Recent Trends in the Regulation of Biopharmaceuticals in Korea

CE in Biotechnology & Pharmaceutical Industries: 22nd Symposium on the Practical Applications for the Analysis of Proteins, Nucleotides and Small Molecules (CE Pharm 2020)

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JINA KIM

Recombinant Protein Products Division
National Institute of Food and Drug Safety Evaluation (NIFDS)
Ministry of Food and Drug Safety (MFDS)

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Disclaimer

The information presented here reflects the views of the presenter and should not be construed to represent MFDS' views or policies.

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I. Updates on Biopharmaceuticals in Korea

- Current Status of COVID-19 products (~18Sep2020)
- Current Status of Approved Biopharmaceuticals (2019)
- Current Status of IND of Biopharmaceuticals (2019)
- Current Status of Biosimilar (as of Oct, 2020)
- Current Status of Cell therapy products (as of Oct, 2019)
- Current Status of Gene therapeutic products (as of Oct, 2019)

1. COVID-19 Vaccines & Therapeutics

- **INDs in Korea (~ 18Sep2020)**

✓ IND approvals : Total 22 studies

✓ Vaccines : 2 products/2 studies
- DNA vaccines
- 2 studies/Phase 1 : underway : all by sponsors

✓ Therapeutics : 20 studies
- Chemical products : 16 studies
- Biopharmaceuticals : 4 products/4 studies
  => Rebif, recombinant IL-7 derivative, recombinant mAb, Hyper Ig
  => Four underway : 3 by sponsors (Phase 1b, 2, 2/3),
  1 by investigator (Rebif)

1. COVID-19 Vaccines & Therapeutics

- **Vaccines**

	Sponsor	Product	Phase	Approval date
1	International Vaccine Institute	INO-4800 (DNA vaccine)	1/2	2020-06-02
2	Genexine	GX-19 (DNA vaccine)	1/2	2020-06-11

**IIT : Investigator initiated trial*

(Reference : IND approvals of COVID19 products in Korea, sourced from Clinical Trial Management Division, MFDS, 18Sep2020)

1. COVID-19 Vaccines & Therapeutics

- **Therapeutics : Chemical products**

	Sponsor	Product	Phase	Approval date
1	Gilead Sciences	remdesivir	3	2020-03-02 (completed)
2	Gilead Sciences	remdesivir	3	2020-03-02 (completed)
3	*IIT*	remdesivir	*IIT*	2020-03-05 (completed)
4	*IIT*	Kaletra tab. (lopinavir/ritonavir), Oxiklorin tab. (hydroxychloroquine sulfate)	*IIT*	2020-03-20 (completed)
5	*IIT*	Haloxin tab. (hydroxychloroquine sulfate)	*IIT*	2020-03-25 (completed)

**IIT : Investigator initiated trial*

(Reference : IND approvals of COVID19 products in Korea, sourced from Clinical Trial Management Division, MFDS, 18Sep2020)

1. COVID-19 Vaccines & Therapeutics

	Sponsor	Product	Phase	Approval date
6	*IIT*	Alvesco inhaler (ciclesonide)	*IIT*	2020-03-27
7	Bukwang Pharm. Co.,Ltd.	Levovir cap. (Clevudine)	2	2020-04-14
8	*IIT*	Futhan inj. (Nafamostat mesilate)	*IIT*	2020-04-17
9	*IIT*	Ferodil Tab. (ifenprodil tartrate)	*IIT*	2020-04-21
10	Enzychem Lifesciences	EC-18	2	2020-05-12
11	ShinPoong Co.,LTD.	Pyramax tab. (Pyronaridine phosphate)	2	2020-05-13
12	*IIT*	baricitinib	*IIT*	2020-05-18
13	ChongKunDang Pharmaceutical Corp.	CKD-314 (nafamostat mesilate)	2	2020-06-17

1. COVID-19 Vaccines & Therapeutics

	Sponsor	Product	Phase	Approval date
14	Crystal Genomics	CG-CAM20 (Camostat)	2	2020-07-01
15	Daewoong Pharmaceutical, Co.,LTD.	DW1248 tab. (Camostat)	2	2020-07-06
16	Eily Lilly	LY3009104 (baricitinib)	3	2020-09-07

- **Therapeutics : Biopharmaceuticals**

	Sponsor	Product	Phase	Approval date
17	*IIT*	Rebif (recombinant interferon)	*IIT*	2020-08-04
18	Genexine	GX-I7 (recombinant protein)	1b	2020-08-07
19	Green Cross	GC5131 (Plasma derived products, Hyper Immunoglobulin)	2	2020-08-20
20	Celltrion Inc.	CT-P59 (recombinant Ab)	1	2020-07-17
			1	2020-08-25
			2/3	2020-09-17

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ty

2. Approved Biopharmaceuticals in 2019

- **Biologics : 2 botulinum toxin products, 4 vaccine products**
- **Cell therapy product : 1 autologous chondrocyte product**
- **Recombinant protein products : total 20 products**
  - ✓ NME 7 (mAb 6 / ADC 1) (including 3 orphan drugs)
    : Emgality(galcanezumab), Evenity(romosozumab),
    Fasenra(benralizumab), Skyrizi(risankizumab)
    Besponsa(inotuzumab ozogamicin), Hemlibra(emicizumab)
    Bavencio(avelumab)
  - ✓ Rekovelle(follitropin delta),
    Xultophy Flex Touch(insulin degludec/liraglutide)
  - ✓ Biosimilars : Terrosa(teriparatide), Panpotin(epoetin alfa)
  - ✓ Line extension : Etoloce, Humira, Opdivo, Humalog quik pen,
    Pergoveris.. etc.

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3. INDs of Biopharmaceuticals

- **INDs in Korea**
  - ✓ Status of IND approval (Chemical + Bio + Herbal) in Korea
    - 628 (2016) ➡ 658 (2017) ➡ 679 (2018)
    - Increase of early phase studies (211 phase 1)
    - Increase of studies for severe and rare refractory diseases
    - Increase of studies for biopharmaceuticals
  - ✓ Of 679 approvals in 2018
    - Oncology 36 % : target 45.0 %, immuno 37.2 %
    - chemical 61 %,
      - Recombinant protein products 26 %,
      - Cell therapy products 3.4 %,
      - Gene therapy products 1.5 %

(Reference : IND approvals in 2018 sourced from Clinical Trial Management Division, Feb, 2018)

3. INDs of Biopharmaceuticals

- **Clinical Development Status of Recombinant Protein Products in 2019 (Jan~Oct, 2019)**

✓ Submission : 575

- 518 (mAb & related products such as Cept) (90 %)
  - Anti-cancer: 383 (74 %)
  - Immune modulator: 73 (14 %)
- In anti-cancer drugs
  - Immune check point molecules: 180 (47 %)
  - Increase of Engineered mAb, ADC, bispecific mAb, etc.

4. Biosimilar

- **Approved products (~2019)**
  - ✓ 10 products by domestic companies
  - ✓ 4 products by foreign companies

- **Popular Reference Products (~Aug2019)**
  - ✓ Remicade, Humira, Enbrel
  - ✓ Herceptin, Mabthera, Avastin
  - ✓ Lucentis, Eylea
  - ✓ Soliris
  - ✓ NESP, (Eprex)
  - ✓ Neulasta
  - ✓ Lantus, Humalog
  - ✓ Gonal-F
  - ✓ Forsteo
  - ✓ Xolair

4. Biosimilar (~2019)

- **10 Biosimilar products developed by Domestic companies**

No	Company	Drug name	Active ingredient	Indication	Approval date	EMA Approval	FDA Approval
1	Celltrion	Remsima* 100mg	Infliximab**	Rheumatoid Arthritis	Jul 20, 2012	Remsima (Sep 10, 2013)	Inflectra (Apr 5, 2016)
2	Celltrion	Herzuma* 150, 440mg	Trastuzumab	Breast Cancer	Jan 15, 2014	Herzuma (Feb 9, 2018)	Herzuma (Dec 14, 2018)
3	Samsung Bioepis	Etoloce 50mg	Etanercept**	Rheumatoid Arthritis, Psoriasis	Sep 7, 2015	Benepali (Jan 14, 2016)	Eticovo (Apr 25, 2019)
4	Samsung Bioepis	Remaloce 100mg	Infliximab**	Rheumatoid Arthritis	Dec 4, 2015	Flixabi (May 26, 2016)	Reneflexis (Apr 21, 2017)
5	Celltrion	Truxima	Rituximab	Rheumatoid Arthritis, Lymphoma	Jul 16, 2015	Truxima (Feb 17, 2017)	Truxima (Nov 28, 2018)

- * PMDA approved
- ** HC approved

4. Biosimilar (~2019)

- **10 Biosimilar products developed by Domestic companies**

No	Company	Drug name	Active ingredient	Indication	Approval date	EMA Approval	FDA Approval
6	Samsung Bioepis	Samfenet 150mg	Trastuzumab	BreastCancer, GastricCancer	Nov 8, 2017	Ontruzant (Nov 15, 2017)	Ontruzant (Jau 18, 2019)
7	Samsung Bioepis	Hadlima 40mg	Adalimumab **	Rheumatoid Arthritis, Psoriatic Arthritis	Sep 20, 2017	Imraldi (Aug 24, 2017)	Hadlima (Jul 23, 2019)
8	LG Chem Ltd.	Eucept* PFS	Etanercept	Rheumatoid Arthritis, Psoriatic Arthritis, etc.	Mar 16, 2018		
9	Chong KunDang Pharmaceutical Corp/	Nesbell*	Darbepoetin alfa	Treatment of anemia	Nov 29, 2018		
10	PanGen	Panpotin	Epoetin alfa	Treatment of anemia	Nov 28, 2019		

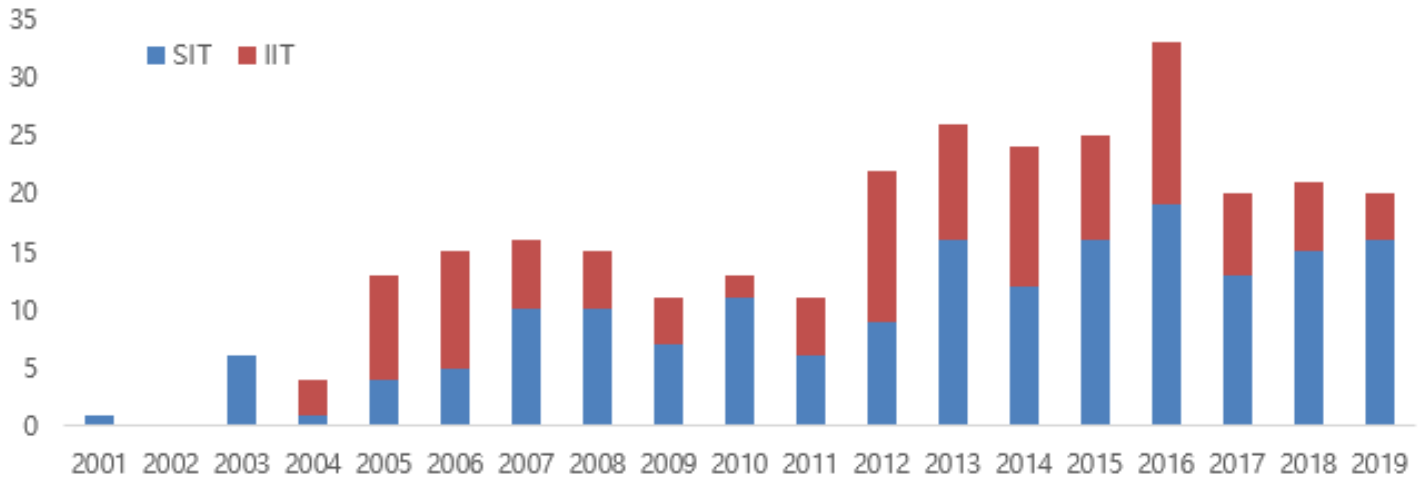
4. Biosimilar (~2019)

- **4 Biosimilar products developed overseas**

No	Company	Drug name	Active ingredient	Indication	Approval date
1	Scigen	SciTropin A	Somatropin	Growth hormone dificiency, etc.	Jan 28, 2014
2	Lilly	Basaglar	Insulin glargin	Diabetes	Nov 25, 2015
3	Green Cross (Biocon)	Glarzia	Insulin glargine	Diabetes	Mar 07, 2018
4	Daewon (GedeonRichter plc.)	Terrosa	Teriparatide	Osteoporosis	Oct 29, 2019

5. Cell Therapy Products

- Approved Clinical Trials (as of Oct. 2019)



Clinical trial No.		Cell Type			
		Stem Cell	Immune Cell	Somatic Cell*	Xenogeneic Cell
SIT	177	109	41	25	2
IIT	121	72	40	9	0
Total	298	181	81	34	2

* keratinocytes, fibroblasts, chondrocytes, osteoblast, etc.

(*By Kyung-Suk Choi from Cell and Gene Therapy Products Division*)

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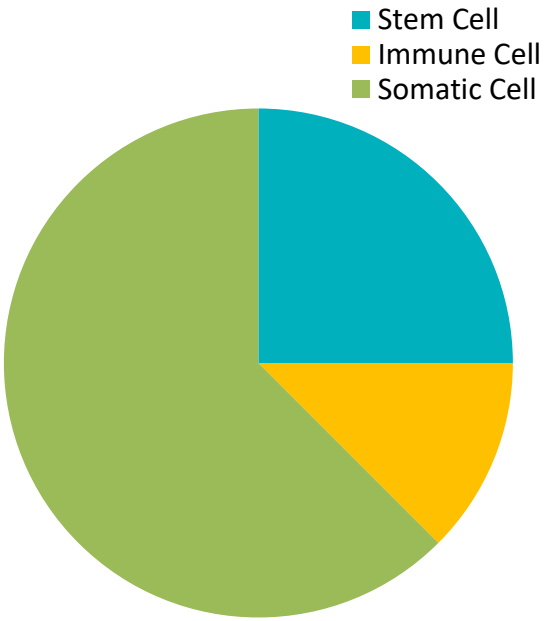
Market Authorization of Cell Therapy Products

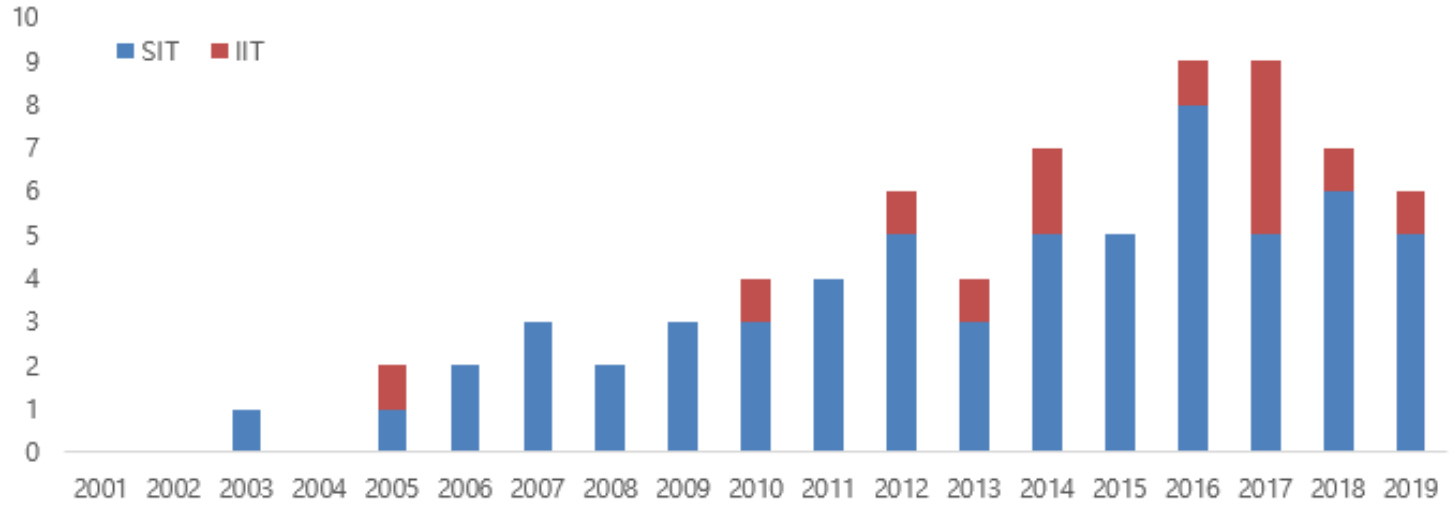
As of Oct. 2019



	Product	Year	Conditional Approval	Indication
Stem Cell Products	**Neuronata-R Inj.**	2014	Orphan	Amyotrophic Lateral Sclerosis
	Cupistem	2012	Orphan	Crohn's disease
	Cartistem	2012		Knee cartilage repair
	Hearticellgram-AMI	2011		Myocardial infarction
Immune Cell Products	**Immunecell-LC**	2007	Cancer	HCC
	CreaVax-RCC	2013		RC (Export only)
Somatic Cell Products	**Cartilife**	2019	autologous chondrocytes	Articular cartilage defect of knee
	Rosmir	2017	autologous skin cells	Nasojugal groove
	KeraHeal-Allo	2015		Burn wounds
	Cure-skin	2011	autologous skin cells	Acne scar
	Queencell (min. manipulation)	2010		SC adipose tissue deficiency
	RMS ossron	2009		Local bone formation
	KeraHeal	2006	autologous skin cells	Burn wounds
	Kaloderm	2005 2010		Burn wounds Diabetic foot ulcer
	Holoderm	2002	autologous skin cells	Burn wounds
	Chondron	2001	autologous chondrocytes	Articular cartilage defect

6. Gene Therapy Products

- Approved Clinical Trials (as of Oct. 2019)



Vector type									
Plasmid	Adenovirus(AV)	AAV	Plasmid +AV	Vaccinia virus	mRNA	Retrovirus	HSV	Bacteria	Total
In vivo									
30	8	0	1	9	2	1	3	1	55
Ex vivo									
1	5	4				9			19

(*By Kyung-Suk Choi from Cell and Gene Therapy Products Division*)

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II. Updates on Regulatory framework for Biopharmaceuticals in Korea

1. Organization

- **Launched the Convergence Innovation Product Support Division (Mar 2019)**

  ****Current Name "Director for Novel Products Approval"**

  ✓ Main duties : Receipt & Approval of MA submission

  ✓ Purpose : For improvement of communication b/t reviewers and applicants (industry)

  ✓ Key mission for 2019

  A. Enhancement of Transparency and Predictability of Procedures
  - Pre-Receipt assessment for Improving quality of *submissions*
  - Management of review procedures and duration (including oral presentation, day-80 meeting, etc.)
  - Introduction of a standardized format for deficiency letter (including detailed descriptions of the reasons for the supplement and the regulatory basis.)

  B. Disclosure of Approval and Review Information in Standardized Format

  C. Development and Implementation of plans for revision of regulations on biopharmacetuicals (Certificate/Document)

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1. Organization

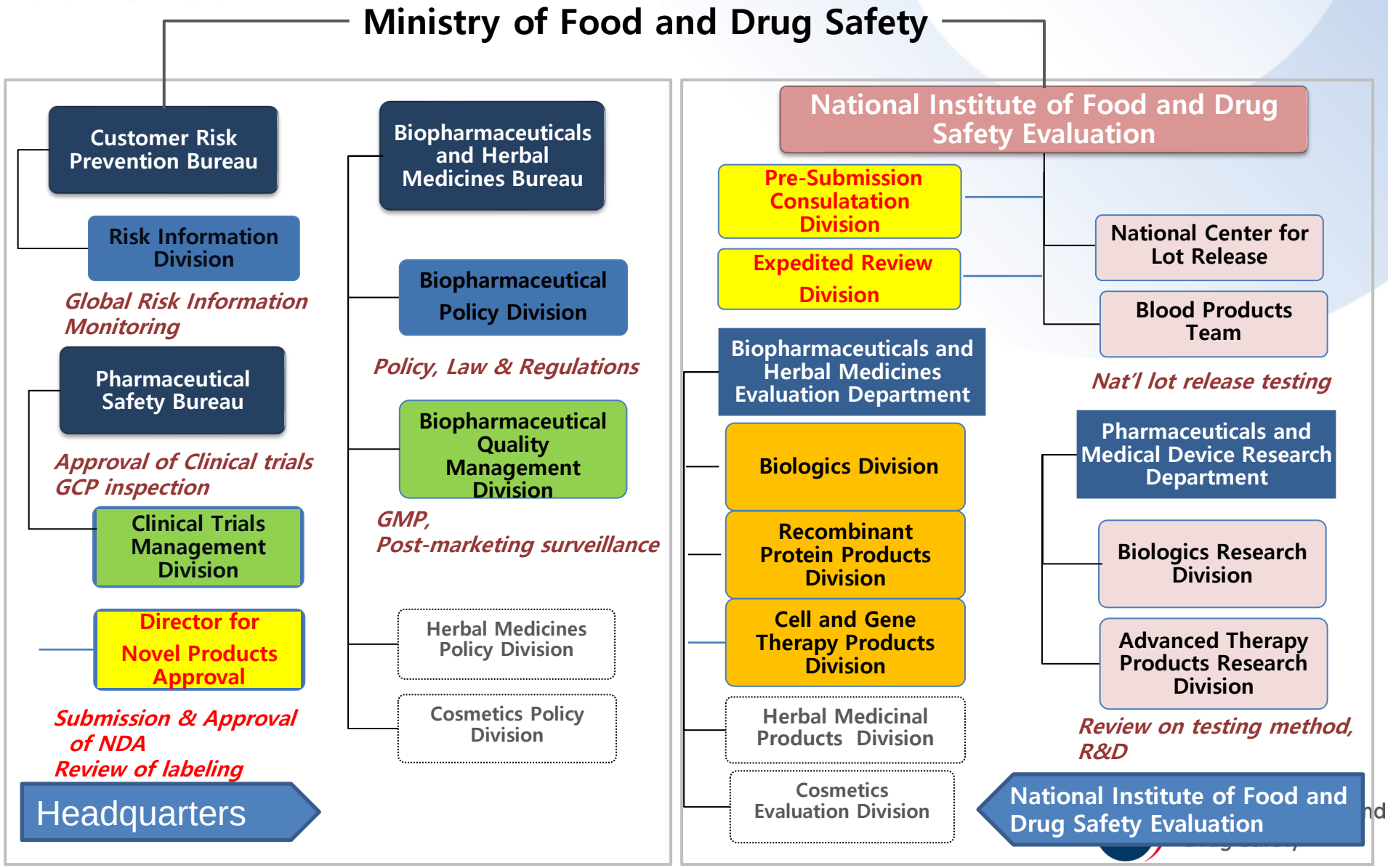
- **Launched the 'Pre-Submission Consultation Division' & 'Expedited Review Division' (31Aug2020)**
  - ✓ Pre-Submission Consultation Division
  - ✓ Expedited Review Division

- **Article 41 (Expedited Review, etc.)**

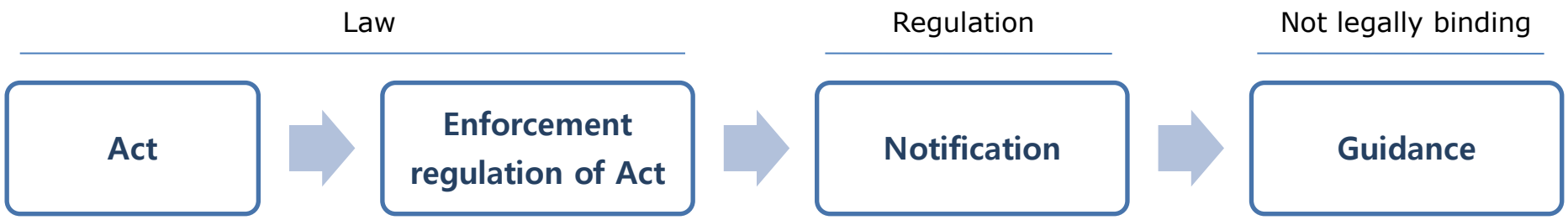
① One of the following should apply:

1. Drugs that can expect therapeutic effects against life-threatening or serious diseases such as AIDS and cancer,
2. Drugs that are judged to be in need of prompt introduction as resistance is manifested and treatment cannot be performed with existing treatments.
3. Medicines that can be expected to prevent or treat the pandemic of bioterrorism infectious diseases and other infectious diseases
4. Orphan drugs
5. Drugs that are used for the purpose of treating or preventing serious diseases, life-threatening diseases, or intractable diseases and have significantly improved safety or effectiveness compared to existing drugs or treatment methods

Biopharmaceuticals Review Management Division was launched!



2. Laws/Acts



- **The Pharmaceutical Affairs Act (Law)**
- **Enforcement Regulation on the Safety of Drug, etc.**
  (Ordinance of the Prime Minister)
  - including Good Manufacturing Practice for Phamarceuticals/Biopharmaceuticals (Subscribed to PIC/S (Jul, 2014))
- **Notifications on the Approval of Pharmaceuticals**
  - Regulation on Review and Authorization of Pharmaceuticals / Biopharmaceuticals
  - Korean Minimum Requirements for biologics
  - The Korean pharmacopoeia (12th)
- **Guidelines**
- **Internal guidelines of processes : MaPPs and SOPs**

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2. Laws/Acts

- **Advanced Regenerative Medicine and Advanced Biopharmaceuticals Safety and Support Act**
  (promulgated in Aug. 2019, to be enacted in Aug. 2020)

✓ Purpose :

To create frameworks to secure safety of **advanced regenerative medicine** and develop measures to support technological innovation in this field and subsequent utilization, and

To provide well-established provisions and guidance necessary to secure quality, safety and efficacy of advanced biopharmaceuticals and support their commercialization,

→ thereby contributing to improving public health and quality of life of the people.

2. Laws/Acts

- **Korean Pharmacopoeia**

✓ Korean Compendia

- The Korean Pharmacopoeia
- The Korea Herbal Pharmacopoeia
- Minimum Requirements for Biological Products

✓ The Korean Pharmacopoeia (KP)

- a compendium of pharmaceuticals established by Korean government to improve public health.
- served as official standards for the description and quality of drugs which are generally recognized as safe and efficacious in the treatment and prevention of diseases.

2. Laws/Acts

- **Korean Pharmacopoeia**

✓ **The components of Korean Pharmacopoeia**

- General Notices and Requirements
- General Requirements for Pharmaceutical Preparations
- Monograph Part I (Frequently used drugs and primary preparations)
- Monograph Part II (Biological drugs, Herbal drugs.. Etc)
- General Tests and Assays (Total 83 methods)
- General Information

✓ **Compendial Updates**

- entire revision : Five-year cycle (recent : 12th edition in 2019)
- supplement : twice in a year

2. Laws/Acts

✓ **12th Revision (Dec 2019)**

- General Tests & Assays

  a. addition of elemental impurities test (ICP, ICP/MS)

  b. addition of arsenic test for glass containers for injection

  c. Improvement of the iron test method to replace testing for harmful reagents

- General Information

  a. Establishment a new section on the evaluation and management of elemental impurities in drug products (ICH Q3D)

2. Laws/Acts

✓ **Recombinant protein products in KP**

- Human Insulin (rDNA)
- Human Insulin Injection (rDNA)
- Somatropin concentrated Solution (rDNA)
- Somatropin for Injection (rDNA)
- Erythropoietin concentrated solution
- Interferon alpha-2 Concentrated Solution (rDNA)
- Filgrastim Concentrated Solution (rDNA)

2. Laws/Acts

✓ General Methods (total 82 methods)

- Elemental impurities tests (ICP, ICP/MS)
- Gas chromatography, Liquid chromatography
- Size Exclusion chromatography, Polyacrylamide electrophoresis
- Peptide mapping
- Total protein assay, Amino acid analysis
- AAS, ICP
- NMR

✓ General Information (total 32 subjects)

- IEF
- Capillary Electrophoresis (CZE, CE-SDS, cIEF, MEKC)
- Statistical analysis of results of biological assays and tests
- Design and development of biological assays
- Viral safety evaluation of Biotechnology Products Derived from Cell lines of Human or Animal origin (ICH Q5A)
- the evaluation and management of metallic impurities in drug products (ICH Q3D)

2. Laws/Acts

- ✓ **Future plans related to the biopharmaceuticals**
  - Analytical Procedures for Recombinant Therapeutic mAbs
  - Tests for Fc Function of Immunoglobulin
  - Glycoprotein and Glycan Analysis—General Considerations
  - Immunological test Methods – General Considerations, Immunoblot, ELISA, and SPR
  - Residual host cell protein measurement in biopharmaceuticals
  - etc..

2. Laws/Acts

The Korean Pharmacopoeia Website

https://nedrug.mfds.go.kr/ekphome

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III.

Regulator's Perspective on Key Considerations for CMC Assessment of Biopharmaceuticals

(specifically focusing on recombinant protein products)

1. Biosimilar

□ Bridging data requirement

when developed using a foreign reference product

✓ Basically, 3-way (foreign RP – Korea RP – Biosimilar) analytical comparability studies are required.

✓ Extensive comparability studies

- Comparative Characterization + Forced Degradation studies (Approximately the same items as comparability studies conducted as main studies)

✓ In case of Korean RPs, it is generally recommended to evaluate more than three batches by obtaining them in order to take into account the variability between batches at different times of manufacture.

*Refer to Q & A on Biosimilar Evaluation (revised in Dec. 2018)

1. Biosimilar

□ Requirements for the batch to be analyzed

✓ Biosimilar batches

- Should be performed for to-be-commercial batches of biosimilar.
- Predominately analyzed in DP lots, but certain parameters can be analyzed in DS lots (DS lots should be representative of DP lots appropriately).

✓ Reference product

- Should include the batches used in the nonclinical and clinical studies.
- Continued analysis during the biosimilar development (with sourcing strategies such as when to buy, when to analyze, where to buy).
- Should provide the batch information analyzed for Analytical Comparability Assessment.

*Refer to Q & A on Biosimilar Evaluation (revised in Dec. 2018)

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동등생물의약품 허가 및 심사를 위한 질의응답집

(Questions and Answers on the Biosimilar Products)

2018. 12.

또한, 비교동등성시험에 사용된 동등생물의약품과 대조약은 상품명, 제형, 조성, 용량, 대조약의 출처, 사용된 배치 수, 배치번호, 제조일(또는 사용기간) 등이 명확히 확인되어야 합니다.

제출자료의 작성 양식은 아래 예시를 참고하시기 바랍니다.

[예시] 동등생물의약품 비교동등성 제출자료 요약

OOO 동등생물의약품 품질 비교동등성 시험물질 요약

구분	상품명 (구매출처)	제형	조성	용량	배치 수 (배치번호)	제조일 (사용기간)	사용 목적

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1. Biosimilar

□ Acceptance Similarity Criteria

✓ We have generally accepted various statistical acceptance criteria, ranging from mean ± 2SD/3SD to tolerance interval, prediction interval, and equivalence testing. Basically, the applicant must justify the selected statistical approach, such as the comparison of various forms of statistical approaches and data.

✓ In addition, we have determined the final analytical comparability by taking into account the representative of the reference product batches, the analytical methods capability, and the impact on safety or efficacy.

✓ If the distribution range and mean values of data between Biosimilar and Reference product are found to differ from each other, it is necessary to analyze the root cause and submit the result of the investigation as to if it is located within the comparability acceptable interval.

2. Common Issues on Stability Data

□ Considerations of stability data requirements not defined in National and International guidelines

* Consequently, there exist some differences b/t national regulatory requirements.

* In 2019, we shared relevant cases and discussed with the industry on the following topics.

- ✓ Flexible application of bracketing design to biopharmaceuticals
- ✓ Labeling & supporting data requirements of 'In-use hold condition' for single-use injections for IV infusion
- ✓ Intermediate Hold times
- ✓ The impact of temperature excursions & light exposure during manufacturing & distribution

2. Common Issues on Stability Data

A. Flexible application of bracketing design to biopharmaceuticals

In general, with rigorous interpretation of ICH Q5C, bracketing has often been applied only when there are three or more fill volumes in liquid formulations.

Recently, the bracketing design is sometimes approved for liquid or freeze-dried powder products with different concentrations based on justification.

ICH Q1D & Q5C

- Q1D : extremes of certain design factors (e.g., strength, container size and/or fill)
- Q5C : Where the same strength and exact container/closure system is used for 3 or more fill contents

* Difference in the use (definition) of strength??

2. Common Issues on Stability Data

B. Labeling and supporting data requirements of 'In-use hold condition' for single-use injections for IV infusion

There are differences in the data requirements, with different labeling requirements for different regulatory authorities (Europe, the US, Korea) regarding the establishment of in-use conditions for single-use injections administered by IV infusion after dilution/reconstitution.

In Korea, we consider the results of the physicochemical stability as well as the microbiological safety assessment (spiking study), and require description of the condition (temperature & period) on the label that is considered appropriate (safety margin is considered).

In Korea, we have only one relevant guideline published; 'Guideline on Aseptic Operation of Injections" <for Medical staff>.

2. Common Issues on Stability Data

C. Intermediate Hold times

No clear requirements of stability studies (testing items, hold time, cumulative approach, etc.) to determine intermediate hold times.

2. Common Issues on Stability Data

D. The impact of room temperature & light exposure during manufacturing & distribution

Based on understanding of the stability profile of the product, assessment is needed to minimize the effect of manufacturing process conditions on quality.

In particular, the drug product manufacturing process is susceptible to exposure to room temperature and visible light conditions, so in case of unstable products, evaluation for process development is required (in case of light exposure, it is more relevant to consider the light conditions of the actual work place than the ICH Q1B conditions.)

3. Other CMC Issues

CCIT

- ✓ Increasing demand for Routine monitoring of Container-closure integrity.
- ✓ In Korea, strongly recommended to domestic companies.
- ✓ Regulatory requirements will be determined in accordance with changes in global regulatory requirements such as GMP regulations and guidelines.

Extractables/Leachables

- ✓ Request for evaluation data on DS / DP container
- ✓ Strongly evaluation required on materials used during the manufacturing process.

4. New Trends

1. New technologies

- ✓ Continuous Manufacturing, Big data, Automation extension
- ✓ Expansion of commercially used expression systems (ex. plant)
- ✓ Advances in drug delivery technologies and devices

➡ New technologies raise new regulatory challenges.

2. Accelerated Development

- ✓ Personalized, Precision Medicine / Rare diseases (Orphan drugs)
- ✓ Rapid development of new (type/class of) products through technological innovation

➡ Less data over short development periods,

➡ What are the regulatory requirements for ensuring quality?

➡ Can we be flexible with our regulatory requirements?

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IV. Summary

- The development and approval of biopharmaceuticals in Korea continues to increase, and the biotechnology industry in Korea is expected to continue to grow.
- I have introduced the current status of development of COVID-19 products, where most regulatory resources are focused, including DNA vaccines and recombinant neutralizing monoclonal antibody.
- In case of Recombinant protein products, biosimilars are still the main focus, but the development of new drug candidates, such as immune check point mAb, bispecific mAb and new types/classes products, is also increasing.

- A total of 16 cell therapy products have been approved to date and over 90 clinical trials are in progress.
- Development of gene therapy products is increasing.
- The MFDS has been reorganized to be better positioned for Expedited Reviews so as to expand treatment opportunities for new medicinal products, and to enhance procedural transparency and predictability.
- I have introduced the regulatory framework for systematic control of drug products in Korea, including laws, regulations and Korean Pharmacopoeia.
- In addition, some examples of issues raised during MFDS CMC review, especially related to biosimilars and stability tests, are presented.

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- Regulatory requirements that raise uncertainty in drug development make the process less efficient. Therefore, scientifically sound regulatory requirements need to be clearly stated to ensure a high level of quality without unnecessary burden.

- The key point is collaboration & harmonization.

- Through collaboration between industries and global regulatory authorities, it will be possible to establish clear regulatory requirements or to address various issues that arise.

- The same goes for the development of COVID-19 products. In the context of the constantly evolving COVID-19 pandemic, the world should work together to accelerate drug development and facilitate access to the products. Many regional regulators, including us, are making various efforts, including expedited review. In-depth cooperation, including sharing of these experience and knowledge, will be essential.

- The MFDS will continue to promote international harmonization and clarification of regulatory standards, including ICH member activities and WHO cooperative activities. We hope this will play a positive role in the global bio-industry.

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Thank you for your attention

JINA KIM
Scientific officer (reviewer-Q)
Recombinant protein products division
NIFDS, MFDS

hahajina79@korea.kr

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