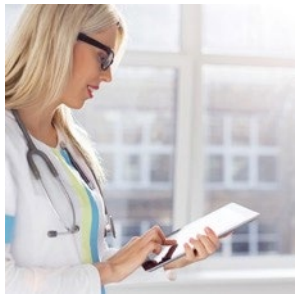
European Federation of Pharmaceutical Industries and Associations

EFPIA Day 2023 Press Event
- Drug Lag/Loss in Japan -






October 5, 2023

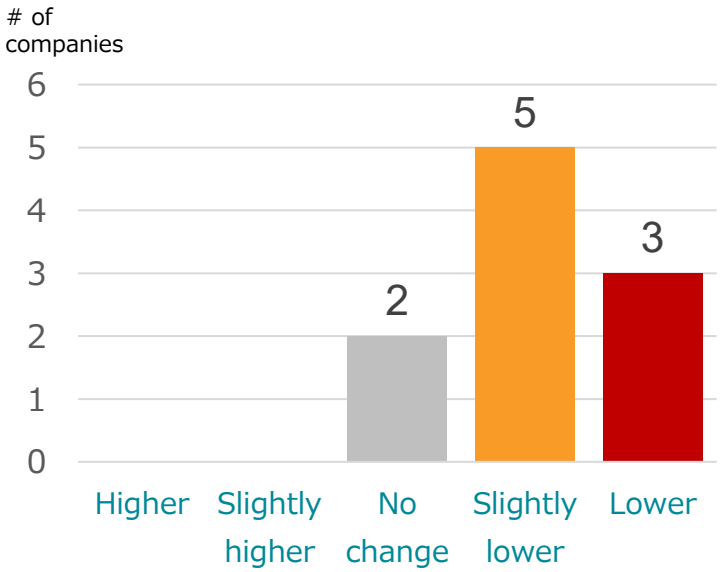
Takahiko Iwaya

Chair of EFPIA Japan

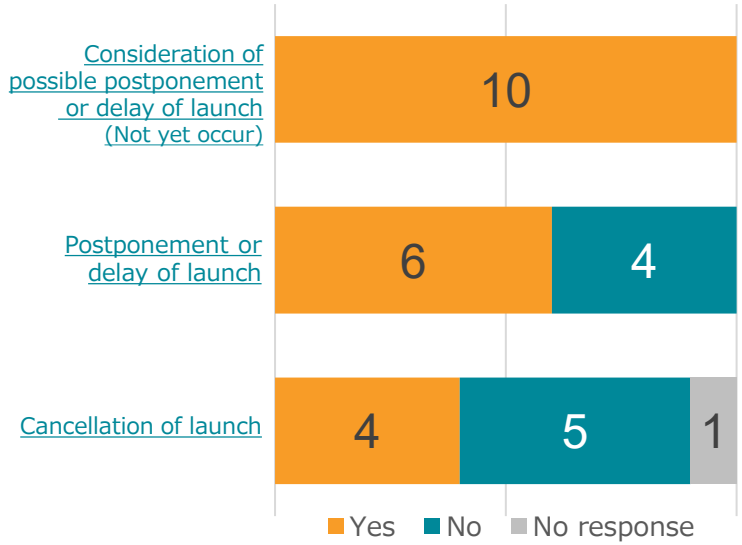
Drug lag/loss emerging in Japan

Impact of NHI Drug pricing system reform 2018 * 1

Changes in priority of the Japanese market in the drug development and launch



Number of companies impacted on new drug launches in Japan



Development status of drugs not approved in Japan * 2

Drugs approved in US/EU but not in Japan (143 products)

Local development not yet started

86 products (60%)

*1: EFPIA Japan Board Member Companies Survey (September 2022)
Responders: AstraZeneca, GlaxoSmithKline, Merck Biopharma, Novartis Pharma, Sanofi, Bayer, Novo Nordisk Pharma, UCB Japan, Janssen Pharmaceuticals

*2: Report of the Expert Review Committee on Comprehensive Measures for Rapid and Stable Supply of Drugs

About European Federation of Pharmaceutical Industries and Associations (EFPIA Japan)

- **Establishment** 2002
- **Overview** EFPIA Japan represents R&D-based European pharmaceutical companies operating in Japan
- **Mission** EFPIA Japan is fully committed to providing innovative medications to improve the health and quality of life (QOL) of patients in Japan.
- **Member company** 23 companies (as of April 2023)

Proportion of EFPIA Japan member companies sales in the Japanese market (2022)*1

31%

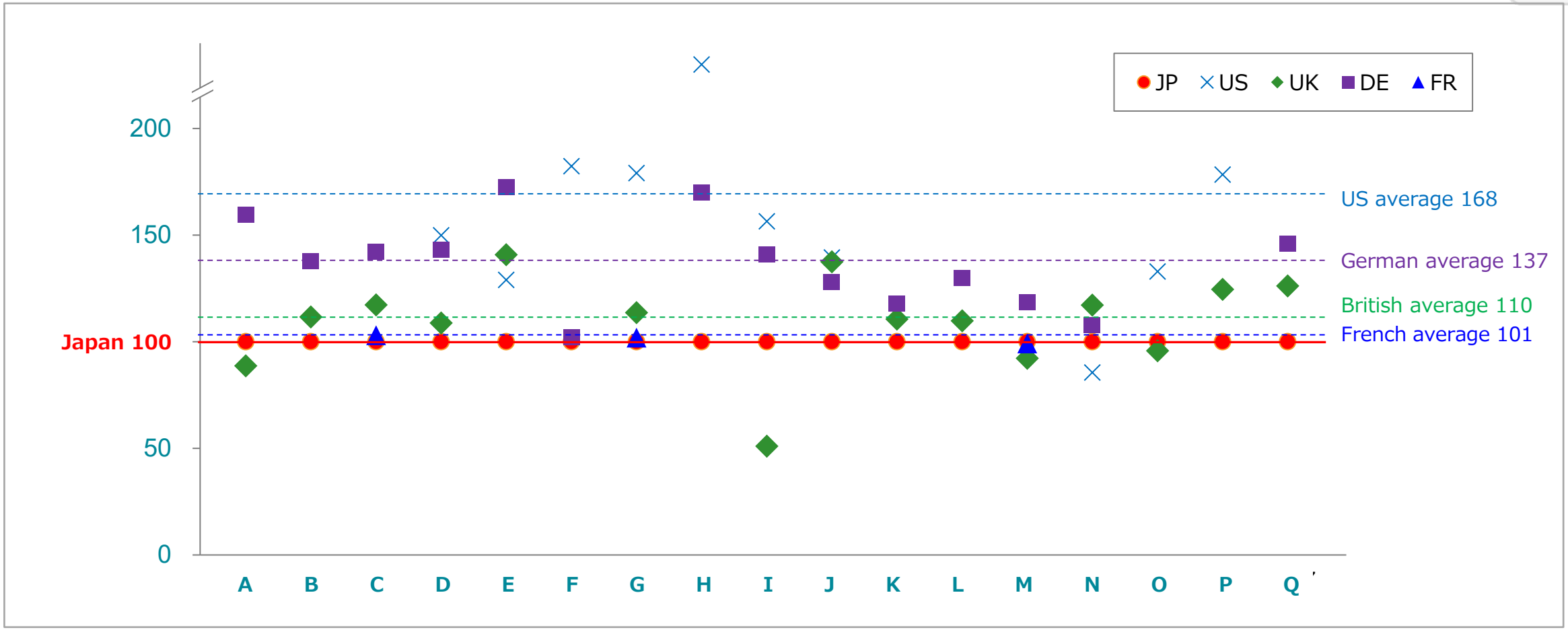
Proportion of Number of Newly Listed Drugs by EFPIA Japan member companies (2022) *2

30.5%

*1: ca. 3.4 trillion yen (EFPIA Japan survey for 2022)
*2: 51 ingredients (EFPIA Japan survey for 2022)

Reimbursement prices at listing in Japan tend to be lower than those in Europe and the US

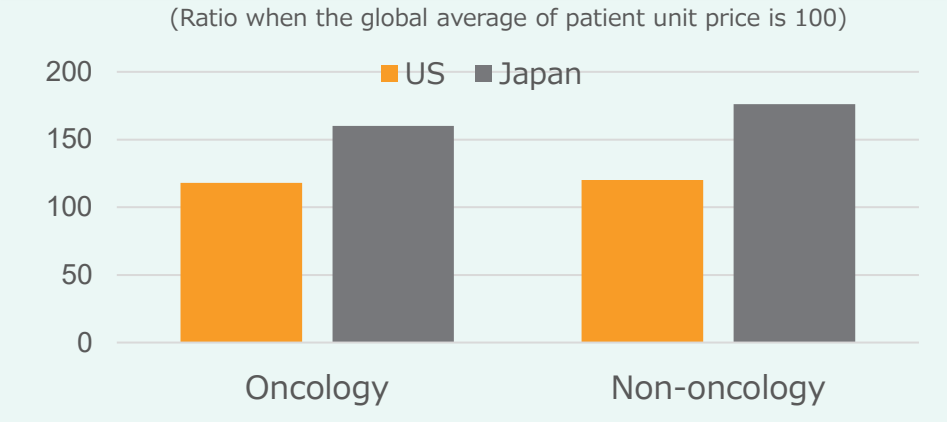
Comparison of new drug prices calculated with the cost calculation method * 1



*1: 17 products listed from April 2018 to May 2023, priced with the cost calculation method, for which at least 2 country prices are available for reference (excluding unapproved drugs for which development is requested by the government)
EFPIA Japan presentation at the 203th Drug Prices Expert Committee Meeting of the Central Social Insurance Medical Council on July 5, 2023

Japan's unique pharmaceutical regulations and costs are also considered to be one of the causes of drug lag/loss

Phase III study costs *1



Cartagena Law example *2

US

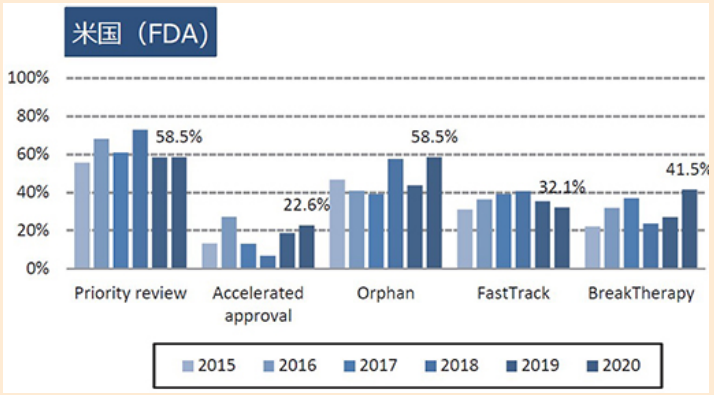
Products containing genetically modified organisms that are not pathogenic or proliferative are exempt from pre-study environmental assessment.

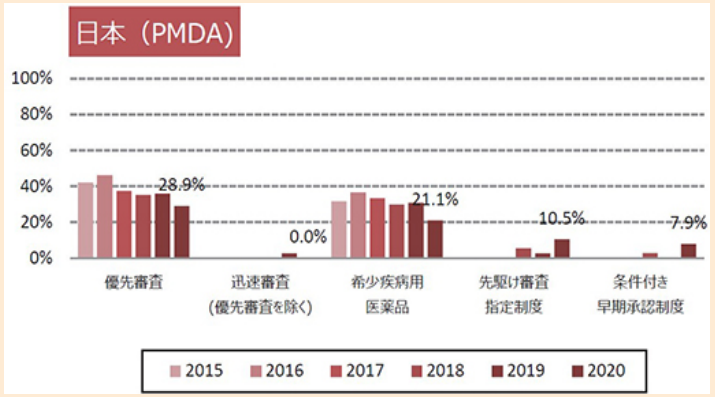
EU

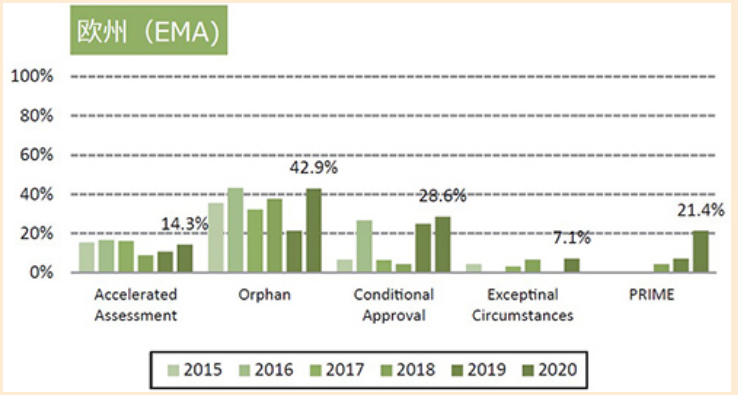
Japan

In both EU and Japan, the above actions are required for products containing genetically modified organisms.

Percentage of NMEs approved between 2015 and 2020 that received preferential treatment in pharmaceutical affairs * 3







*1: Clinical Evaluation Committee, Drug Evaluation Committee, Japan Pharmaceutical Manufacturers Association, "Discussion on optimization of medical institution expenses in clinical trials, " April 2015; PhRMA/EFPIA Joint Seminar "In order not to be excluded from global studies: Cost awareness activates clinical trials in Japan ", October 3, 2020

*2:Tajima G, Huh S, Schmidt NA, Macdonald JC, Fleischmann T, Wonnacott KM. Impact of genetically modified organism requirements on gene therapy development in the EU, Japan, and the US. Mol Ther Methods Clin Dev. 2022;26:74-83.,

*3: Comparison of New Drug Approval Status and Review Period in Japan, the U.S., and Europe | Policy Research Institute News | Pharmaceutical Industry Policy Institute (jpma.or.jp)

To solve the drug lag/loss issue, it is necessary to reflect the voices of patients in the pharmaceutical affairs system and healthcare policies

Patient's voices *1

I am afraid that I cannot receive the treatment developed in Europe and the US while I am alive...

Many patients in Japan are not aware that drug losses prevent them from receiving treatment already available in the world

I want opportunities to deepen my knowledge and understanding of drug development and healthcare policies so that patients have equal discussion opportunities with the government, academic societies, and people involved in the pharmaceutical industry

EFPIA Japan thoughts

We need to rethink for whom innovative drugs and therapies are originally intended

We believe that innovative drugs and therapies are for all patients and people in Japan

We should not leave behind the voices of patients who cannot receive treatment due to drug lag/loss

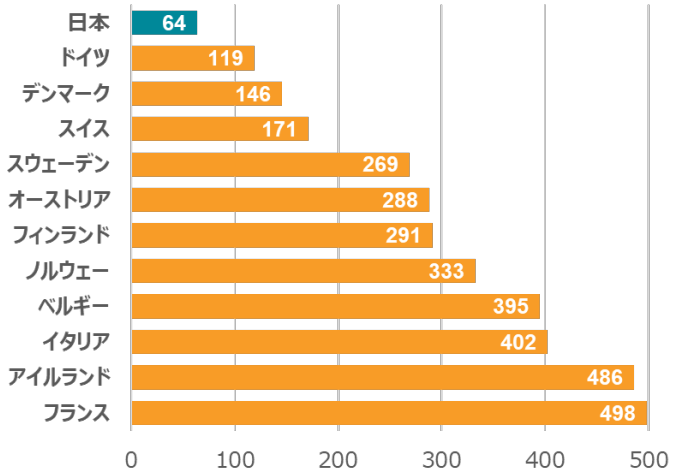
Patients and the public should be made aware of the drug lag/loss issue. A platform is needed to discuss clinical trials and healthcare policies with patients

*1: Interviews by EFPIA Japan with patient organization representatives (conducted in August 2023)

Takes long in Japan to implement routine immunization for preventive vaccines, while access to new therapeutic drugs after regulatory approval is faster in Japan than in European countries

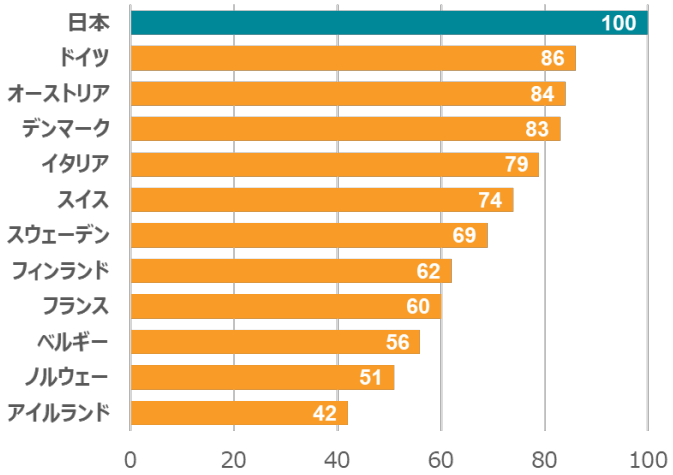
Pharmaceuticals *1

Waiting time after regulatory approval (ave. days)



Waiting time after regulatory approval: The number of days from the date of marketing approval in the EU to the date when the drug is made available at medical institutions, etc. (2015 to 2017)

Percentage of available drugs (%)



Percentage of available drugs: Percentage of drugs available to patients at the time of price listing in the national health insurance system (as of 2018)

Vaccines *2

	Routine vaccination	Years taken from the start of review
Rotavirus vaccine	Started in 2020	8 years until the start of routine vaccination
Mumps vaccine	Under consideration	13 years
Herpes zoster	Under consideration	7 years
Triple combination vaccine (booster dose)	Under consideration	13 years
Inactivated poliomyelitis vaccine (booster dose)	Under consideration	10 years

*1: EFPIA. (2019). EFPIA Patient W.A.I.T. Indicator Study 2018 Results.
*2: Material of the 32 Health Science Council, Immunization and Vaccine Committee, R&D and Production/Distribution Subcommittee

EFPIA Japan proposal of solutions to mitigate the drug lag/loss

Drug Pricing System

- Introduction of incentives for launch first in Japan prior to other countries
- Highly predictable system without risk of sudden change
- System in which the value of pharmaceuticals is appropriately evaluated and reflected in drug prices
- Maintaining the current mechanism where new drugs are listed and reimbursed promptly after regulatory approval
- Sustainable healthcare systems

Regulatory System

- Improvement of clinical trial environment in Japan (strengthening international competitiveness of clinical trial expenses, streamlining clinical trial processes, promoting digitization)
- Improvement of local pharmaceutical regulations aiming at further international harmonization and promotion of further acceptance of overseas clinical study data as NDA data
- Significant increase in the designation of pioneering drugs (currently fewer than that in the US), and introduction of a new system aimed at earlier initiation of regulatory review and approval for innovative new drugs that address unmet medical needs

Patient Involvement

- Promotion of patient involvement in discussions to solve issues from development to post-marketing of new drugs by referring to examples in Europe such as EUPATI (European Patients Academy on Therapeutic Innovation)

EFPIA commitment to solving the drug lag/loss Issue

- Drug lag/loss is an issue for all stakeholders involved in healthcare in Japan
- To solve the issue, we need to mutually understand the positions of multi-stakeholders in the healthcare community, including patients, citizens, industries, government, and academia, and discuss solutions
- EFPIA Japan is committed to leading resolution by working together with our stakeholders

- Develop and implement a program to promote knowledge and understanding among patients through industry-government-academia collaboration
- Establish a platform for multistakeholder dialogues and policy proposals for healthcare policy/system

efpia

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Thank you