Transparency and Interaction in Japan

Session E : GRevP Workshop
8 November, 2012 in Chinese Taipei

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Today’s contents

1. “Good Regulation”
2. For transparency to the review process
3. Others for communication

1. “Good Regulation”

“Good Regulation”?

- Efficient: Cost-beneficial
- Effective: Achieve the regulatory outcome
- Transparent
- Clarity: Understandable, practicable
- Equity: fairness
- Harmonization: International Standard
- Consistent
- Flexible: Continuously updated and maintained

“Good Review Practice”

We do not have the word “Good Review Practice” in Japanese regulation, but acknowledge the necessity of “General Review Principles” in PMDA

- To standardize general review policy
- To avoid inconsistent decision making
- To clear minimum check points in the review
- To accelerate review time
- To be Transparent in regulatory review process

- To standardize general review policy
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"Points to consider documents" in April, 2008

- To be Transparent in regulatory review process

"Sharing review situation of an individual product" in December, 2010

2. For transparency to the review process

“Sharing review situation of an individual product”

In December, 2010

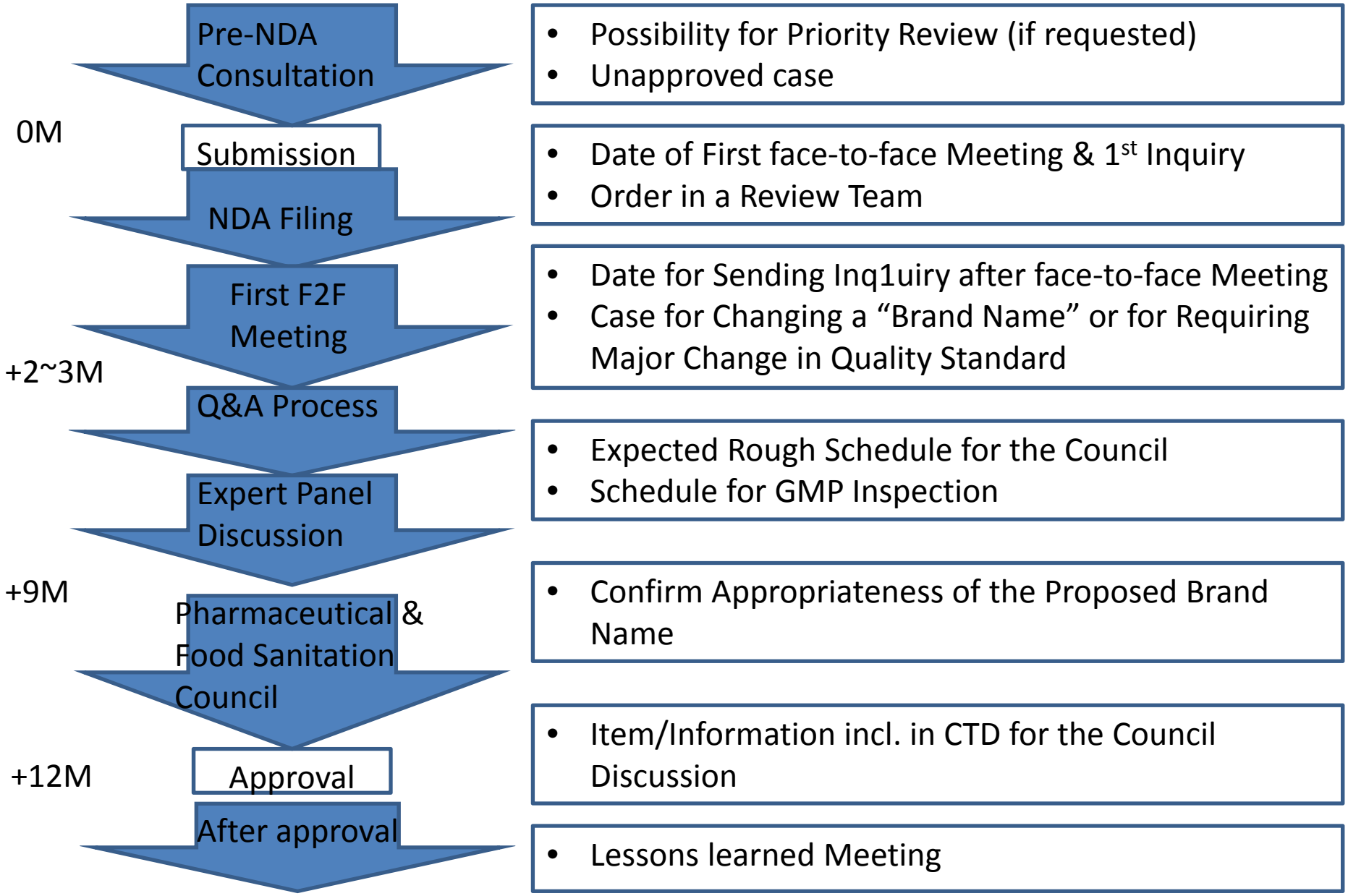
By Chief Executive Director, PMDA

Purpose

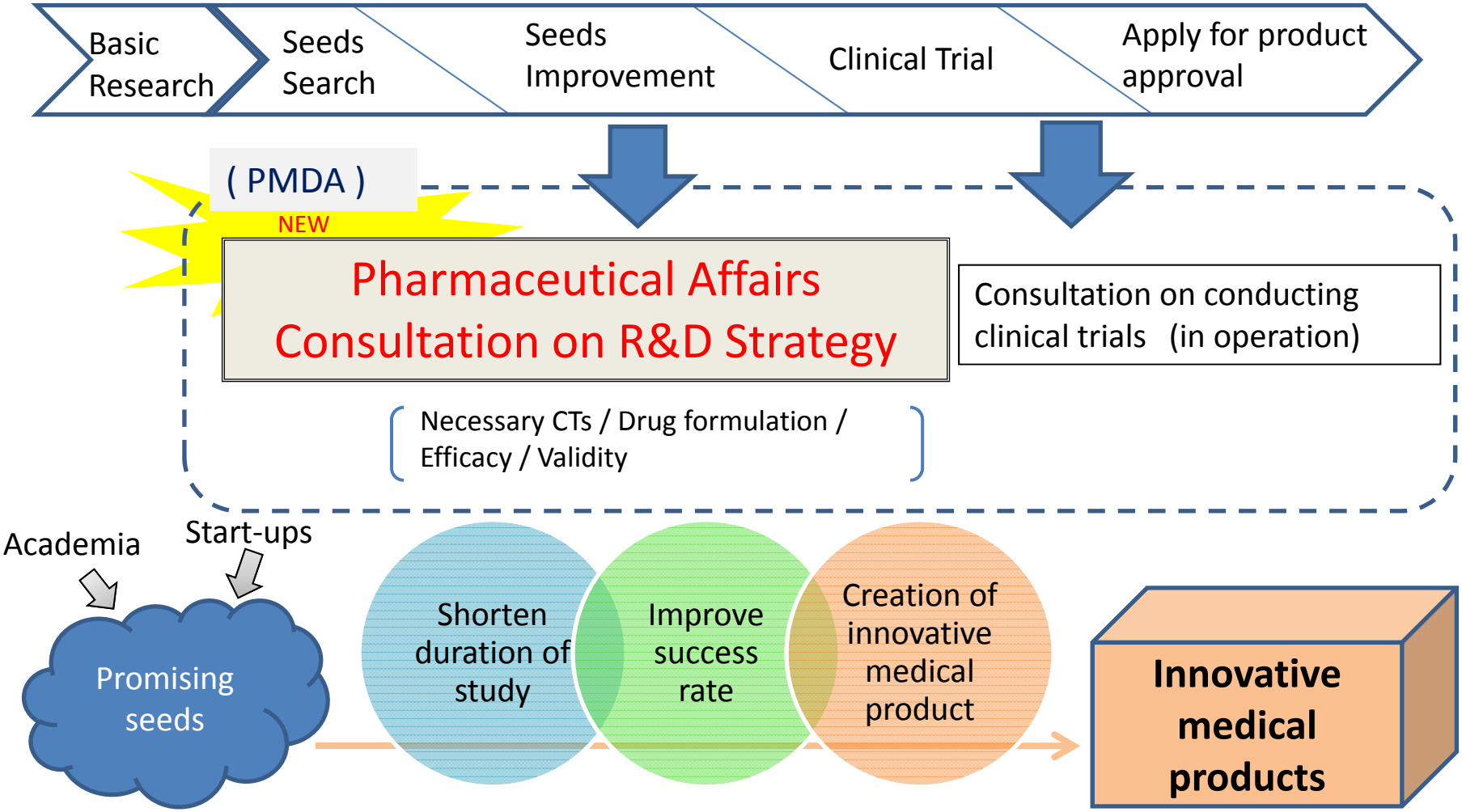
- Smooth Review
- More transparent
- More predictable

http://www.pmda.go.jp/topics/file/1227001_shintyoku.pdf

Items Informed by PMDA



Pharmaceutical Affairs Consultation on R&D Strategy (from July 2011)



3. Others for communication

Others

1. **Openness of the Review report** (new pharmaceuticals, new medical devices)
   through PMDA HP

2. **Public consultation** at the preparatory phase when new regulation is prepared
   (Period: 1 month at least)

3. **Stakeholder's involvement or communication**
   when influential document is under consideration
   e.g. To be member of the preparatory meeting

* case by case dependent on the contents