

The Article 77-2 of the Pharmaceutical Affairs Law

Article 77-2 (1) When an application has been made by a person who engages in marketing a drug or medical device which fall under any and all of the following items (including those engaging in manufacturing, etc. in foreign countries of those which are intended to be exported to Japan), the Minister of Health, Labour and Welfare may designate the drug or medical device in the application as an orphan drug or medical device, after hearing the opinion of the Pharmaceutical Affairs and Food Sanitation Council.

- (i) The number of subjects for whom the drug or medical device is used does not satisfy the requirement of number laid down by Ordinance of the Ministry of Health, Labour and Welfare in Japan;
- (ii) The drug or medical device in the application, if approved for manufacturing and sales, is expected to prove especially valuable when applied in medical practice in terms of the usage.

(2) When the Minister of Health, Labour and Welfare has made a designation pursuant to the provision of the preceding paragraph, the Minister shall give public notice of the fact.

<Note>

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