

## **Data Exclusivity**

### **A. Comparison of Data Exclusivity with Patents**

There are two steps in developing an innovative drug, that is, the discovery of a new compound and the investigation on the safety and efficacy of the drug.

Patents provide the incentive for the first step and reward the invention. On the other hand, in the second step, where most of the cost and of the risk is involved, the only process that confers protection on the owner from piracy of data generated with “considerable effort” to demonstrate safety and efficacy of the innovative drug is “data exclusivity”. The importance of this data exclusivity process, which is independent from patent protection, is recognized by the GATT TRIPs Art. 39.3, and obliges the WTO members to implement such protection on the unpublished data that are submitted to the Authorities for obtaining marketing approval.

Additionally, there are many cases where patent protection on an important medicine is weak or nonexistent since it takes long time to develop a medicine in Japan. Weak or non-existent patent protection for a specific medicine does not mean the product is not important for patients. In these situations, data exclusivity plays a vital role by providing the necessary incentive to develop important and sometimes life-saving treatments for patients. It provides a supplementary protection to the patent system, giving innovators the possibility of reasonable compensation for the generation of safety and efficacy data on these compounds or indications from its approval date.

Regulatory data exclusivity differs fundamentally from patent protection as it does not protect the substance itself, only the registration data. It does not prevent generic companies from gaining approval for a similar medicine by independently generating the necessary test and clinical trial data. So it offers no market exclusivity – merely legal title to data for a limited period.

Therefore, both patents and data exclusivity are necessary for supporting a vigorous, globally competitive research based pharmaceutical industry.

## **B. Data Exclusivity**

Japan does not have data exclusivity legislation like that of, for example, CA, US or EU. However, there are regulations in Japan that provide a Post Marketing Surveillance (PMS) period, also known as Reexamination period, which effectively produces a period of data exclusivity. The concept underlying the PMS period, which came into effect in April 1980, is that no further approvals of a pioneer product would be granted until the safety and efficacy of the pioneer product has been demonstrated by extensive clinical experience and surveillance of the marketed product. At the end of the stipulated PMS period, a data package provided by the pioneer company describing the clinical experience with the product is reexamined by the authorities. After expiry of the PMS period, third parties (generic companies) would be allowed to rely on the pioneer company's submission data in order to obtain approval for their own version of the product. Therefore, the PMS period effectively results in data exclusivity.

The drugs subject to PMS include products designated by MHLW at the time of “Manufacturing-marketing approval” as drugs with, e.g., active ingredients, dose, dosage form, administration route and/or indications that are distinctly different from drugs that have already been approved (PAL Art. 14-4).

**The duration of the PMS period starts on the day of approval, according to the following categories:**

|           | Categories of drugs  | Duration of PMS period                       |
|-----------|--|--|
| New Drugs | Orphan drugs <sup>1</sup>  | 10 years <sup>2, 3</sup>                     |
|           | Drugs requiring review of adverse reactions <sup>4</sup> for a period of more than 6 years from “Manufacturing-marketing approval” (PAL Regulation Art. 57(1)) |  |
|           | Drugs for which clinical studies (clinical trials or post-marketing clinical trials) to set paediatric doses, etc. continue after approval                     |  |
|           | Drugs containing new active ingredients  | 8 years as from April 1 <sup>st</sup> , 2007 |
|           | New combination drugs  | 6 years <sup>5</sup>                         |

<sup>1</sup> Less than 50,000 patients for the drug in Japan, high level of efficacy, etc

<sup>2</sup> The duration of the PMS period is designated by the Minister based upon a recommendation from the PFSC (PAL Art. 14-4 (1) (i) (a)).

<sup>3</sup> When the Minister confirms it particularly necessary to perform proper reexaminations of new drugs, the Minister may extend the examination period to a period not exceeding 10 years from the date of the marketing approval after seeking the opinion of PFSC (PAL Art. 14-4 (2)).

<sup>4</sup> The result of use including disease, disability, death suspected to be caused by adverse reactions of infections suspected to be due to the use

<sup>5</sup> A period of at least 6 years for drugs from the date of the marketing approval for drugs other than those indicated in Art. 14-4 (1) (i) (a) or (b) [Art. 14-4 (1) (i) (c)].

|                             |   |  |
|-----------------------------|---|--|
|                             | Drugs with new routes of administration |  |
| Improved Drugs <sup>6</sup> | Drugs with new indications              | 4 to 6 years (normally 4 years) <sup>7</sup> |
|                             | Drugs with new dose/dosage form         |  |

### **PMS Period for Subsequent Approval Approved during the Original PMS**

#### **Period**

| <b>PMS period for the original approval</b>                       | <b>Subsequent approval</b>                | <b>Duration of PMS period for the subsequent approval</b> |
|---|---|---|
| 6 / 8 years (more than 4 years remain at the subsequent approval) | As "Improved Drugs"                       | Remaining PMS period for the original approval            |
| 6 / 8 years (less than 4 years remain at the subsequent approval) |   | 4 years   |
| 6 or 10 years   | As "Orphans"                              | 10 years  |
| 8 years (more than 6 years remain at the subsequent approval)     | As drugs with new route of administration | Remaining PMS period for the original approval            |
| 8 years (less than 6 years remain at the subsequent approval)     |   | 6 years   |
| 10 years  | As "Improved Drugs"                       | 5 years and 10 months                                     |

### **C. PMS Term Extension Based on Development for Paediatric Indication**

The Drug GPMSP (Good Post-marketing Surveillance Practice) was partially revised by MHW Ordinance No. 151 dated December 27, 2000, and "Early Post-marketing Surveillance" for new drugs was newly established. One item in this Ordinance is the extension of PMS term up to 10 years in case the

<sup>6</sup> Drugs which have clearly different indications (excluding routes of administration) or doses but have the same active ingredients and routes of administration as drugs that have already been approved or otherwise differ only slightly from drugs which have already been approved (PAL Regulation Art. 57(2)).

<sup>7</sup> The duration of the PMS period is designated by the Minister based upon a recommendation from the PFSC (PAL Art. 14-4 (1) (i) (b)).

originator of a drug plans to conduct clinical trials (clinical trials or Phase IV Study) for setting up the dose of the drug for paediatric indication. Compared with 6 months of US (6 months in EU as well), in Japan, i.e. additional 4 years (10 years – 6 years) can be afforded for the development of paediatric indications. Besides, although the actual development of paediatric indication is needed in US and EU, the planning per se may be enough to extend the PMS term up to 10 years in Japan.

To date, the PMS terms of following medicines/active ingredients are extended to 10 years according to PAL Art. 14-4 (2) in order to conduct Phase IV study for setting up the dose for paediatric indication.

1. Bulk of loratadine
2. “Claritin” (the active ingredient is loratadine)
3. “Targocid” (the active ingredient is teicoplanin)
4. Bulk of fluvoxamine maleate
5. “Luvox” (the active ingredient is fluvoxamine maleate)
6. “Depromel” (the active ingredient is fluvoxamine maleate)
7. “Allegra” (the active ingredient is fexofenadine hydrochloride)
8. “Amaryl” (the active ingredient is glimepiride)
9. “Myslee” (the active ingredient is zolpidem tartrate)
10. “Onoact” (the active ingredient is landiolol hydrochloride)
11. “Azilva” (the active ingredient is azilsartan)
12. “Imigran” (the active ingredient is sumatriptan succinate)
13. “Seibule” (the active ingredient is miglitol)

14. "Adoair" (the active ingredients are salmeterol/fluticasone)

15. "Abilify" (the active ingredient is aripiprazole)

16. "Adcirca" (the active ingredient is tadalafil)

17. "Lonasen" (the active ingredient is blonanserin)