Korea Pharmaceutical Market & Approval system

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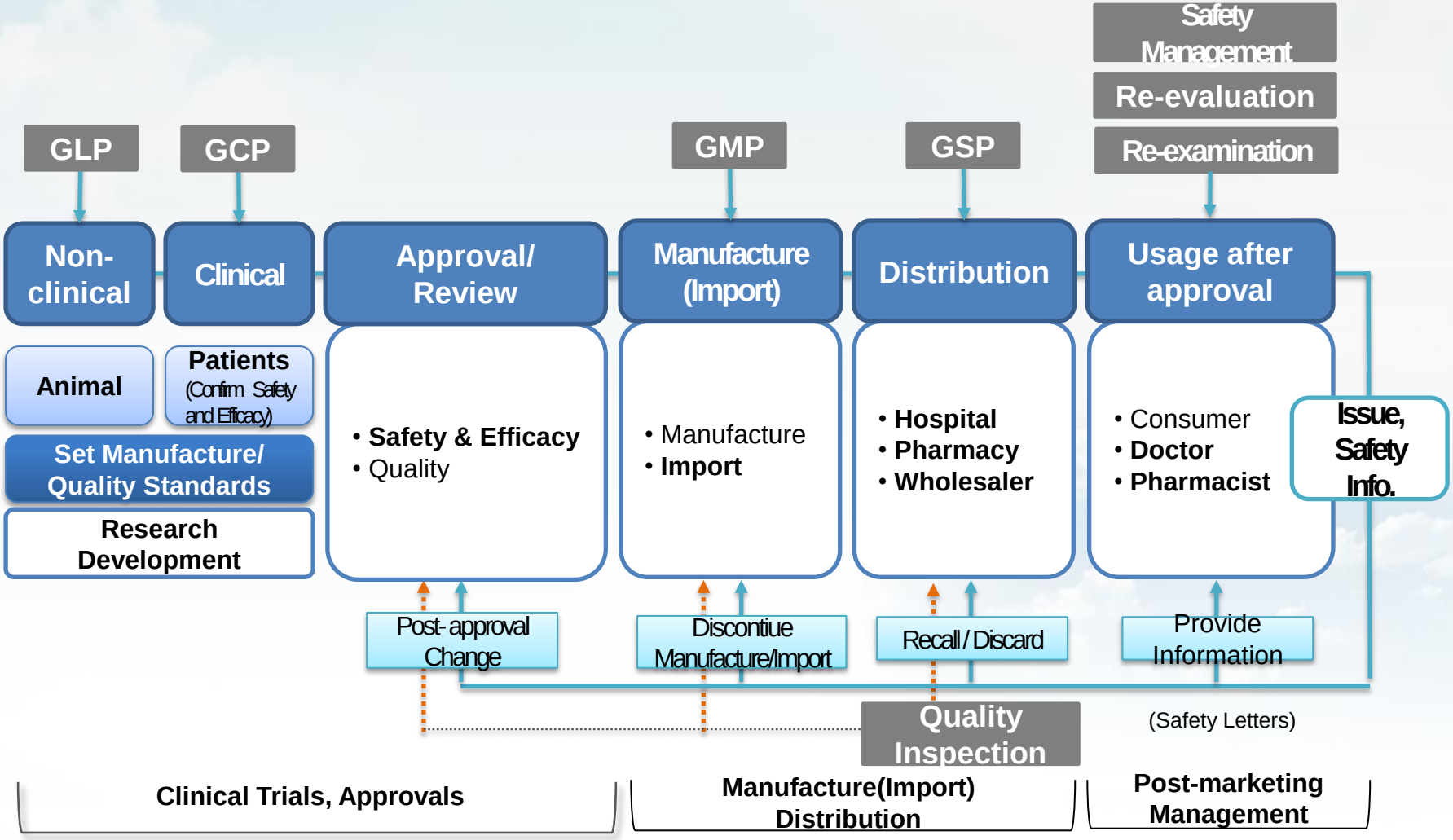
Korea Pharmaceutical Market

(Unit : ₩ 100 million)

Years	Production	Export	Import	Market Size	Import Share	Market Growth Rate
2010	157,098	17,810	54,184	193,472	28.0	6.18
2011	155,968	19,585	55,263	191,646	28.8	-0.94
2012	157,140	23,409	58,535	192,266	30.4	0.32
2013	163,761	23,306	52,789	193,244	27.3	0.51
2014	164,194	25,442	54,952	193,704	28.4	0.24

Source: MFDS, KPTA

Pharmaceutical Approval System



Pharmaceutical Approval System

- **New Drug(ND), New Molecular Entity(NME)**
  - An active ingredient never marketed in Korea

- **Incrementally Modified Drugs (IMD)**
  - ✓New derivative
  - ✓ New efficacy
  - ✓ New formulation
  - ✓ New combination
  - ✓ New intended use
  - ✓ New route of Administration

- **Generic Drugs**

Pharmaceutical Approval System

- **NDA**

- **Generic**
  - **Bioequivalence study**
  - **GMP documents**
  - **Chemistry, Manufacturing, Controls**

Pharmaceutical Approval System

✓ **DMF** (scope of drug substances to register)

1) Active drug substances of new drug
2) Drug substances designated (206 drug substances and their salts and hydrates)
3) Drug substances derived from human placenta

✓ Following data should be included in conformity with Regulation

1) Data on facility for manufacture and quality management
2) Data on physicochemical properties and stability
3) Data on manufacturing process, packaging, container, cautions in storage and handling, etc.
4) Data proving the eligibility of the substance (equivalent to KGMP or above the level of KGMP)
5) Data including batch analysis, analytical procedures, used solvent of drug substance
6) Sample drug substance for test

* Data can be submitted using the Common Technical Document

Thank You