

Review Efficiency and Timeline Predictability of Pre-Review and Online Registration Systems in Asian countries

○Yuto Kurooka¹, Masaaki Kannno¹, Kunihiro Kiyono¹, Yukio Washio¹, Yoshiaki Ito¹, Junichi Nishino¹

¹Otsuka Pharmaceutical Co., Ltd. Regulatory Affairs Department



Background

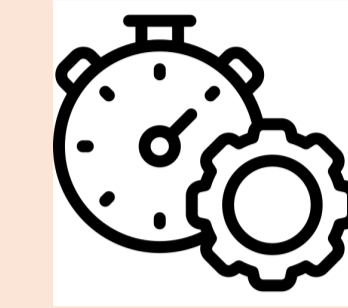
- In Asian countries, there is an increasing trend of countries implementing the systems of pre-review and online registration for Health Authority(HA)'s review process of drug application.
- In some countries, HAs request the applicants to complete online registrations of administrative and CMC data on API, excipients, and packaging materials, which are needed in advance to get the mentioned pre-review initiated.

Challenges

- These situations has the potential to complicate the review process and cause delays in the review timeline for drug approval.

Purpose

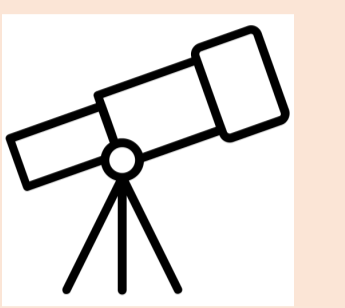
From the perspective of early access to patients, in Asian countries, we made a survey on the role and actual operation of pre-review and online registration system, and considered from the view point of review efficiency, transparency and predictability.



Efficiency



Transparency



Predictability

Method

- Survey Methods
Using Microsoft Forms, questionnaires were distributed to the subsidiaries of Otsuka in 13 Asian countries in Q4 2022.

Main Topics of Survey

- The role of pre-review stage and whether it is conducted prior to a full-scale NDA review
- The timeline and process of the review from NDA submission to acceptance
- Online registration system

| Country | Alpha-2 code | Country | Alpha-2 code |
|-------------|--------------|---------------------|--------------|
| China | CN | Philippines | PH |
| Hong Kong | HK | Singapore | SG |
| Indonesia | ID | Thailand | TH |
| India | IN | Turkey | TR |
| South Korea | KR | Taiwan | TW |
| Myanmar | MM | Vietnam | VN |
| Malaysia | MY | Total: 13 countries | |

Results

Definition of the terms

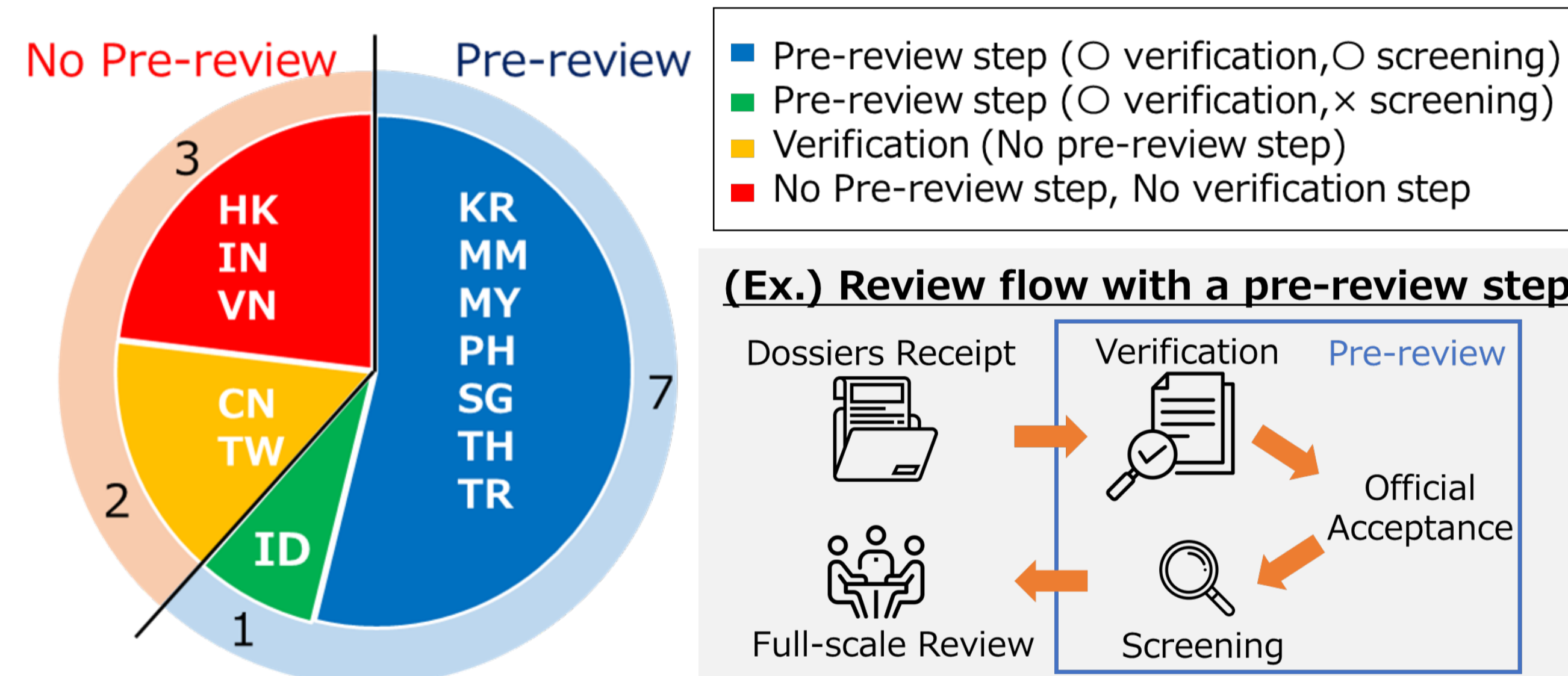
- ✓Pre-review
: To conduct a screening review before entering NDA full scale review stage, and in some countries, verification takes place before screening.
- ✓Screening
: to evaluate qualification for entry to NDA stage, and

determine appropriate review path.

- ✓Verification
: To check completeness and assess acceptability of application dossiers. If the application has passed Verification, it means the application gets official acceptance by HA.
- ✓Official acceptance
: To accept the application for HA's review (Not just receiving the application dossiers from applicants).

1. Pre-review and Verification

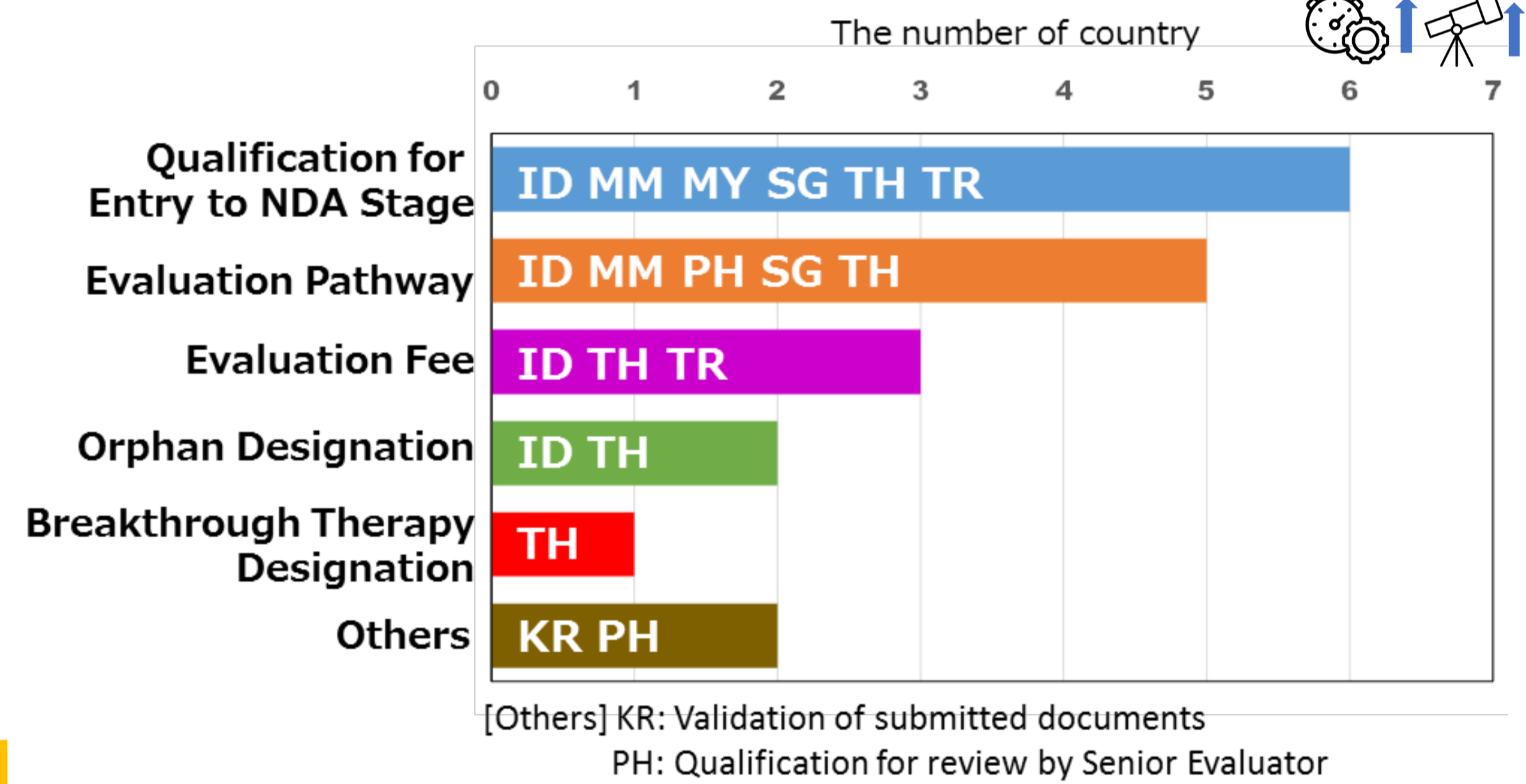
1-1. The existence and role of pre-review



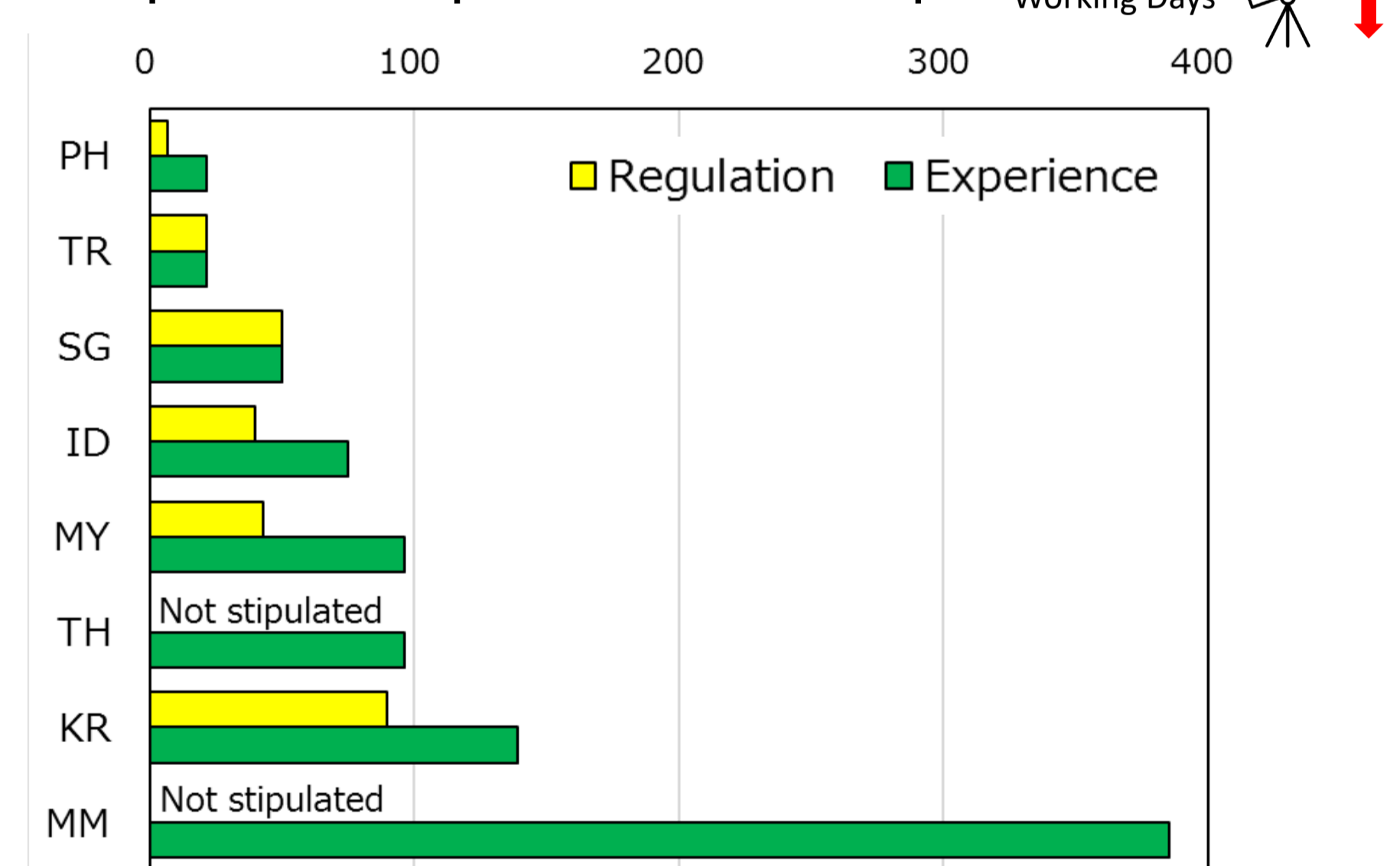
| Country | Role of Pre-review (Examples) |
|---------|---|
| SG | To ensure the <u>correctness of the application type</u> and the completeness of the dossier for review. |
| ID | As pre-screening of registration including to determine <u>registration category, review pathway, review fee and registration document.</u> |

- 8 countries have implemented a pre-review system, 9 countries conduct a formal verification before officially accepting the application, and 3 countries immediately acknowledge official acceptance at the time of submission and proceed directly to full scale NDA review.
- The role of Pre-review is not only to check the completeness of application dossiers but also to determine appropriate review path or designate special review track.

1-2. Things to be determined during pre-review step

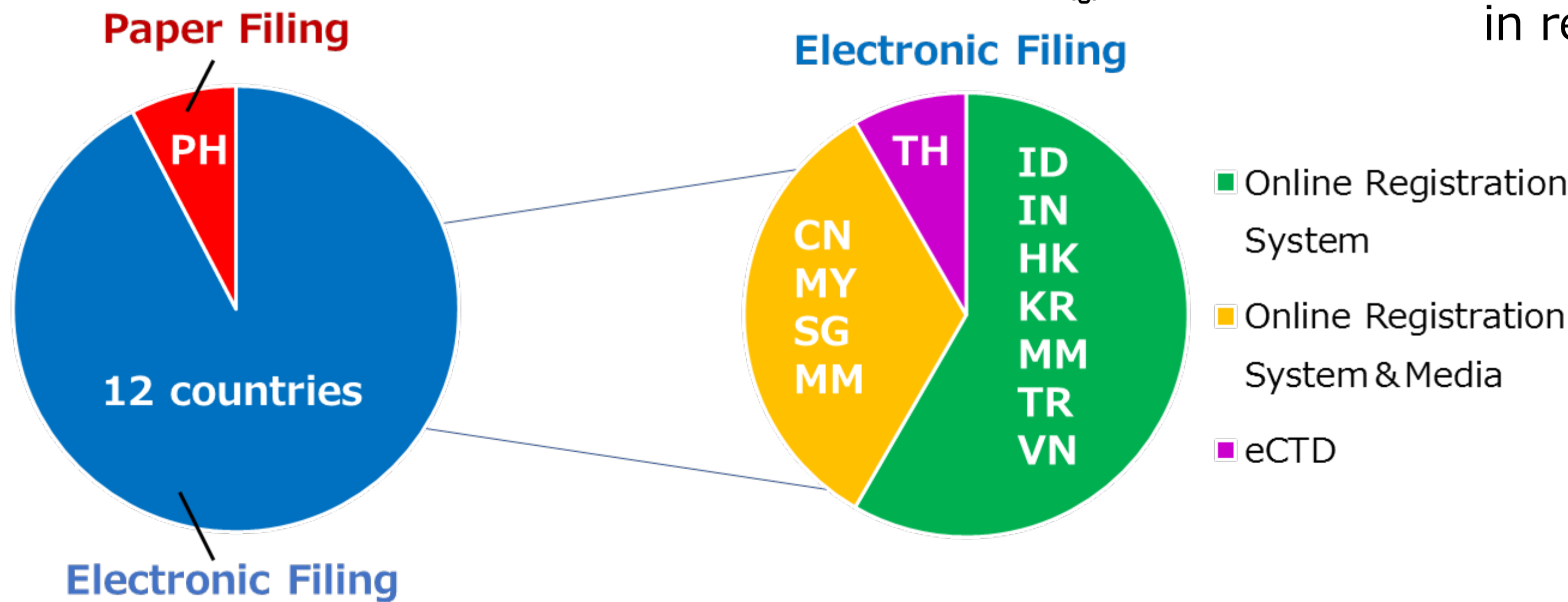


1-3. The period of pre-review step

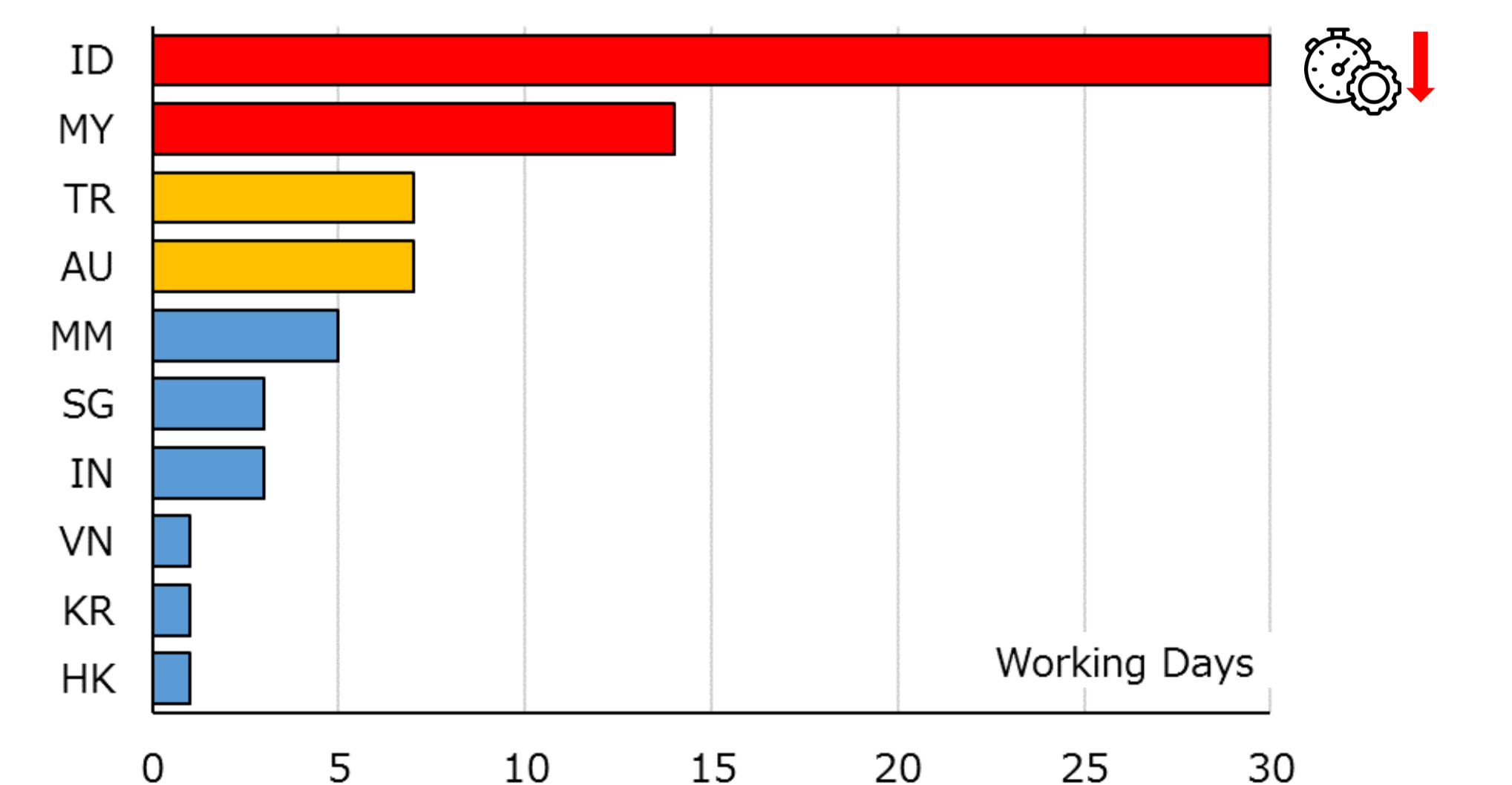


2. Online Registration System

2-1. Method of filing application dossiers



2-2. Number of days to enter application information in registration system online based on the experience



2-3. Whether or not applicants can check HA's review progress

| HA Review Process | Method | Country |
|------------------------------------|----------------------------|--------------------|
| Time-clock | HA's website | ID |
| Review Milestone | Online Registration System | HK, MM, MY, SG |
| | HA's website | CN, KR, PH |
| None of the above can be confirmed | - | IN, TH, TR, TW, VN |

- 10 countries implement the online registration system or eCTD, however, some countries faced challenges such as the applicant requiring a significant amount of time for inputting the information into the system.

Conclusion

Pre-review system not only confirms the completeness of submitted dossiers, but also serves as crucial step to decide the review path in the subsequent NDA stage, which helps applicants to adapt to the deficiencies and/or designated path in early stage, improving the review efficiency and timeline predictability. Furthermore, online registration systems could facilitate applicants to track the progress of review milestones, while contributing to the transparency of review processes.