Session 3
Strengthen cooperation
between industry and regulator

Accelerate AtM & Drive Innovation

December 3, 2018

Chairperson of JPMA IP Committee

Koichiro Morihira

Contents

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Business Environment : Top Important Partners

➢ Main Trading Partners for Brazil

Export from Brazil

	Country	%
1	China	21.8
2	USA	12.3
3	Argentina	8.1
4	Netherland	4.2
5	Japan	2.4
6	Chile	2.3
7	Germany	2.3
8	India	2.1
	Others	44.5

Import to Brazil

	Country	%
1	China	18.1
2	USA	16.5
3	Germany	6.3
4	Argentina	6.1
5	Korea	3.5
6	Itary	2.6
7	Japan	2.5
8	France	2.5
	Others	41.9

(Data: 2017, Ministry of Development, Industry and Trade (MDIC), Source: "Ministry of Foreign Affairs of Japan)

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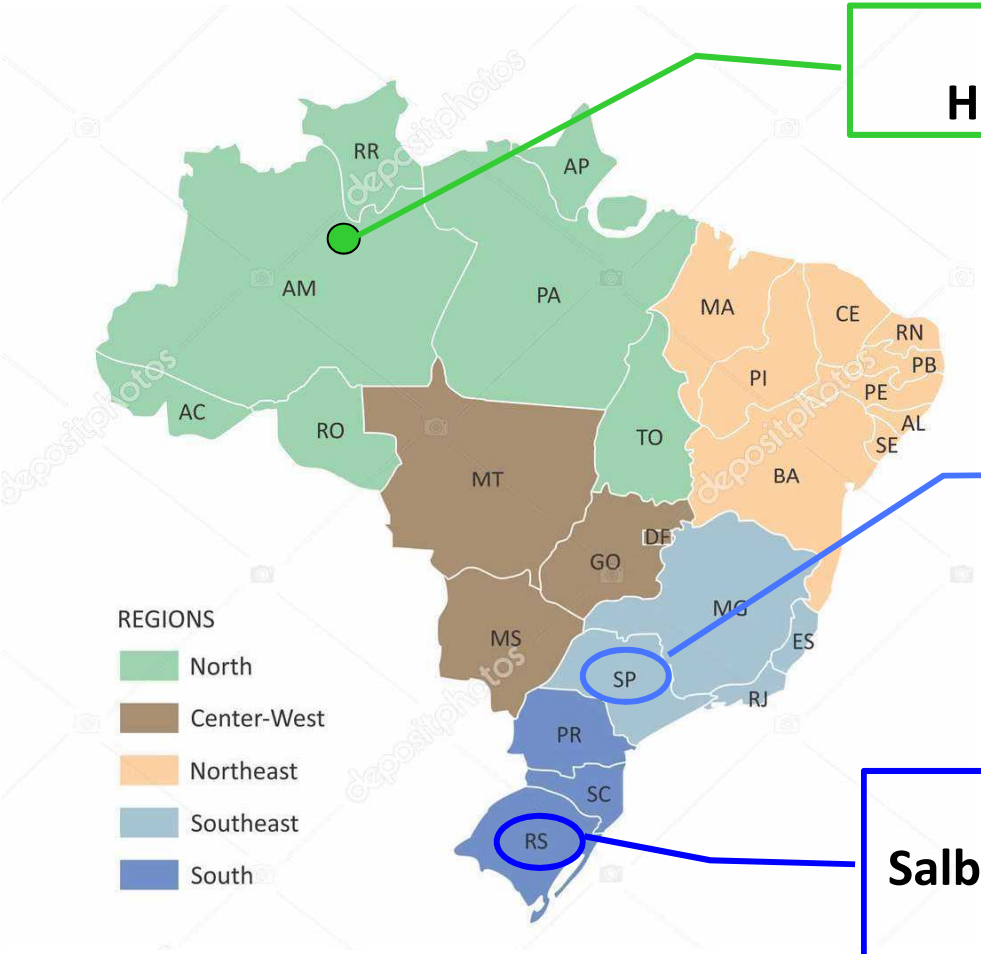
Japanese Pharmaceutical Companies in Brazil



<Manaus Free Zone>
Hisamitsu Farmacêutica do Brasil

<Sao Paulo>

- **Astellas Farma Brasil**
- **Daiichi Sankyo Brasil Farmacêutica Ltda.**
- **Eisai Laboratórios Ltda.**
- **Takeda Pharma Ltda.**

<Rio grande do sul>
Salbego Laboratório Farmacêutico Ltda. acquired by NIPRO

(Reference: "Japanese Industry's activities in Brazil" by JETRO, October 4 in 2016
"Medical International Development Country Report" by METI, in March 2018)

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Pharmaceutical Market in Brazil

➢ Pharmaceutical Market

- Brazil is 6th largest Pharma market in the world
- Expected to grow another 7%-10% annually until 2020
- Biological Products represent 43% of total spent annually by the Ministry of Health drugs, instead these products represent 5% of all drugs distributed by the government (2014)

(Citation: Licks Attorneys' presentation material for JPMA in 2017)

➢ Local Pharma Industry

- Top 10 companies accounted for 44% of the market share as of 2009
- Local company's share was 43% (EMS Pharma, Ache, EuroFarma etc.)

(Citation:"Medical International Development Country Report" by METI, in March 2018)

- Local company's share was increased to 50.8% in the first half year 2014

According to the Brazilian newspaper Veja, national pharmaceutical companies remain focused on "copy" products, with domestic producers . . . The local industry has also gained ground in the production of innovative medicines, reporting an 18% share in this market, reports Henry Tada, CEO of Alanac.

(Citation: IHS Markit, https://ihsmarkit.com/country-industry-forecasting.html?ID=1065995031)

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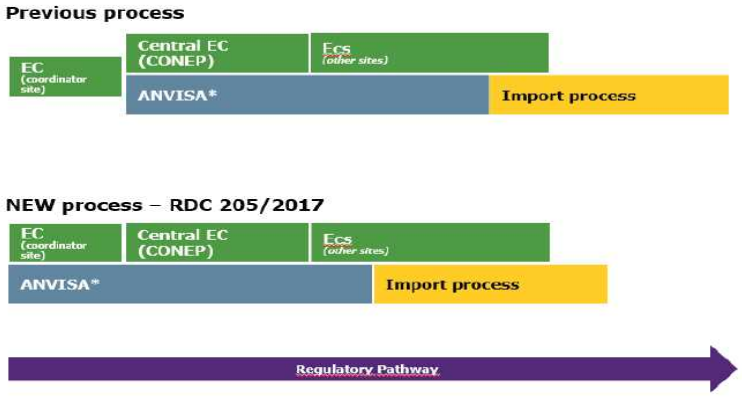
Recent Positive Changes for Drug Approval Process

➢ Clarifying Requirements

- Clarifying required information for approval process
  by "Guideline of efficacy and safety analysis of synthetic drugs" in 2018
- Expectation of simpler process
  (For example, acceptance of summary submission on CMC and nonclinical data)

➢ Speed up of Drug Approval Review

- Shortening review period (Innovative Drug: Average 909 days→ 356 days)
  by Law 13.411 (effective date : 03/30/2017)
- Change of submission process by ANVISA in March 2015;
  Resolutions RDC 09/2015 for clinical trials with drugs]
- ANVISA review in parallel with Ethics Process (RDC 205/2017)



(Citation: "Brazil's Regulatory Environment Offers Positive Changes for clinical Trials" by Regulatory Affairs professionals Society in June 2018)

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Contents

1. Accelerate AtM
   - Investment and business environment
   - Resent positive changes for drug approval process

2. Drive innovation
   - **Patent examination practice in Brazil**
   - **Patent as driver of innovation**

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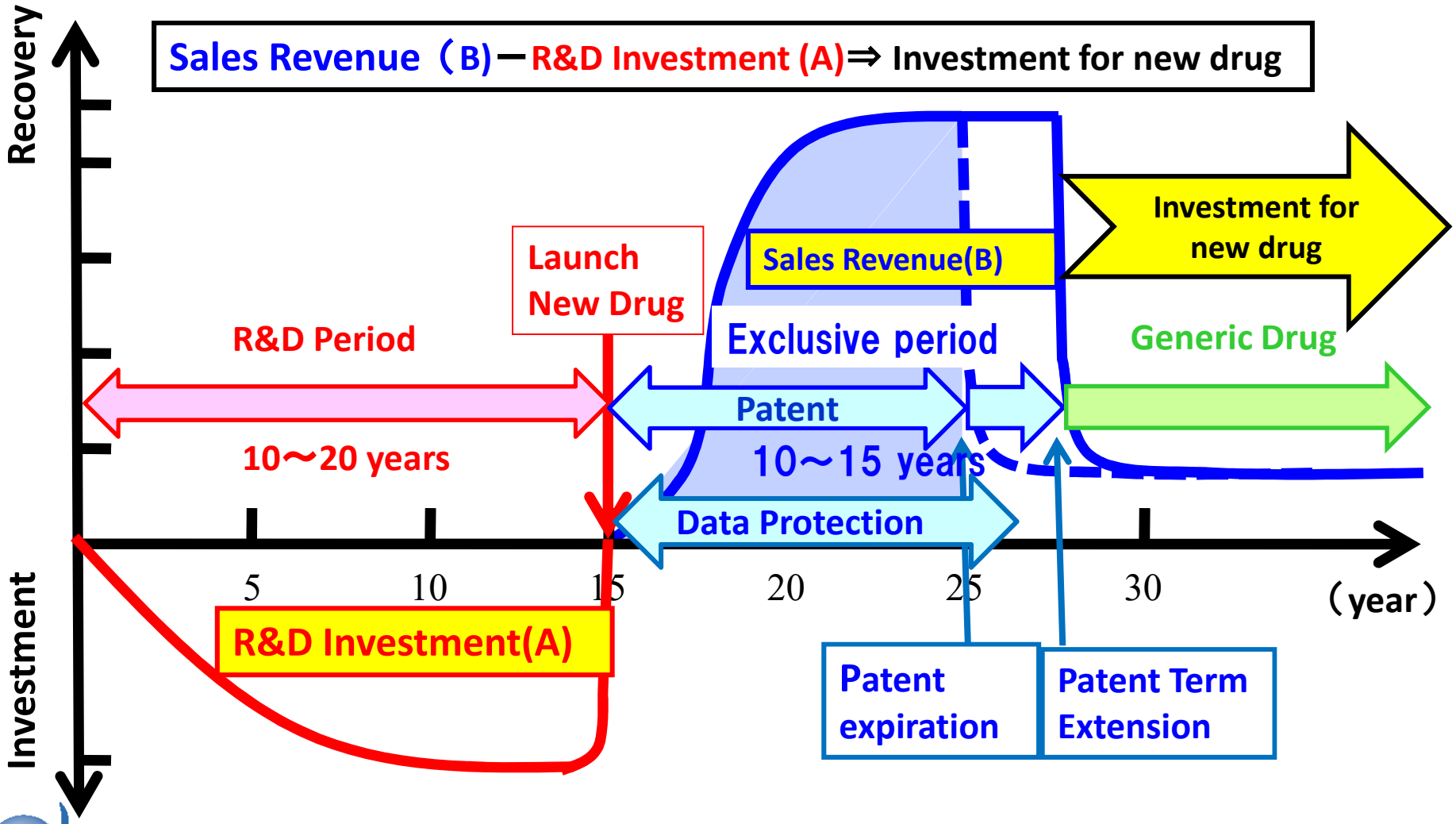
Driving Innovation Cycle



<Patent and Data protection are critical as Driver of Innovation>

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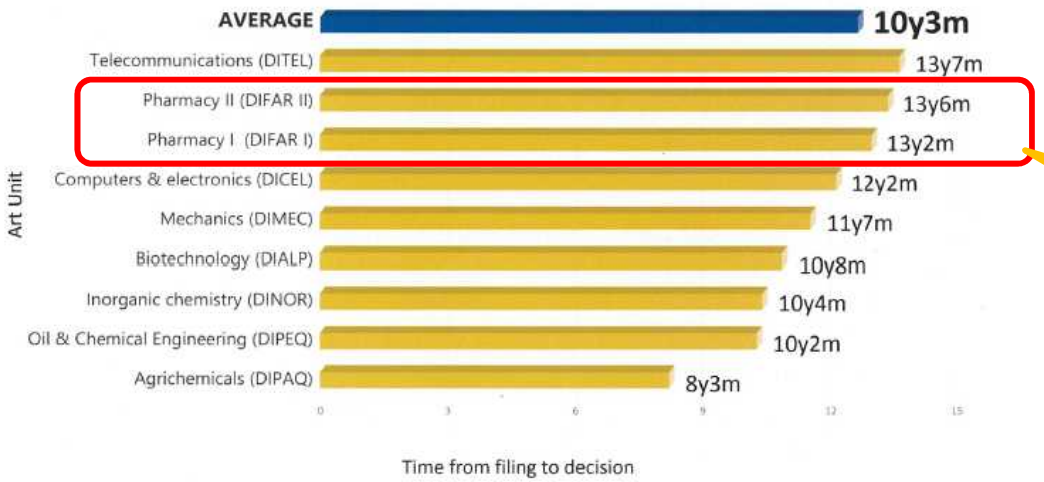
Patent Examination Status



Pharmacy applications have longer term backlog than average; over 13 years

Lifesciences Bio & Chemistry is the largest backlog category

(Citation: Licks Attorney's presentation material for JPMA in November, 2018)

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Various Approaches for Expediting Patent Examination

Appreciation for the efforts of expediting patent examination

- **Priority examination**

  Patent applications related to followings will be prioritized
  - the treatment of AIDS, Cancer, Rare diseases, Neglected diseases etc.
  - the strategies within the scope of SUS

- **Patent Prosecution Highway (PPH)**

  BRPTO-JPO PPH pilot program started on April 1, 2017 for application claiming IT and machinery. The PPH facilitates a grant of patent and promotes its business. Expansion of the scope would be expected

- **Proposal of simplified examination procedure**

  Patent Office would automatically grant applications, although pharmaceutical applications may be excluded

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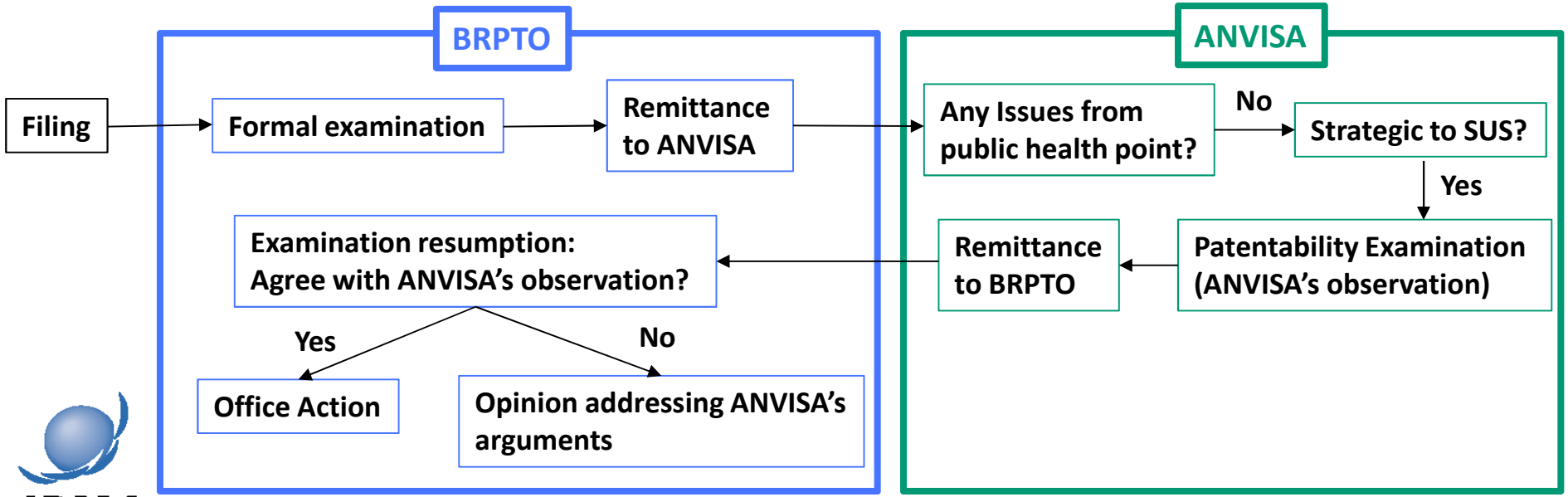
Patent Examination Procedure in Brazil

Interagency Ordinance #1/2017

- On April 12th, 2017, BRPTO and ANVISA signed Interagency Ordinance #1/2017 establishing new procedures for the agencies interaction regarding the prior approval of patent applications under art.229-C of the IP Statute

- Art4. provides that ANVISA's prior approval will be decided solely in light of public health issues

- ANVISA may issue a technical opinion, based on patentability requirements, that will correspond to third party observation, during the BRPTO's substantive examination (Art.5). When in disagreement with the technical opinion issued by the ANVISA, the BRPTO must manifest its opinion with technical grounds, addressing the reasons of such disagreement(Art.6)



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Expectation for ANVISA-BRPTO Harmonized Examination

Interagency Ordinance #1/2017

Art 9. An Interagency Policy Group will be instituted, with the participation of representatives of the BRPTO and the ANVISA, with the purpose of providing a wide exchange of technical information and the harmonization of understandings between the Agencies

Expect the harmonized examination to respect value of both substance and secondary patent as driver of innovation

- ✓ **Function of promoting innovation of "Secondary Patent" including new uses and prodrugs**
- ✓ **Development of cutting-edge treatments such as regenerative medicine by a lot of kind of patent**

(Reference: Licks Attorney's news site on April 15, 2017 http://lickslegal.com/ja/client-alerts-ja/the-brpto-inpi-and-the-brazilian-fdaanvisa-issue-ordinance-12017-on-prior-approval-of-pharmaceutical-patent-applications-under-art-229-c-of-the-patent-law/)

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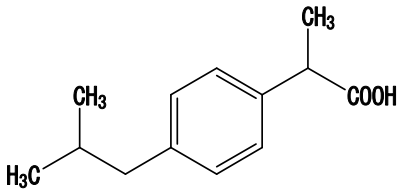
Increasing Diversity of Pharmaceutical Inventions (1)

Repurposing of Existing Drugs

- E.g. Repositioned Drugs or Medicine with New Added Values -



New substance

Secondary medical use

Hypertension → Hair growth stimulant

New Formulation

Controlled-release preparation

Combination drugs

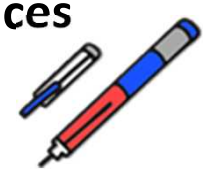
DPP-4 inhibitor +SGLT2 inhibitor, Vaccine

Prodrug

ACE inhibitor, 5-FU

Combined with medical devices

Insulin pen



Patent protection is necessary for new research incentives

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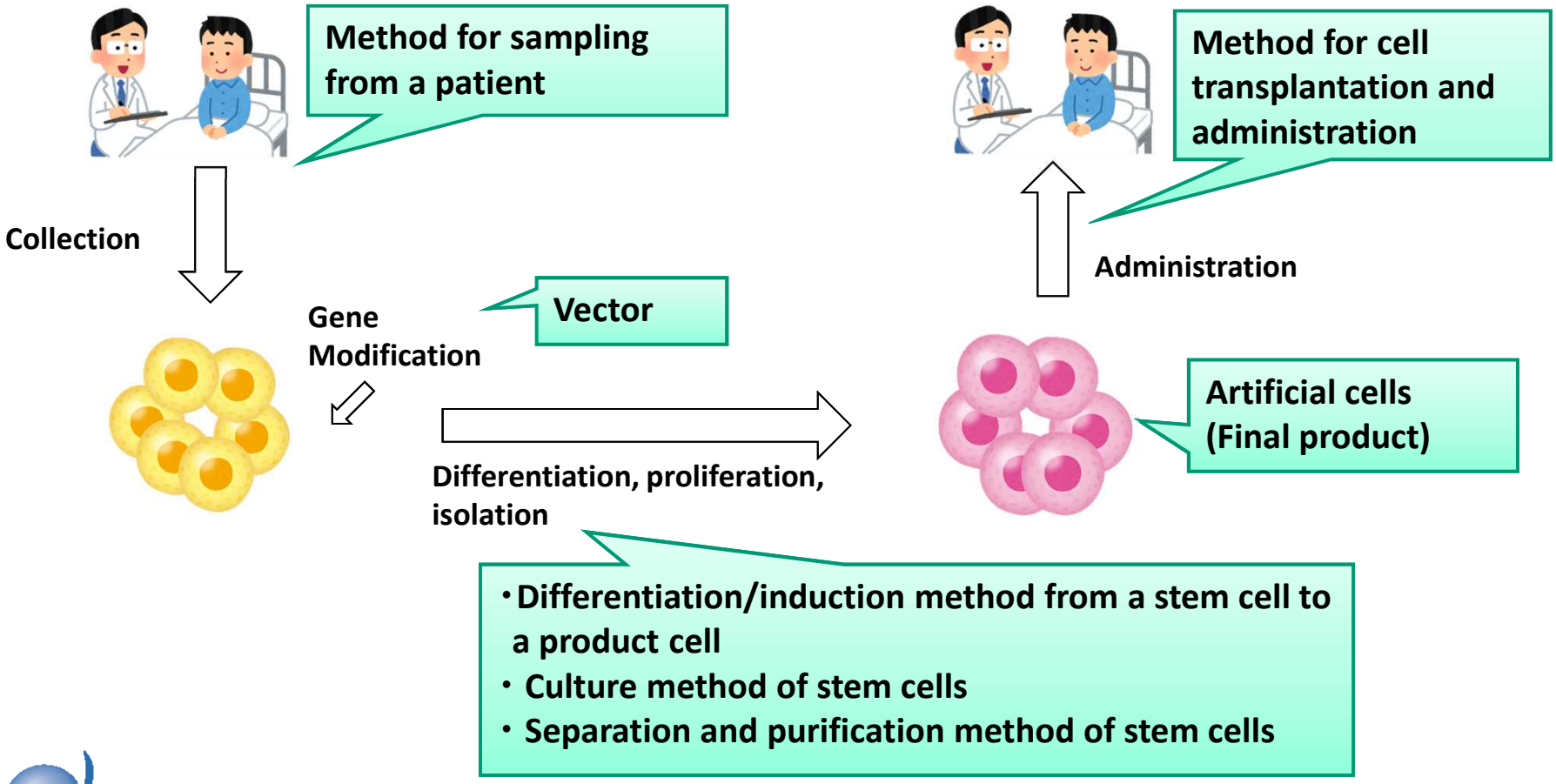
Increasing Diversity of Pharmaceutical Inventions (2)

Drugs in New Categories

- E.g. Regenerative Medicine -



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Patent protection is necessary for new research incentives

Cooperation between Industry and Regulator

Proposal of Briefing Session

- JPMA provides foreign government's regulators a briefing session where we explain some cutting-edge technology and so on

- We could provide ANVISA and BRPTO persons a briefing session using an opportunity of an interagency Policy Group meeting

- In the session, we would explain technologies at the request of regulators and discuss together

- Briefing session is good opportunities to understand not only technologies but also each idea on the field

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Thank you for your attention!

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