Brief Instructions for the Form of Summary of the Orphan Drug/Medical Device

Form of summary of the orphan drug/medical device

Name of the orphan drug/medical device:
- Fill out as indicated in the application form of orphan designation.

Name of the company:
- Fill out as indicated in the application form of orphan designation.

Expected indication:
- Fill out as indicated in the application form of orphan designation.

Description of the target disease:
- Fill out a brief explanation of the target disease and the number of patients etc.

Efficacy of the drug/medical device for the target disease, etc.:
- Fill out medical needs, results of clinical studies to date (including clinical studies conducted outside Japan) and development status, etc.

<Note>
1. Size of this form shall be A4.
2. Applicant may as well attach an accompanying sheet(s) for more detailed explanations, if needed.

Fill out this form in Japanese.