Ministry of Food and Drug Safety

Korea Healthcare Strategy for the Improvement of Access

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Contents

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I. Background

- **INCREASED SOCIAL NEEDS** for drug development to address unmet medical need in the treatment of a serious or life-threatening conditions

- **DECREASED DVELOPMENT** of the drugs with less lucrative and small number of patients (orphan drug, Anti-biotic drugs, etc.)

- **INCREASING probability of New Orphan Drugs using Advanced science and technology** to identify rare or serious disease

- **New Drug development Support** as New Growth for the future

2. Current Status

- Continuous Investment for New drug development and 26 New drugs developed by Korea local company.
  - Increased Technology Contract (transfer/export) with foreign Countries : 5 cases including 3 New Drugs

- Outcome of orphan drug development in Korea
  - 6 items (Hunter syndrome, Gauchers disease, etc.)
  - Orphan Drug Designation process
    - 213 API, 341 Approved Drug Products (Current)

  * US, Japan : financial support for Orphan drug development and Exclusivity

- To expedite development and approval of new, potential “orphan” or "breakthrough" drugs,
  - Regulatory process improvement is needed based on International Regulatory Environment
  - Proactive regulatory support needed for new drug development

Korean new drug list

No.	Trade Name	Company name	API	Indication	Approval
1	SUNPLA Injection	SK chemical	Heptaplatin	Anti-cancer	'99.7.15
2	EASYEF Topical Solution	Daewoong	Human epidermal growth factor	Diabetic foot infection	'01.5.30
3	MILICAN Injection	Donghwa	Holmium Nitrate-166	Anti-cancer(Liver cancer)	'01.7.6
4	Q-roxin Tab	JW	Balofloxacin	Anti-infective	'01.12.17
5	FACTIVE Tab	LG	Gemifloxacin	Anti-infective	'02.12.27
6	APITOXIN Injection	Guju	Dried Honey Bee Venom	Arthritis treatment	'03.5.3
7	PSUDOVAXIN	CJ	Dried, purified Pseudomonas Vaccine	Pseudomonas aeruginosa	'03.5.28
8	CAMTOBELL Injection	CKD	Belotecan	Anti-cancer	'03.10.22
9	REVANEX Tab	Yoohan	Revaprazan	Anti-ulcer	'05.9.15
10	ZYDENA Tab	Donga	Udenafil	Erectile dysfunction	'05.11.29
11	LEVOVIR Cap	Bukwang	Clevudine	Hepatitis B	'06.11.13
12	FELUBI Tab	Daewon	Felubiprofen	Osteoarthritis	'07.4.20
13	EMBIX Tab	SK chemical	Mirodenafil	Erectile dysfunction	'07.7.18
14	NOLTEC Tab	Ilyang	Ilaprazol	Anti-ulcer	'08.10.28
15	KANAB Tab	Boryung	Fimasartan	Hypertension	'10.9.9
16	PYRAMAX Tab	Shinpoong	Pyronaridine Artesunate	Malaria	'11.8.17
17	ZEPEED Tab	JW	Avanafil	Erectile dysfunction	'11.8.17
18	SUPECT Cap	Ilyang	Radotinib	Anti-cancer(Leukemia)	'12.1.5
19	ZEMIGLO Tab	LG	Gemigliptin, Tartaric acid	Diabetes	'12.6.27.
20	DUVIE Tab	CKD	Lobeglitazone	Diabetes	'13.7.4
21	RIAVAX Injection	KAEL GemVax	Tertomotide	Pancreatic Cancer	'14.9.15
22	ACELREX Cap	Crystalgenomics	Polmacoxib	Osteoarthritis	'15.2.5
23	ZABOLANTE Tab	Donghwa	Zabofloxacin	Anti-infective	'15.3.20

III. Global Trends and their implications

USA	Japan	EU
BTD	Sakigake	PRIME
The Food and Drug Administration Safety and Innovation Act (FDASIA) Section 902 provides for a new designation - Breakthrough Therapy Designation. If a drug is designated as breakthrough therapy, FDA will expedite the development and review of such drug. All requests for breakthrough therapy designation will be reviewed within 60 days of receipt, and FDA will either grant or deny the request.	The SAKIGAKE Designation System was established in the context of the "Japan Revitalization Strategy" (2014) and "SAKIGAKE Package Strategy" (June 17, 2014, [MHLW]) to lead the world in the early practical application of innovative pharmaceuticals, medical devices, and regenerative medicine. To promote this development, the goal was set to "designate treatment methods expected to radically improve existing methods and to achieve more speedy practical application by priority consultations and review.	PRIME, priority medicines, is a scheme launched by the European Medicines Agency (EMA) to enhance support for the development of medicines that target an unmet medical need. This voluntary scheme is based on enhanced interaction and early dialogue with developers of promising medicines, to optimise development plans and speed up evaluation so these medicines can reach patients earlier.
http://www.fda.gov	http://www.mhlw.go.jp	http://www.ema.europa

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IV. MFDS's new policy initiatives

- New legislation to promote and support Orphan Drugs' development

- Revision of priority review process and accelerated approval process, etc. (under discussion)

  - Expedite the clinical development of new, potential "breakthrough" drugs or treatments and collaborate with sponsor(s) to determine the best regulatory path forward

1. New legislation to promote and support Orphan Drugs' development

- **Objectives**
  - To provide policy supports through the product life cycle from clinical developments, review and approval and post approval to new drugs by incentivizing R&D sponsors and advancing patients' access in order to treat rare diseases

- **Criteria of Orphan Drug Designation**

  - Revised regulation to repeal the upper bound of sales amount of the orphan drug

    - (current) The orphan drug shall not exceed 1.5 M USD by estimated annual sales at the designation.
    - (revised) No upper bound of annual sales applied

- **Review and approval process**
  - Ease GMP requirement at the initial approval of the orphan drug
    - (current) Require three BMRs by strength/presentation /configuration
    - (revised) accept single BMR
  - Waiver of pre-consultation fee

- **Post-approval**

  - Extension of license renewal cycle

    - (current) License renewal required every five years since initial approval
    - (revised) license renewal every ten years for drugs designated as an orphan drug

  - Data exclusivity

    - (current) 4 to 6 years since initial approval date
    - (revised) up-to 10 years since initial approval date

- **Government's supply of orphan drugs and essential drugs**

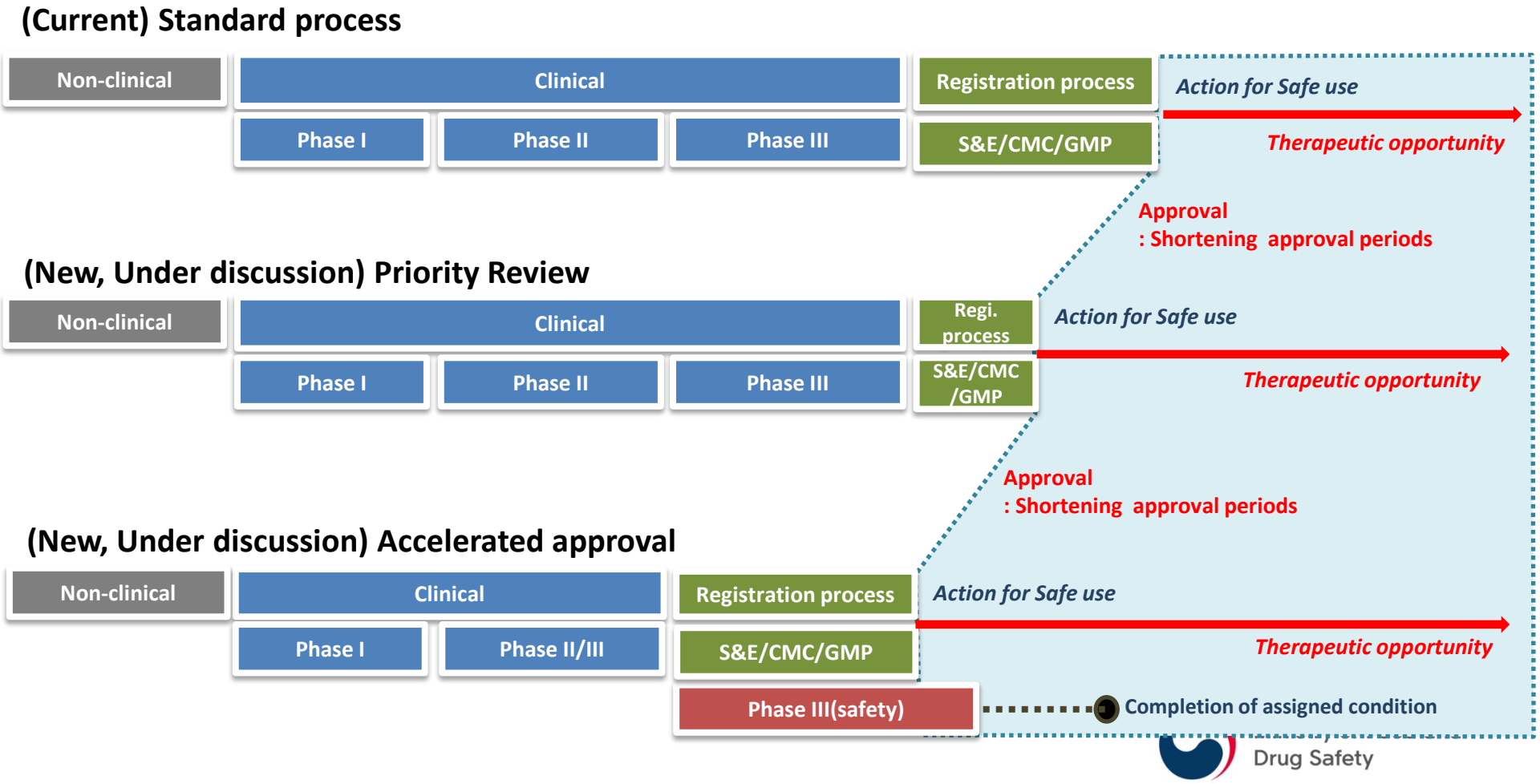
  - (current) Supply suspension of some orphan drugs and essential drugs because of low profit and API shortage

    * Drug supply suspensions have been reported as 77 cases in 2012; 85 cases in 2013; 59 cases in 2014

  - (proposal) The MFDS will have Korea Orphan Drug Center, KODC, supply the orphan/essential drugs in shortage via local toll manufacturing, etc. (under discussion)

2. Revision of priority review and accelerated approval process

A. Priority Review & Accelerated approval



B. Introduction of BTD Regulation

- **Objective**
  - Gives special consideration to facilitate and expedite development and review of new drugs to address unmet medical needs in the treatment of a serious or life-threatening condition

- Categories of BTD and Fast Track designation (under discussion)
  - intended to treat serious or life threatening disease including AIDS and Cancer
  - potential to meet an unmet medical needs
  - provide significant meaningful therapeutic benefit over existing therapies
  - drugs intended to treat broad range of serious disease and public health

- Regulatory support for New drug from development to approval (under discussion)
  - Priority review
  - Organizational commitment: Planning and collaboration with sponsor to have a condensed or abbreviated development program
  - Conditional approval (Accelerated approval)
  - Rolling review
  - Implement REMS (Risk evaluation and mitigation strategy) to ensure patient safety
  - Action for safe use based on the results of Post-marketing surveillance

- Clinical Value Evaluation of Breakthrough therapy and Fast Track drugs

IV. Expected benefit

- To provide patients suffering from serious or life-threatening diseases with expedited access to breakthroughs

- To give opportunities for compliance to introduce their innovative products

  - A smart regulatory strategy to utilize these programs to pave the best way to expand the validity of a product's commercial life, as well as to stir excitement and anticipation among investors

  - Shortening of “Time-to-Approval” and Time from “First in Human trial” to NDA final approval

V. Further discussion

- Need for Harmonization of BTD regulation among regulatory agencies

- Parallel Scientific Advice Program among Asian Regulators : e.g. Japan's PMDA and Korea's MFDS about development and approval of BTD

- Asian Regulators' Fora to reach International Consensus of BTD implementation

Thank You

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