Improve Patients Access to Innovative Drugs and Sustainable Supply

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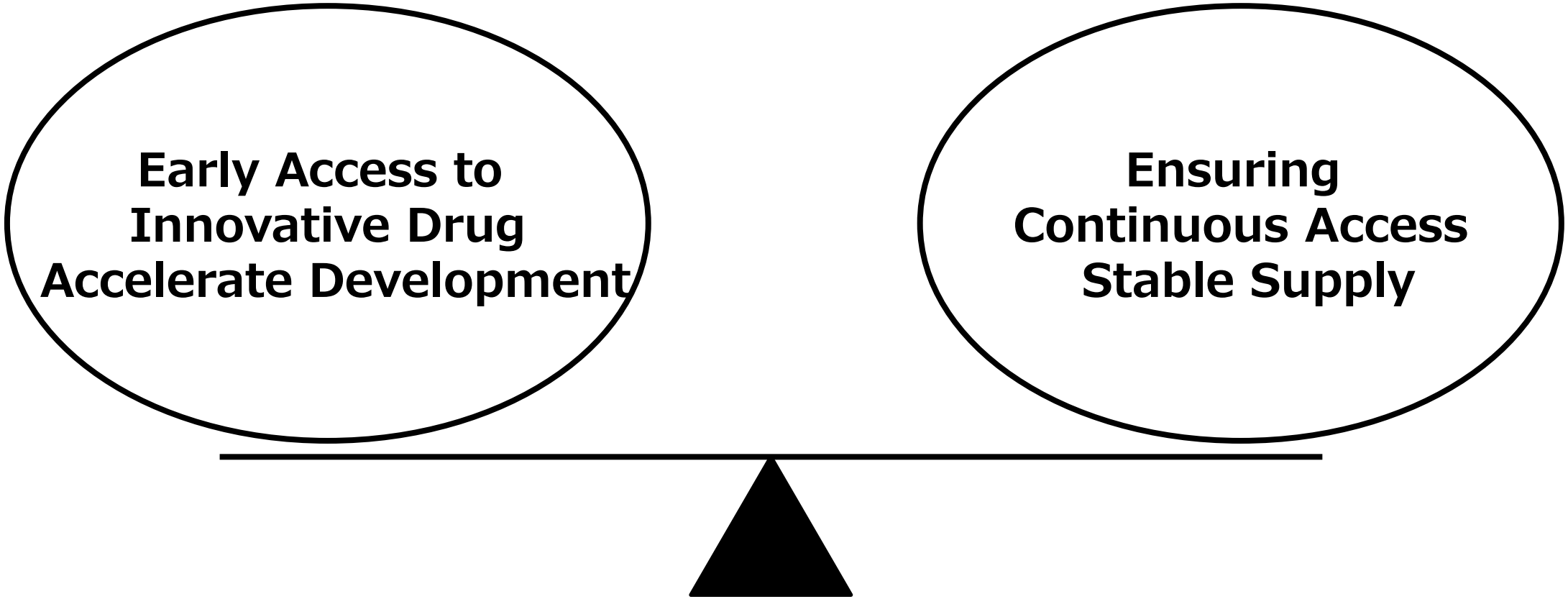
Mission of the Pharmaceutical Industry



Improve Patients Access to Innovative Drugs

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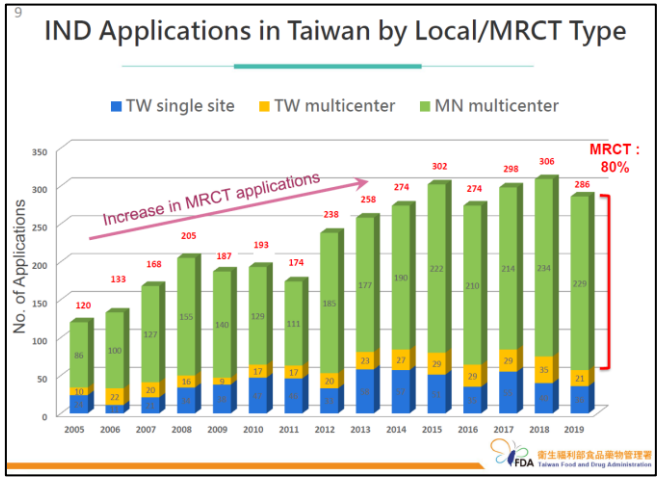
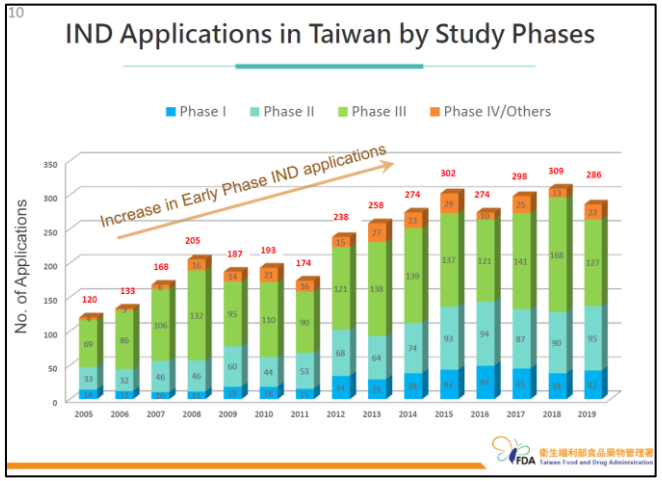
The Opportunity to Access to Innovative Medicine

- ✓ **Clinical trial** is one of the opportunity to access innovative medicine and the number of Clinical trials in Japan and Taiwan are increasing.
  - ➢ Start-up is quick (e.g., shorter or expedited CTN/IND review period/and HA Submission and IRB review in parallel)
  - ➢ Quality is high

The No. of IND about CTN

出所：独立行政法人医薬品医療機器総合機構 事業年度業務報告書[6] をもとに医薬産業政策研究所にて作成





Ref) 2019 日台医薬交流会議（Link）

Ref) Office of Pharmaceutical Industry Research（ https://www.jpma.or.jp/opir/news/066/05.html ）

Attractiveness of Conducting Clinical Trial

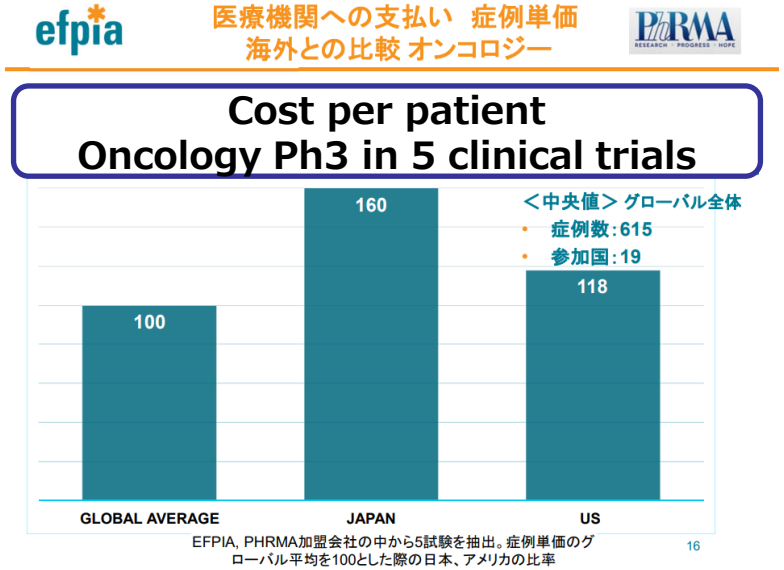
Global Head ⟷ Local

Negotiation
For country selection

Local Language should be reduced as much as possible.

	Japan	Taiwan
System	CTA	IND
Timeline	30 days for initial submission 15 days for after second submission	45 days for standard review 15 days for fast track system
Local Language	**PRT** **IB** ICF(consider to common template) Patient related document（e.g., PRO）	PRT synopsis ICF（TFDA released common documents） Patient related document（e.g., PRO）
HA/IRB review	Parallel	Parallel

Cost-effectiveness should be increased.



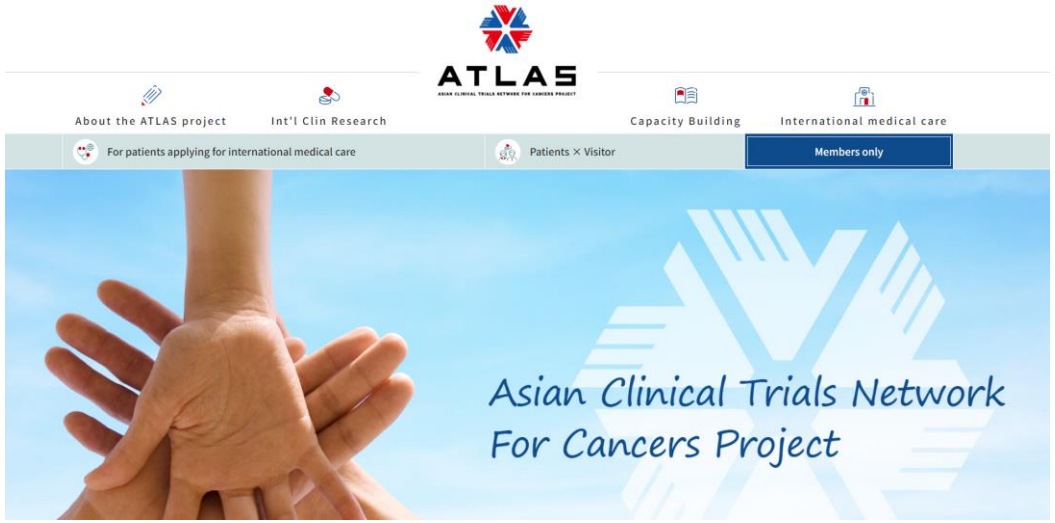
Ref) 第20 回 CRCと臨床試験のあり方を考える会議 2020 in NAGASAKI, PHRMA/EFPIA JAPAN 共催seminar

Industry Effort to Increase Transparency and Awareness of Clinical Trial

Ideally, the information should ba combained in one web site from user point of view.

How to Increase the Attractiveness to Development in Japan/Taiwan and Asia?

Strengthen the Network in Asia for accelerate evidence generation （e.g., ATRAS project）



https://en.atlas.ncc.go.jp/index.html

Establish the platform to accelerate clinical trial

Ref) 2022 日台医薬交流会議（Link）

Summary for Improving Patient Access

- ✓ Pharma companies choose Japan and Taiwan for MRCT because of high quality and early start-up, however some challenges should be improve for patient access to innovative drug.
  - ➢ Reduce local specific correspondence as far as possible (e.g., translation into local language etc.,)
  - ➢ Improve Cost effectiveness (e.g., the No. of recruitment per site)

- ➢ To strengthen the network in Asia and recruitment platform are important to increase attractiveness because it could be possible to accelerate clinical trials.

How to achieves sustainable supply for innovative medicines in Japan

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Agenda

1. Background
2. Necessity of sustainable supply chain
3. Risk factors
4. Specific proposal
5. Expected effects and challenges
6. Conclusion

Background

It is the responsibility of pharmaceutical companies to provide a stable supply of drug products to patients in need of treatment.

The pandemic of COVID-19 has had a significant impact on the pharmaceutical supply chain.

Factors that can affect the globally interconnected supply chain, such as the emergence of unknown infectious diseases, natural disasters, and international conflicts, are expected to continue to arise, making it necessary to implement countermeasures.

Necessity of sustainable supply chain

New Innovative Medicines are in high demand and are needed global supply.

There is only one pharmaceutical company that can provide them.

To respond to the expansion of the market, it is necessary to establish a continuous supply system.

Risk factors

Production halt at the manufacturing site

- Outbreak of an unknown infectious disease
  - Natural disasters(earthquakes, volcanic eruptions, floods, fires, etc.)
    - International conflicts
      - Disruption of raw material supply
        - Others

Our proposal

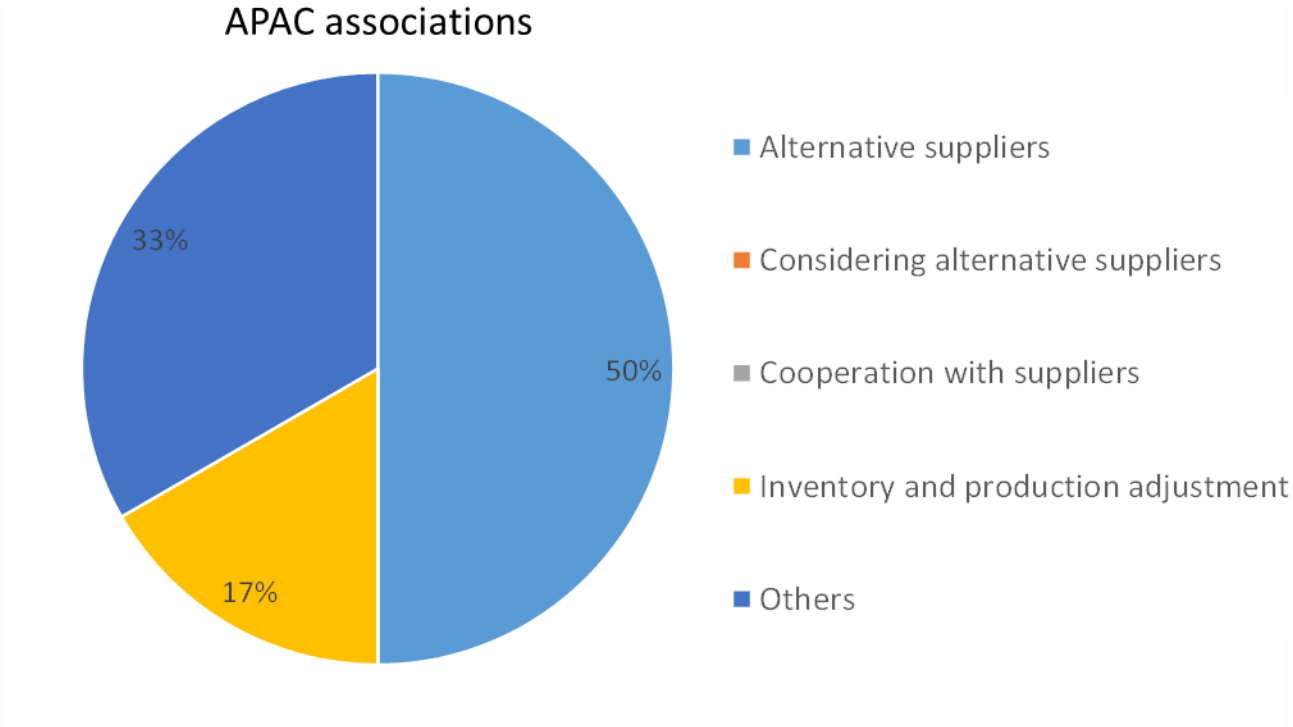
Securing a Second Manufacturing Site

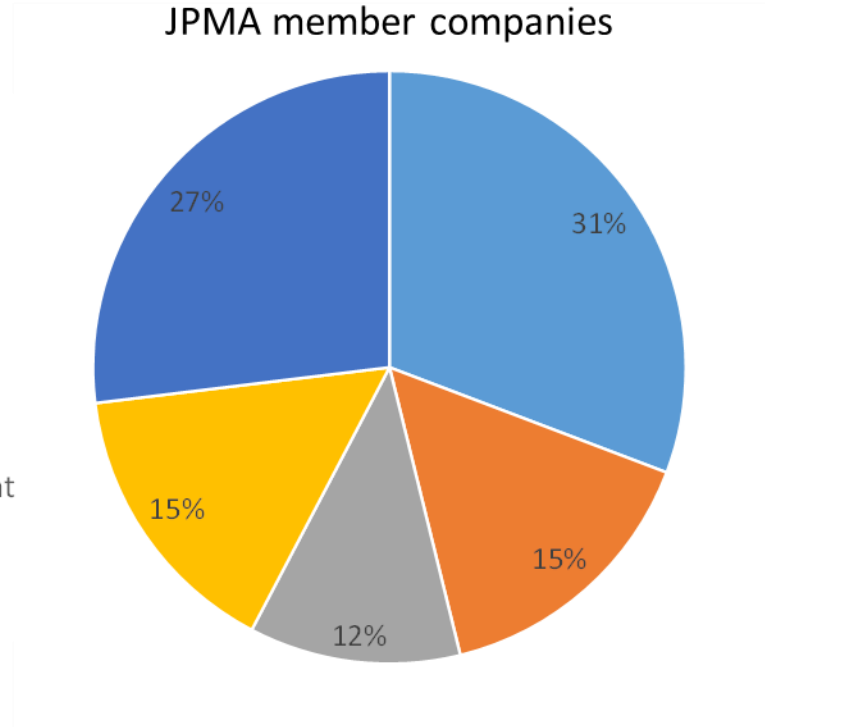
- Survey results (MQS-TF, 13th APAC Conference)
- Case studies in companies
- Utilization of CMO(Contract Manufacturing Organization)

Our proposal

- Survey results (MQS-TF, 13th APAC Conference)

Q How were delays or disruptions in supply of raw materials addressed?





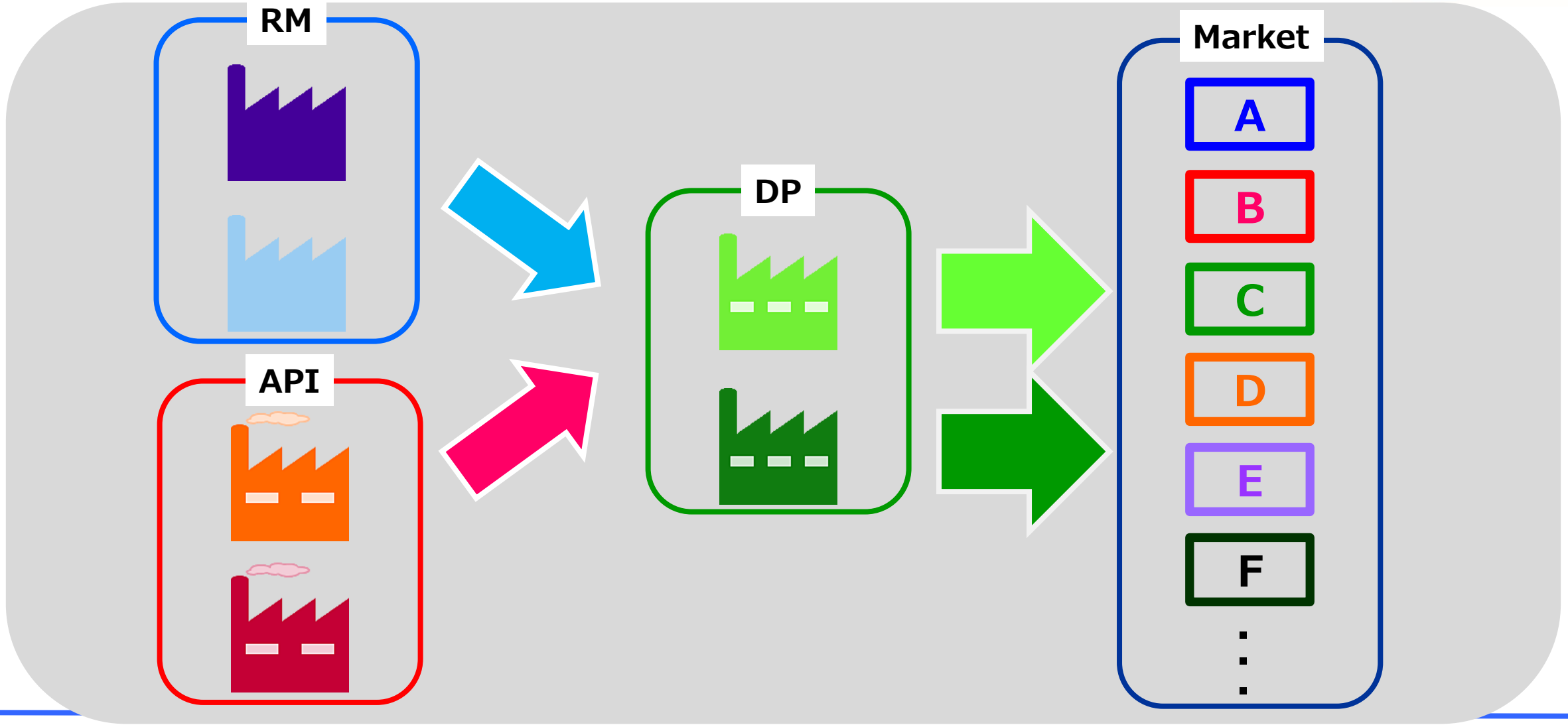
Our proposal

- A case study in a company

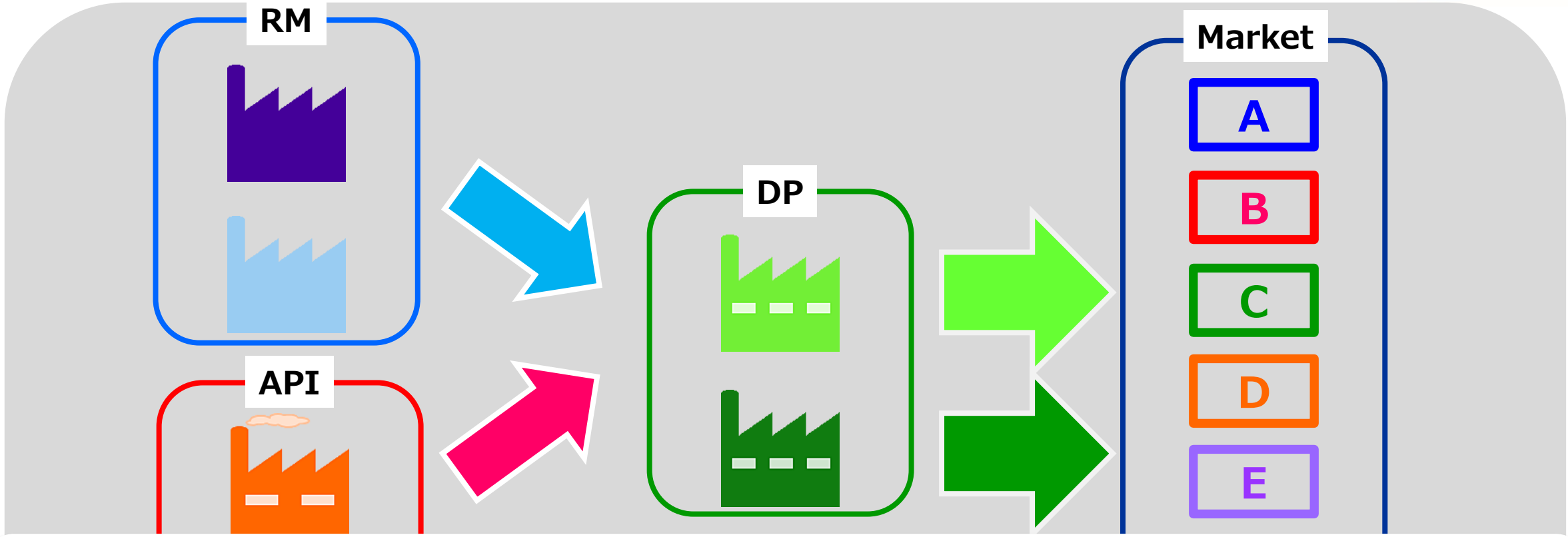
DS	DP	Region				
		A	B	C	D	E
DS-1-L1	DP-1-L1	●	●			●
DS-1-L1	DP-2-L1			●		
DS-2-L1	DP-1-L1	●	●		●	○
DS-2-L1	DP-2-L1			●		
DS-2-L1	**DP-2-L2**	○				
DS-1-L2	**DP-2-L2**			○		
DS-2-L1	**DP-1-L2**		○			○
DS-2-L2	**DP-1-L2**		○		○	

●: Approved
○: Under application/Planned application

Our proposal



Our proposal



It is important to secure multiple manufacturing sites in all schemes to ensure a stable supply of innovative medicines

Expected effects and challenges

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Effects of securing second manufacturing sites

- Enable quick response to supply disruptions/delays at the manufacturing site
- No regulatory response required in case of emergency due to prior securing

Challenges of securing second manufacturing sites

- Cost increases to secure multiple sites
- Production volume between sites need to be adjusted
- If there are unapproved regions, allocation management becomes burdensome

Conclusion

- ✓ Securing other manufacturing sites are important for stable supply of pharmaceuticals
- ✓ A multi-site manufacturing system can respond to a variety of supply risks
- ✓ Registration of manufacturing sites in all supplied regions is desirable

Thank you for your attention!