

## (別紙2) Attachment No.2

## Review Categories for New Drugs, Medical Devices and Regenerative Medical Products

## 1. New Drugs and Regenerative Medical Products

Review Categories	
Category 1	Gastrointestinal drugs, dermatologic drugs, immunosuppressive drugs, and others (not classified in other categories)
Category 2	Cardiovascular drugs, antiparkinsonian drugs, anti-Alzheimer's drugs
Category 3-1	Central/peripheral nervous system drugs (excluding anesthetic drugs)
Category 3-2	Anesthetic drugs, sensory organ drugs (excluding drugs for inflammatory diseases), narcotics
Category 4	Antibacterial drugs, antiviral drugs (excluding AIDS drugs), antifungal drugs, antiprotozoal drugs, anthelmintic drugs
Category 5	Reproductive system drugs, drugs for urogenital system, combination drugs
Category 6-1	Respiratory tract drugs, anti-allergy drugs (excluding dermatologic drugs), sensory organ drugs (drugs for inflammatory diseases)
Category 6-2	Hormone drugs, drugs for metabolic disorders (including diabetes mellitus, osteoporosis, gout, and inborn errors of metabolism)
Oncology drugs	Antineoplastic drugs
AIDS drugs	Anti-HIV drugs
Radiopharmaceuticals	Radiopharmaceuticals
In vivo diagnostics	Contrast agents, reagents for function tests (excluding in vitro diagnostics)
Bio-CMC	Quality of biologics, biosimilars
Vaccines	Vaccines (only those to be used for prevention of infection), antitoxic serum, etc.
Blood products	Blood products
Cellular and tissue-based products	Cellular and tissue-based products Cell/tissue-processed products among regenerative medical products
Gene therapy products	Gene therapy products among regenerative medical products, Cartagena

(Note)

- (1) Drugs for immunosuppression in transplantation, antidotes, drugs for kidney diseases, etc. fall into Category 1.
- (2) "Gastrointestinal drugs" in Category 1 include drugs for liver diseases and drugs for pancreatic diseases. "Dermatologic drugs" do not include those not intended for external use and those generally intended for systemic absorption.
- (3) Ophthalmic agents, etc. containing an antibiotic as an active ingredient do not fall into Category 3-1, Category 3-2, and Category 6-1. They fall into Category 4.
- (4) "Combination drugs" in Category 5 mainly refer to prescription combination drugs with similar formulations. Other combination drugs fall into the respective categories of intended indications.

- (5) “Anti-allergy drugs” in Category 6-1 are drugs for internal use. Among “anti-allergy drugs,” drugs for external use fall into Category 1.
- (6) “Hormone drugs, drugs for metabolic disorders” in Category 6-2 include anti-diabetic drugs, anti-osteoporosis drugs, hormone drugs other than gastrointestinal hormone, anti-gout drugs, and drugs for inborn errors of metabolism. However, among hormone drugs, drugs for urogenital system fall into Category 5, not Category 6-2.

## 2. Medical Devices (Including in vitro diagnostics)

Review Categories	
Robotics, IoT, and other devices	Mainly innovative medical devices utilizing robotics and advanced IoT technologies, multicategory medical devices, and other uncategorized medical devices
Orthopedic and Plastic Surgery	<ul style="list-style-type: none"> <li>- Medical devices mainly pertaining to hips, knees, upper extremities, hands, and digits, etc. among orthopedic devices</li> <li>- Medical devices such as plates, screws, intramedullary nails, spinal implants and related instruments, as well as medical devices used in plastic surgery, dermatology, etc.</li> </ul>
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	<ul style="list-style-type: none"> <li>- Materials used in the fields of brain and circulatory medicine (excluding cardiology) as well as respiratory medicine, neurology, and psychiatry</li> <li>- Mechanical appliances used in the fields of brain and circulatory medicine (excluding cardiology) as well as respiratory medicine, neurology, and psychiatry</li> </ul>
Gastroenterology, Genitourinary and Reproductive Medicine	Mainly devices pertaining to the fields of gastroenterology, urology, and obstetrics/gynecology
Dentistry and Oral Medicine	Mainly devices used in the field of dentistry
Ophthalmology and Otorhinolaryngology	Mainly devices pertaining to the fields of ophthalmology and otorhinolaryngology
Cardiopulmonary Circulation	<ul style="list-style-type: none"> <li>- Mainly cardiology-related materials used in medical devices pertaining to the circulatory system</li> <li>- Mainly cardiology-related mechanical appliances pertaining to the circulatory system</li> </ul>
Program	Mainly single-unit program medical devices
In vitro diagnostics	Mainly in the field of laboratory tests (in vitro diagnostics)