Japanese Drug Regulations Related to Data Exclusivity (Excerpts)

Pharmaceutical Affairs Law

Article 14

3 Anyone who wishes to obtain approval… shall attach documents on the results of clinical trials and other pertinent information to its application therfor, as specified by a Ministerial ordinance [Article 40 of the Implementation Rules]....

Article 14-4

1. A person who received approval of marketing approval of drugs… falling under any of Items (1) and (2) shall have the drugs… reexamined by the Minister of Heath, Labor and Welfare, and shall apply therefor within the period prescribed in the relevant Item:
   (a) Drugs… which shall be designated by the Minister of Heath, Labor and Welfare at the time of the grant of marketing approval as being those drugs whose active ingredients, content, administration, dosage, indications and effects, etc… are evidently different from the drugs… that have already been approved: Within three (3) months… from the end of the following period:.
      (1) For orphan drugs or other drugs to be designated by a Ministerial ordinance [Article 57 of the Implementation Rules]…, a period to be determined by the Minister of Heath, Labor and Welfare within the range over six (6) years but not exceeding ten (10) years from the date of the approval….;
      (2) For drugs… which evidently differ from the drugs already approved only in terms of the indications or effects, or other drugs to be designated by a Ministerial ordinance [Article 57 of the Implementation Rules], a period of less than six (6) years in length to be determined by the Minister of Heath, Labor and Welfare…from the date of the approval….;
      (3) For drugs other than (a) or (b) above, six (6) years from the date of approval…

Implementing Rules of the Pharmaceutical Affairs Law

Article 40

2. …it shall not be necessary to attach documents required under... Article 14, Paragraph 3 of the Law…, in cases where the subject matter of the application is in the pubic domain medically or pharmaceutically… However, in the event drugs [for which approval is sought] have the same active ingredients, content, administration, dosage and indications and effects as one of the new drugs defined by Article 14-4, Paragraph 1, Item (a) of the Law…, the subject matter shall not be considered to be in the pubic domain medically or pharmaceutically, during the reexamination period of the new drug concerned….

Article 57

1. Drugs to be designated by a Ministerial ordinance under Article 14-4, Paragraph 1, Item (a)(1) of the Law shall be drugs… which require a survey of diseases, disability or deaths

suspected to be caused by adverse reactions or infections suspected to be caused by its use and other results of the use for a period over six (6) years from the date of the approval….

2. Drugs to be designated by a Ministerial ordinance under Article 14-4, Paragraph 1, Item (a)(2) of the Law shall be those drugs which evidently differ from the drugs already approved in terms of their administration (excluding administration routes) or dosages, but have the same active ingredients and administration routes… or those drugs whose difference from the drugs already approved are not material.