Japanese Pharmaceutical System & Market

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Pharmaceutical Production in Japan

Source: Yakujikogyoseisandotatokeichosa, MHLW

Haichi Drugs: Direct Household Marketing Non-prescription Drugs

Pharmaceutical Production in Japan

Year	Total Drug Production	Prescription Drugs	OTC Drugs	Other Drugs	Haichi Drugs
				million yen	
2005	6,390,722	5,741,280	611,492	649,442	37,951
2006	6,438,082	5,803,581	599,259	634,501	35,243
2007	6,452,166	5,828,086	592,963	624,080	31,117
2008	6,620,091	5,992,765	598,438	627,327	28,889
2009	6,819,589	6,174,202	616,601	645,387	28,786
2010	6,779,099	6,148,876	602,193	630,223	28,030
2011	6,987,367	6,344,512	617,231	642,855	25,624
2012	6,976,712	6,263,010	689,018	713,702	24,684
2013	6,894,014	6,193,983	677,407	700,031	22,624
2014	6,589,762	5,868,927	700,376	720,835	20,459

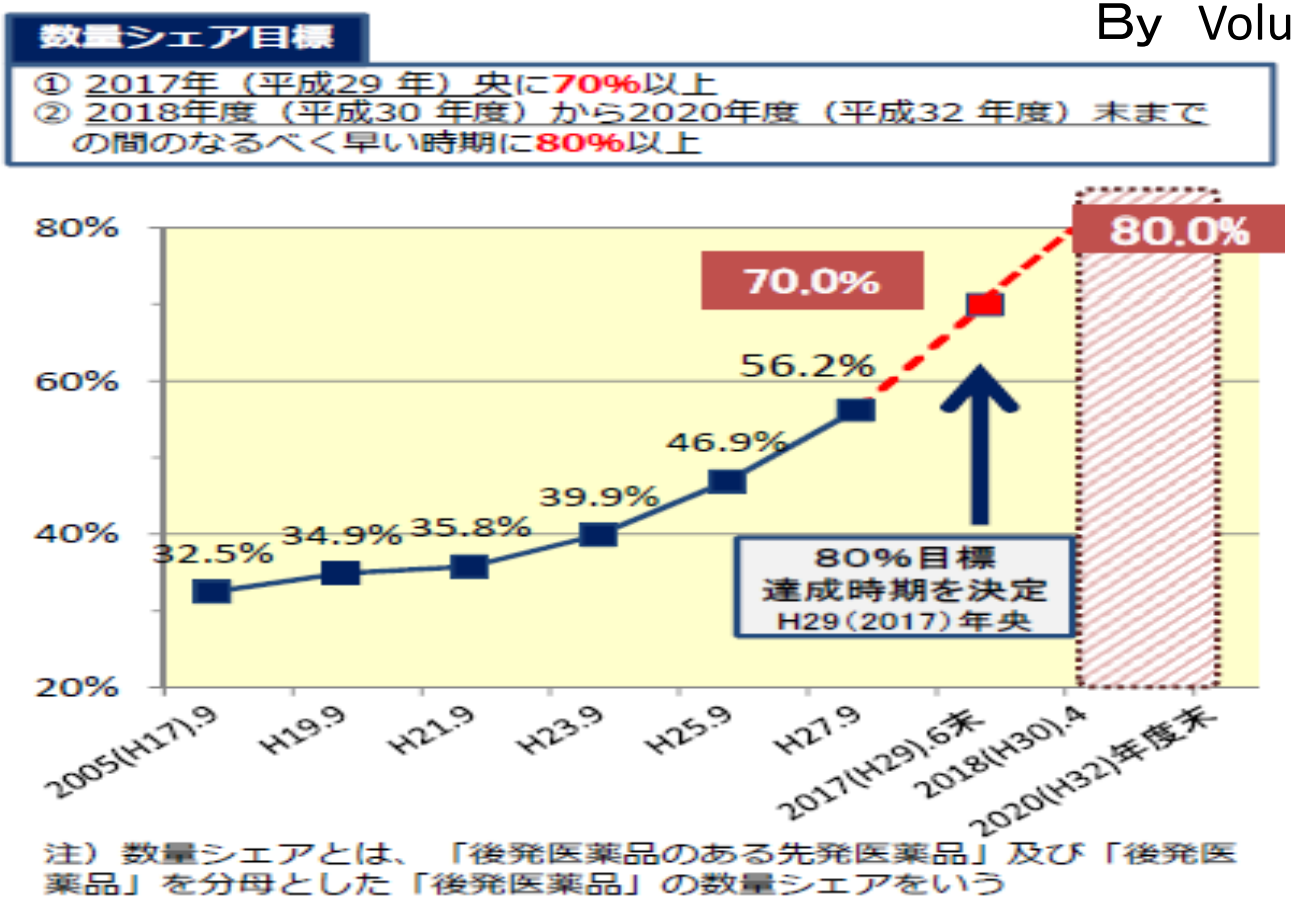
Source: Yakujikogyoseisandotatokeichosa, MHLW

Haichi Drugs: Direct Household Marketing Non-prescription Drugs

Evolution of Generic Drug Business & A New Target (80% in March 2020)

我が国の後発医薬品の数量シェアの推移と目標

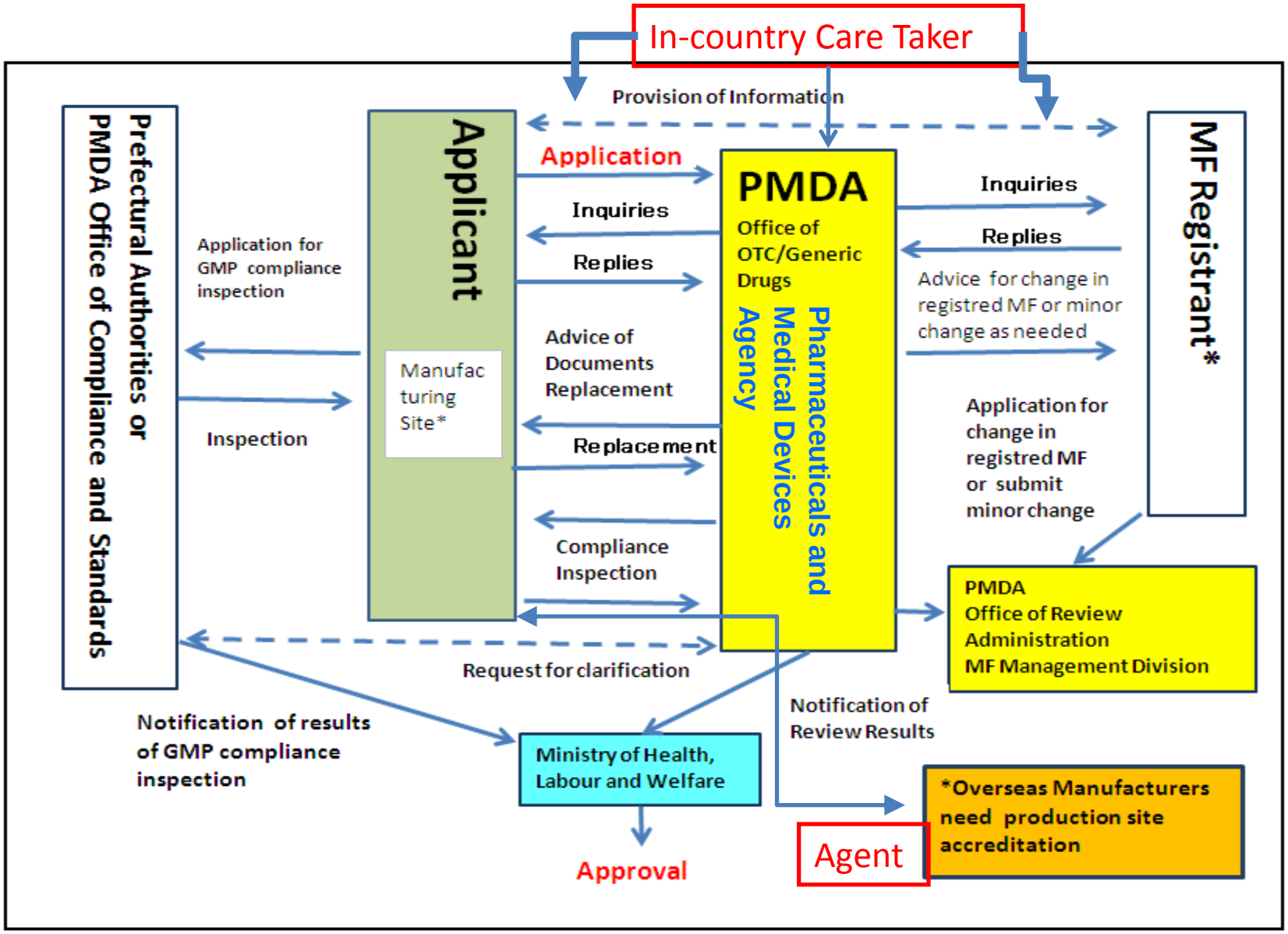
By Volume



注）数量シェアとは、「後発医薬品のある先発医薬品」及び「後発医薬品」を分母とした「後発医薬品」の数量シェアをいう

Source:
MHLW

Pharmaceutical Approval Reviews



Source:PMDA

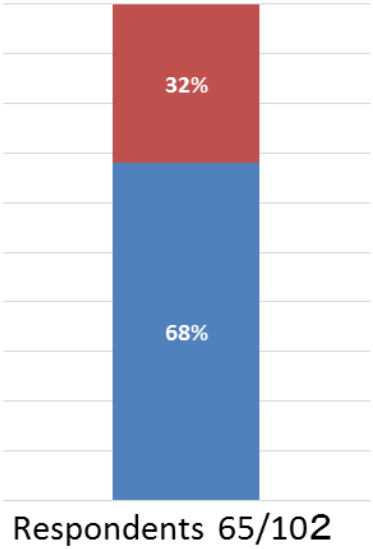
Japanese DMF and Change Control Systems

- Regarding MF registration and reference systems, basically actual operation is very similar to many of the same systems in other countries.
- However, there are some differences such as requirement to appoint an In-country Care-Taker
- Regarding “Change Control”, there are only two categories as “major” changes which require a review and “minor” changes which require only submission of the necessary documents and no “medium level”.
- Experience tells us PMDA tends to guide the DMF Holder to apply “minor” changes as “major” .

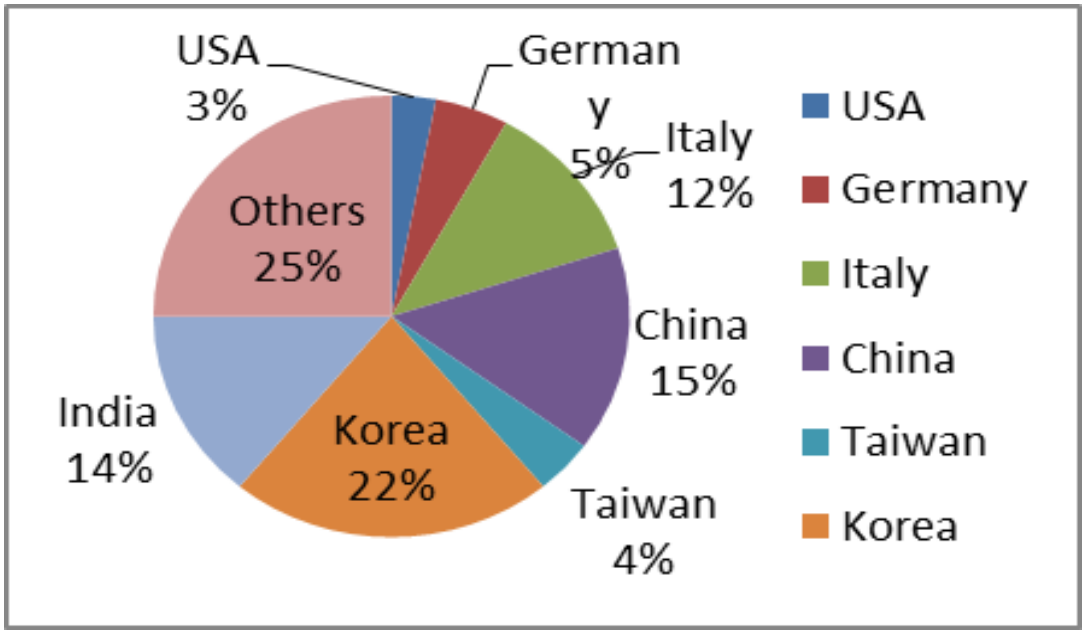
DMF and In-Country Care-Taker

JAPAN PHARMACEUTICAL TRADERS' ASSOCIATION is of importers of APIs and they on many occasions act as In-Country Care-Takers, which is compulsory for DMF registration by overseas API manufacturers. We will show you the ratios among about 100 member companies:

1. Ratio of member companies acting as in-country care-taker for MF



2. Ratio of MF registered APIs by country

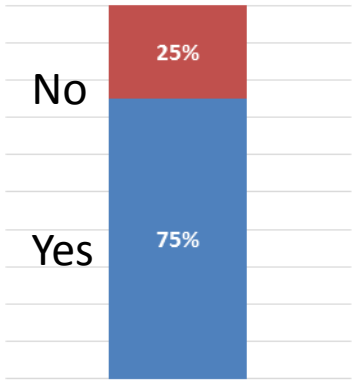


Source: JAPTA, March 2016

Production Facilities Accreditation

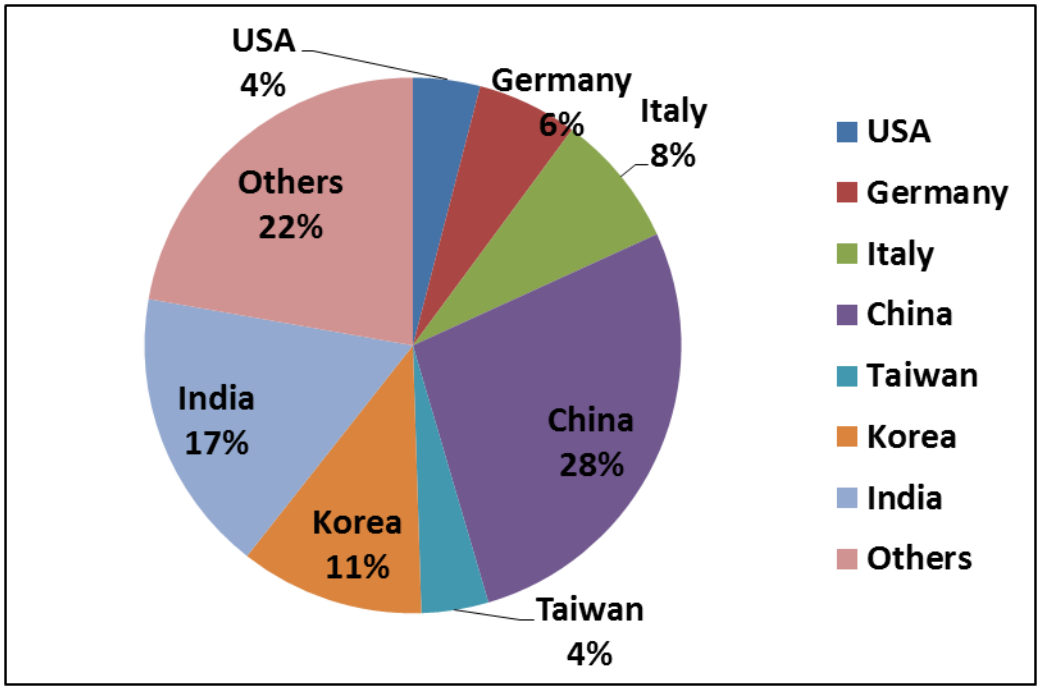
- Another important issue is to find and appoint an agent for Production Site Accreditation before exporting APIs from such designated facilities. Traders play another role as below:

1. Ratio of member companies acting as agent for site accreditation



Respondents: 65/102

2. Accreditations given by MHLW per Country



Source: JAPTA, March 2016

Policy of Promoting the use of Generic Drugs

- Pricing policy for New Generic Drugs
- Pricing policy for Long-listed Drugs (after patent expiry)
- Policy of Promoting the use of Generic Drugs for Pharmacies
- Revision of Prescription Format
- Other measures

Thank You