Data required for obtaining a manufacturing-marketing approval on a drug.

The below Table 1 shows the data which are required to be disclosed in the application for the drugs in each category (Notification No. 1121-2 of the Pharmaceutical and Food Safety Bureau dated November 21, 2014).

Table 1

	a 1 2 3	b 1 2 3	c 1 2 3	d 1 2 3	e 1 2 3 4 5 6	f 1 2 3 4 5 6 7	g	H
1. New ingredients	○ ○ ○	○ ○ ○	○ ○ ○	○ ○ △	○ ○ ○ ○ × △	○ ○ ○ △ ○ △ △	○	○
2. New combination	○ ○ ○	× ○ ○	○ ○ ○	○ △ △	○ ○ ○ ○ × △	○ ○ × × × △ ×	○	○
3. New administration route	○ ○ ○	× ○ ○	○ ○ ○	○ △ △	○ ○ ○ ○ × △	○ ○ × △ ○ △ △	○	○
4. New indication	○ ○ ○	× × ×	× × ×	○ × ×	△ △ △ △ × △	× × × × × × ×	○	○
5. New formulation	○ ○ ○	× ○ ○	○ ○ ○	× × ×	○ ○ ○ ○ × △	× × × × × × ×	○	○
6. New dosage	○ ○ ○	× × ×	× × ×	○ × ×	○ ○ ○ ○ × △	× × × × × × ×	○	○
7. Follow-on Biologics	○ ○ ○	○ ○ ○	○ △ △	○ × ×	△ △ △ △ × △	△ ○ × × × △ △	○	○
8. Additional formulation (Under PMS Term) 8-2. Additional formulation (Not under PMS Term)	○ ○ ○	× ○ ○	△ △ ○	× × ×	× × × × ○ ×	× × × × × × ×	×	○
9. Similar composition (Under PMS Term) 9-2. Similar composition (Not under PMS Term)	○ ○ ○	× ○ ○	○ ○ ○	△ △ ×	× × × × × ×	○ △ × × × △ ×	○	○
10. Others (Under PMS Term) 10-2. Others relating to changes on manufacturing methods of Biological Products etc (Under PMS Term) 10-3. Others (Not under PMS Term) 10-4. Others relating to changes on manufacturing methods of Biological Products etc (Not under PMS Term)	× × ×	× △ ○	× × ○	× × ×	× × × × ○ ×	× × × × × × ×	×	○

○: Data required; ×: Data not required; △: Data required depending on individual cases;

“New formulation” means a new drug which has the different usage from the already-approved drug based on some changes in terms of pharmaceutics and does not include any drugs specified in “Additional formulation”.

“Additional formulation” means a drug which has same active ingredients, administration route, indications, effects, usages and dosages as the already-approved drug, but has

different formulation or content.

“Biological Products” means “Drugs Applying Biotechnology/Drugs Originating from Living Organisms”.

Table 2 : Meanings of Terms of “a” to “g” in the First Row of Table 1

a. Origin or background of discovery, conditions of use in foreign countries	1. Origin or background of discovery 2. Conditions of use in foreign countries 3. Special characteristics, comparisons with other drugs, etc.
b. Synthetic route, physicochemical properties, standard, and test methods	1. Chemical structure and physicochemical properties, etc. 2. Synthetic methods 3. Standards and test methods
c. Stability	1. Long-term storage tests 2. Tests under severe conditions 3. Accelerated tests
d. Pharmacological action	1. Tests to support efficacy 2. Secondary pharmacology, Safety pharmacology 3. Other pharmacology
e. Absorption, distribution, metabolism, and excretion	1. Absorption 2. Distribution 3. Metabolism 4. Excretion 5. Bioequivalence 6. Other pharmacokinetics
f. Acute, subacute, and chronic toxicity, teratogenicity, and other types of toxicity	1. Single dose toxicity 2. Repeated dose toxicity 3. Genotoxicity 4. Carcinogenicity 5. Reproductive toxicity 6. Local irritation 7. Other toxicity
g. Clinical studies	Clinical trial results
h. Contents to be described in the insert (Art. 52 (1)	The contents

With regard to clinical studies including post-marketing clinical trials, "Standards on the Implementation of Clinical Trials on Drugs (New GCP)" (MHLW Ordinance No. 28 dated March 27, 1997) was fully enacted in April 1998 aiming to satisfy scientific and ethical requirements. In addition, efforts for securing international harmonization among regulations on pharmaceuticals are being promoted aiming to provide excellent drugs promptly to nationals, through, for example, "International Conference on Harmonization (ICH) of Technical Requirements for the Registration of Pharmaceuticals for Human Use among Japan, US and EU".