5.4.4.3 What if there are already competitive products on the market in Japan?

There is no regulation preventing more than one orphan drug designation and approval for the same indication in Japan. For instance, if a product is already on the market in Japan and designated as an orphan drug for the treatment of Disease A, this *does not* prevent another drug from receiving orphan drug designation and entering the Japanese market to also treat Disease A. However, the MHLW will almost always be reluctant to support two drugs with the same indication, so the applicant of the second drug should be able to show significant superiority to the drug already on the market.

5.4.4.4 Supportive Data

The following types of data will be supportive in showing that the disease/condition treated by the orphan drug affects less than 50,000 persons in Japan.

- Statistical data from an "official" source (government health authority, medical organization, etc.) showing the estimated number of patients with the disease. Note: there are research groups organized by the MHLW which often issue reports with patient data.
- If statistical reports are unavailable, the applicant can interview Japanese doctors, contact medical associations or hire an investigational consultant to determine the estimated number of patients in Japan.
- The applicant can refer to http://wwwdbtk.mhlw.go.jp/toukei/ for statistical data on patient numbers. This information is located on the MHLW website, but available in Japanese only.

The MHLW determines the amount of clinical data required for an orphan drug application and approval on a case-by-case basis. The following types of data are accepted by the MHLW.

- Any Japanese clinical data.
- Clinical studies done under the same conditions (same dosage, etc.) and for the same indication as the current orphan drug application. Foreign data under the same conditions may also be supportive.
- Data from off-label use in Japan.
- Any bridging or comparative studies done under the same conditions (same dosage, etc.) as the current indication that demonstrate the safety and efficacy of the drug.
- Other important data such as the raw data from clinical studies compiled in the NDA package, Clinical Safety Data Management, etc.

Of course, Japanese data is most valuable. Generally, foreign or Asian (non-Japanese) data is considered more as reference data by the MHLW. Japanese data is considered supportive in terms of getting the product approved.