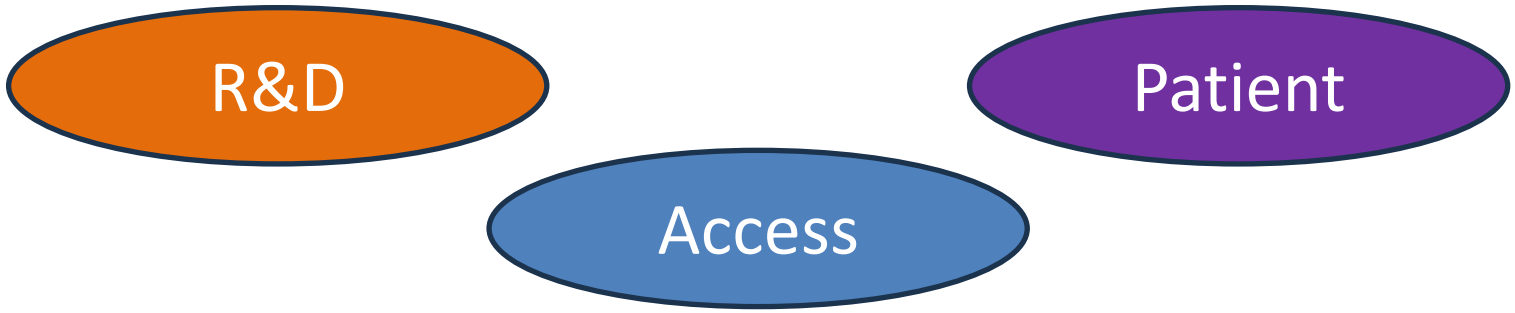
Compliance

Sustainability

Industry Expectations for M4Q (R2)

4. Compatible with new product modalities and new technologies

   - Facilitates submission of new modalities and technologies



Considerations for M4Q (R2) as industry

- Internal information/document management system(s)
- CTD preparation process to realize simultaneous submissions worldwide
- How to utilize AI/automation from data/report to prepare CTD

- How will M4Q (R2) be implemented in Japan?
- How will the Approval Application Form in Japan be handled?

Implementing M4Q(R2)

Implementing M4Q(R2) will take dedication and resources, but the effort we put in today will build the efficiencies of tomorrow--creating a faster, more reliable pathway for patients.

Acknowledgements

- ICH M4Q(R2) EWG
- JPMA ICH Project

Thank you!

Hiroshi Ohtsuka

(JPMA, Bayer Yakuhin Ltd.)