European Federation of Pharmaceutical Industries and Associations

What PhRMA/EFPIA expect from PDG

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About PhRMA

Pharmaceutical Research and Manufacturers of America (PhRMA)

Pharmaceutical Research and Manufacturers of America (PhRMA) was formed as a group of major research-oriented pharmaceutical companies which are conducting business operations in the US in 1958, representing biotechnology companies. Since the opening in Japan in January 1987, PhRMA Japan has actively deployed various activities, and promote activities that focus directly on all relevant associations such as administrative, healthcare policy, physicians and other healthcare professionals, media professionals, and patient groups.

About PhRMA

Members of PhRMA Japan

Amgen Astellas BioPharma K.K.
Alexion Pharma G.K.
Gilead Sciences K.K.
Eli Lilly Japan K.K.
Pfizer Japan Inc.
Mundipharma K.K.

Abbvie GK
MSD K.K.
Celgene K.K.
Biogen Japan
Bristol-Myers Squibb K.K.
Janssen Pharmaceutical K.K.

About EFPIA

European Federation of Pharmaceutical Industries and Associations (EFPIA)

EFPIA represents the pharmaceutical industry operating in Europe. Through its direct membership of 36 national associations and 39 leading pharmaceutical companies, EFPIA's mission is to create a collaborative environment that enables our members to innovate, discover, develop and deliver new therapies and vaccines for people across Europe, as well as contribute to the European economy.

EFPIA Japan provides the voice of the European research-based pharmaceutical companies in Japan. We are committed to bringing innovative medicines to improve patients' health and quality of life in Japan.

About EFPIA

Members of EFPIA Japan

Actelion Pharmaceuticals Japan Ltd.
Bayer Yakuhin, Ltd.
Chugai Pharmaceuticals Co., Ltd.
Ferring Pharmaceuticals Co., Ltd.
GlaxoSmithKline K.K.
Ipsen Pharma Japan
LEO Pharma K.K.
Merck Biopharma Co., Ltd.
NIHON SERVIER CO. LTD.
Novartis Pharma K.K.
Sanofi KK
AstraZeneca K.K.
Bracco-Eisai Co.,Ltd
CSL Behring K.K.
GE Healthcare Japan
Guerbet Japan
Janssen Pharmaceutical K.K.
Lundbeck Japan K.K.
Mylan Pharmaceuticals
Nippon Boehringer Ingelheim Co., Ltd.
Novo Nordisk Pharma Ltd.
UCB Japan Co., Ltd.

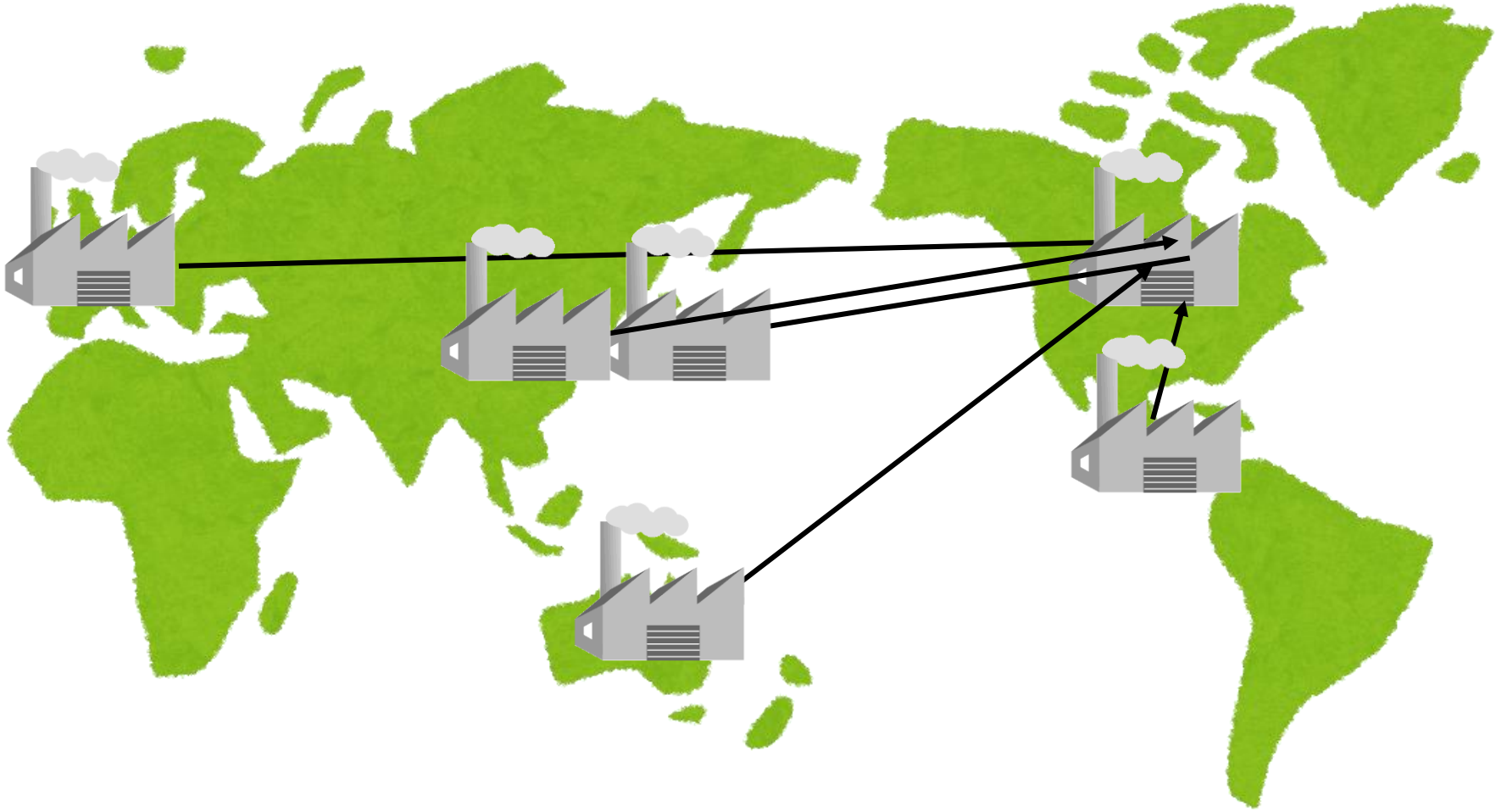
Expectations from PDG

- Achieve “complete harmonization” of three pharmacopeias (desired goal)

- Allow mutual use of each specifications/test method, etc., of the three pharmacopeias in each area, if it is difficult to achieve complete harmonization

International Supply Chain

Supply Chain Example



Example; Lactose Hydrate

- Monographs in JP are harmonized with monographs in EP/USP except for some specification items. The parts that are not harmonized are marked with symbols (◆◆).
  - Description, ID (IR), Heavy metals, Loss on drying, Microbial limit, etc. (◆◆).

Can we say acceptance criteria in JP are the same as those in EP or USP??

Example; Particulate Matter Test for Injections

- Particulate Matter Test for Injections is one of the harmonized methods.
- BUT there are so many differences in the monograph

  (e.g. Apparatus, Evaluation and etc.)

Since the test methods are not unified, the company needs to repeat the test even if the acceptance criteria are identical.

Example; Not yet Harmonized

HPLC

- Under discussion as G20
- Still yet to be harmonized - are there any obstacles to reaching agreement?

Water determination

- No discussion yet??
- This test is often used as one of the quality tests, but …

It is important to accelerate harmonization

Importance of Harmonization

- Pharmacopeial test methods are well validated and specifications are set to assure safety of the test methods. It seems possible to harmonize pharmacopeial specifications and test methods even in different regions
- If a unified Pharmacopoeial specification for excipients is available
  - multiple tests will not be required.
  - multiple suppliers can be used, and the risk management of the supply chain would be easy.

Ensure stable supply of products

Expectations to PDG

- Achieve “complete harmonization” of three pharmacopeias (desired goal)

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Our future situation

Consequently by realizing our “Expectations” in this presentation

- Patients can have more rapid and easier access to quality medicines
- Regulators can reduce additional efforts to review the monograph, or cancel the review itself
- Industries can reduce or eliminate additional efforts to follow the regional specific monographs