Application examples of the specific technical fields of
“Examination Guidelines for Patent and Utility Model”
This annex provides the examples of the application of “Examination Guidelines for Patent and Utility Model” to the following specific fields of technology:

See Examination Guidelines in relation to matters for patentability requirement which are not explained in this Annex B.

1. Computer software related inventions;
   - Enablement requirement,
   - Clarity requirement,
   - Eligibility for Patent,
   - Novelty,
   - Inventive Step,

2. Biological inventions;
   - Enablement requirement,
   - Clarity requirement,
   - Eligibility for Patent and Industrial Applicability,
   - Novelty,
   - Inventive Step,

3. Medicinal inventions;
   - Enablement requirement,
   - Support Requirement
   - Clarity requirement,
   - Industrial Applicability,
   - Novelty,
   - Inventive Step.

(Points to note)

The following points should be noted when each case example is made reference to.

(1) These cases provide a determination of an examiner based on the descriptions of prior art or the common general knowledge shown in each case.

(2) These cases explain a determination of an examiner or a response of an applicant on the subject of patentability requirements in each case (for example, when a case is related to novelty, the requirements for novelty are only considered).

(3) The descriptions of the claims in these cases are properly simplified as necessary to facilitate explanation on the requirements.
Chapter 3 Medicinal Inventions

Definition of Terms used in this Chapter

1. Description and Claims

1.1 Requirements for Description

1.1.1 Enablement Requirement (Article 36(4)(i))

1.2 Claims

1.2.1 Support Requirement (Article 36(6)(i))

1.2.2 Clarity Requirement (Article 36(6)(ii))

2. Patentability

2.1 Industrial Applicability (the main paragraph of Article 29(1))

2.2 Novelty (Article 29(1))

2.2.1 Basic Principles of Determination of Novelty related to Medicinal Inventions

2.2.2 Determination Method for Novelty

2.3 Inventive Step (Article 29(2))

2.3.1 Determination Method for Inventive Step relating to Medicinal Inventions

2.3.2 Specific Examples of Determination of Inventive Step

3. Cases

3.1 Cases relating to Determination of Novelty and Inventive Step

3.1.1 A therapeutic agent characterized by its medicinal
use in which the drug is applied to a specific disease

3.1.2 A therapeutic agent characterized by its medicinal
use in which the drug is applied to a specific disease
in a specific dosage or administration

3.1.3 A therapeutic agent characterized by a combination
of materials having specific attributes

3.2 Cases relating to Determination of Description Requirements