Translated by PhRMA Japan (Pharmaceutical Research and Manufacturers of America Japan) and EFPIA Japan (European Federation of Pharmaceutical Industries and Associations Japan) with consultation to MHLW (Ministry of Health, Labour and Welfare) and PMDA (Pharmaceuticals and Medical Devices Agency).

This English version is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

PSEHB/SD Notification No.0608-1

June 8, 2017

To: Director-general, Department of Health, Prefectural Governments

Director,
Safety Division,
Pharmaceutical Safety and Environmental Health Bureau,
Ministry of Health, Labour and Welfare
(Official seal omitted)

Points to Consider for the Instructions for Package Inserts of Prescription Drugs

The above-mentioned matter has been notified through the "Instructions for Package Inserts of Prescription Drugs" (PSEHB Notification No.0608-1 dated June 8, 2017 from the Director-general of the Pharmaceutical Safety and Environmental Health Bureau [PSEHB], Ministry of Health, Labour and Welfare [MHLW]) (hereinafter referred to as the "Director-General's Notification"). Points to consider for its operation are organized as presented in the Appendix. Please, therefore, make this Instruction thoroughly known to all relevant industries and organizations under your supervision with attention being paid to the below-mentioned points, and also make the necessary arrangements for appropriate instructions to be given with regard to the package inserts for prescription drugs.

Please be advised that copies of this notification will be sent to the president of each separately listed organization.

1. Date of implementation
   The date of implementation of this notification shall be the same as that of the Director-General's Notification.

2. Revision and repeal of existing notifications

(1) Repeal

The "Instructions for Package Inserts of Prescription Drugs" (PAB/SD Notification No. 59 dated April 25, 1997 from the Safety Division [SD], Pharmaceutical Affairs Bureau [PAB], Ministry of Health and Welfare [MHW]) (hereinafter referred to as the "Former Director's Notification") will be repealed and replaced with the contents herein.

(2) Revision

With the repeal of the Former Director's Notification "Instructions for Package Inserts of Prescription Drugs' (PAB/SD Notification No. 59 from the SD, PAB, MHW)" mentioned in Appendix 1 of the "Instructions for Package Inserts of Biological Products" (PMSB/SD Notification No. 0520004 from the Director of the SD, Pharmaceutical and Medical Safety Bureau [PMSB], [MHLW] dated May 20, 2003) will be amended to "'Points to Consider for Instructions for Package Inserts of Prescription Drugs' (PSEHB/SD Notification No.0608-1 from the Director, SD, PSEHB, MHLW)."

(Appendix)

Points to Consider for Instructions for Package Inserts of Prescription Drugs

I. General Points to Consider for Drafting

1. Information in each section shall be written, in principle in an 8-point font so that the information can be clearly and easily understood. If the font size is reduced because of spatial considerations, it shall be at least a 6-point font. However, at least an 8-point font shall be used for the Sections from "1. WARNINGS" to "15. OTHER PRECAUTIONS" except for the Section "3. COMPOSITION AND PRODUCT DESCRIPTION" and information presented in tables and footnotes.
2. The format and specifications of the package inserts shall be, in principle, as follows using Appendix 1 as a reference:
   (1) Specifications
   A4 size paper
   Generally up to four pages
   A 1.7 cm left-hand margin shall be secured.
   (2) Format
   Drugs for which there are "1. WARNINGS", the package inserts shall be printed on a white sheet of paper with a red band on the corner of the upper right-hand side.
   Other drugs: The package inserts shall be printed on a white sheet of paper.
3. In principle, the package insert shall be written using a Ming-style font and two-byte characters for Chinese characters, hiragana, and katakana, and one-byte characters for alphanumeric characters. However, a Gothic font should be used for important descriptions such as a section name to make them clearer than other descriptions. Red should not be used for letters, except for sections otherwise specified.
4. Unless otherwise specified, in general the heading shall use that which is indicated in the "Instruction for Package Inserts of Prescription Drugs (PSEB Notification No.0608-1 dated June 8, 2017 from the Director-General, PSEB, MHLW)" (hereinafter referred to as the "Director-General's Notification"). However, the Japanese notation for "効能又は効果" in the section title "4. INDICATIONS," and "5. PRECAUTIONS CONCERNING INDICATIONS,", as well as that for "用法及び用量" likewise in the section "6. DOSAGE AND ADMINISTRATION," and "7. PRECAUTIONS CONCERNING DOSAGE AND ADMINISTRATION" can be replaced with "効能効果" or "効能・効果", and "用法用量" or "用法・用量", respectively.
5. The section numbers listed in the Director-General's Notification shall be used. When lower-level sections are established, sections down to the third level such as "1.1.1" may be formed. If section numbers are needed further, parentheses such as "(1)" shall be utilized.

6. When a related section is mentioned as a section that should be referred to, a section number shall be used, and it shall be stated at the end of the text, for example, “see the Section 1.1.1.”
7. When the data comparison with other drugs is described, in principle, the non-proprietary names of comparator drugs shall be included. However, if the results of a bioequivalence study are described, the brand names of the reference drug or reference biological drug shall be included.
8. When the results of a bioequivalence study are described, they shall be included in the Section “16. PHARMACOKINETICS,” “17. CLINICAL STUDIES,” or “18. PHARMACOLOGY” according to endpoints for equivalence.

II. Points to Consider for Each Section

A. Date of Preparation or Revision (year/month)

(1) The dates of preparation or revision (year/month) followed by the version number in parentheses shall be included in the upper-left corner of the package inserts.

(2) Revisions shall be made in the following manner when items that will have a major effect on the use of the drug are revised.

[1] The preparation date (year/month) or the revision date (year/month) shall be displayed for two consecutive revisions, and when a new revision date (year/month) is entered, the revision date (year/month) before the previous revision, shall be deleted (the preparation date at the time of the second revision), and the new revision date (year/month) shall be added to the previous revision date (year/month). In addition, it shall be made clear whether the revisions are for the current revision or the previous revision.

[2] The part that is revised shall be marked by an asterisk (*) before the applicable section number. In addition to clarifying the location of a revision, the corresponding revision date (year/month) and version number shall be indicated with the same symbol. When the lower-level sections are entirely revised, an asterisk “*” shall be attached to the one upper-level section. In the second or subsequent revisions, revised information shall be identified with “**” for the current revision and “*” for the previous revision.

[3] When a revision results from the release of reexamination or reevaluation results or changes in the indications or dosage and administration, in the parentheses after the date of revision (year/month), “Reexamination Results” or “Reevaluation Results,” “Change in the Indications,” “Change in the Dose,” or “Change in the Administration” shall be stated following the version number.

B. Standard Commodity Classification Number of Japan

Under the heading of the “Standard Commodity Classification Number of Japan”, the number shall be clearly indicated, enclosed in a box on the upper-right side of the package inserts.

C. Approval Number, Date of Initial Marketing in Japan

(1) Under the heading of the “Approval Number”, the number shall be clearly indicated, enclosed in a box and entered below the “Standard Commodity Classification No. of Japan” as a rule.

(2) When indicating the date of initial marketing in Japan (year/month), the heading for the date of initial marketing in Japan (year/month) shall be shortened to "Initial Marketing in Japan," enclosed in a box and entered below the "Approval Number."

D. Storage, Shelf Life

Subsections shall be added for "Storage" and "Shelf Life" and presented below the "Date of Preparation or Revision (year/month)."

E. Therapeutic Category

(1) Consideration shall be paid to drugs that are classified into the same therapeutic category so that their classification names are consistent.

(2) It is, in principle, unnecessary to provide the characteristics of the drug product. However, this is not applicable to cases where it is necessary to differentiate drugs with different indications or dosage and administration by the therapeutic category name for promoting their appropriate use.

F. Regulatory Classification

(1) Drugs subject to the regulatory classification shall be those specified as follows: Poisonous drugs and powerful drugs in Article 44, Paragraphs 1 and 2 of the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics (Law No. 145 in 1960; hereinafter referred to as the "PMD Act"); narcotics and psychotropic drugs in Article 2, Items 1 and 6 of the Narcotics and Psychotropics Control Law (Law No. 14 in 1953); stimulants and stimulant raw materials in Article 2, Paragraphs 1 and 5 of the Stimulants Control Law (Law No. 252 in 1945); habit-forming drugs in Article 50, Item 11 of the PMD Act; special approval drugs in Article 14-3, Paragraph 1 of the PMD Act; and prescription drugs in Article 49, Paragraph 1 of the PMD Act.

(2) The complete name that indicates the regulatory classification shall be entered above or on the left-hand side of the brand name.

(3) For psychotropic drugs, subcategories of Class 1, 2, or 3 psychotropic drugs shall be included in parentheses after "Regulatory Classification" in accordance with the Cabinet Order to designate narcotics, raw material plants of narcotics, psychotropic drugs and raw materials of narcotics and psychotropic drugs (Cabinet Order No. 238 in 1990).

(4) For habit-forming drugs, specially approved pharmaceuticals, or prescription-only drugs, notes for each piece of information shall be provided as follows: For habit-forming drugs, "Caution - The drug may form habits"; for specially approved pharmaceuticals, "Caution - Specially approved pharmaceutical"; and for prescription-only drugs, "Caution - Use it under a prescription of a physician, etc."

G. Name of Product

The names shall be included in the following order:

(1) Non-proprietary name and then the standard name or the name stipulated in the Japanese Pharmacopoeia (JP)

(2) Brand name

1. WARNINGS

   Information shall be written in red, including the heading, and enclosed within a red box, using a Gothic font.

2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.)

   Information including the heading shall be enclosed within a red box; however, the text shall not be written in red.

3. COMPOSITION AND PRODUCT DESCRIPTION

   (1) "3.1 Composition"

   [1] The information shall be described for each brand name in a table format and include the name of the active ingredient (s) (if the active ingredient has a non-proprietary name, then that non-proprietary name should be stated) and the quantity (if the active ingredient is unclear, then its physicochemical property and a summary of the manufacturing method should be stated) in a standard amount of the product (for dosage forms such as tablets, which can be counted, a fixed number of units should be stated, and for other dosage forms, a fixed weight or amount should be stated).

   [2] For drug excipients, in principle, all ingredients, except for those listed in Appendix 2, shall be described. They shall be listed in reference to the "Implementation of the 'Voluntary agreement on listing drug additives'" (PMSB/SD Notification No. 0409001 and PMSB/CND Notification No. 0409001 dated April 9, 2002 jointly issued by the Directors of SD and Compliance and Narcotics Division [CND], PMSB, MHLW).

   (2) "3.2 Product Description"

   [1] The information shall be described for each brand name in a table format.

   [2] Products that needs to be described as sterile include ophthalmic solutions ophthalmic ointments, and individual products that are required to be sterile at approval.

4. INDICATIONS

   (No points to consider)

5. PRECAUTIONS CONCERNING INDICATIONS

   Precautions for clarifying the scope of indications approved, such as tests and diagnostic criteria necessary for patient selection, shall be included in this section.

6. DOSAGE AND ADMINISTRATION

   When it is necessary to separately describe dosage and administration according to indications, titration, and dosage form, etc., information shall be described in an easy-to-understand manner such as in table format.

7. PRECAUTIONS CONCERNING DOSAGE AND ADMINISTRATION

   When a drug requires adjustments within the range of increases and decreases as appropriate but out of the scope of the usual dosage and administration, information shall be included in this section.

8. IMPORTANT PRECAUTIONS

(No points to consider)

9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS

(1) Information in the Section "9.1 Patients with Complication or History of Diseases, etc." shall be described by adding an appropriate section, "9.1.1 Patients with XX," according to complications, past history, family history, genetic predispositions, and other relevant factors.

(2) When describing information in the Section "9.2 Patients with Renal Impairment," specific parameters such as creatinine clearance and estimated glomerular filtration rate (eGFR) shall be used for the severity of renal impairment to the extent possible.

(3) When describing information in the Section "9.3 Patients with Hepatic Impairment," specific parameters such as Child-Pugh classification shall be used for the severity of hepatic impairment to the extent possible.

(4) When stating that "this drug should not be administered" and "women should be instructed to avoid breastfeeding" as precautions related to the Sections "9.5 Pregnant Women" and "9.6 Breast-feeding Women," they shall be described while fully considering clinical effects such as exposure to fetuses or lactating babies (particularly for a topical formulation), clinical use experience, and the availability of alternative drugs.

(5) When providing information in the Section "9.7 Pediatric Use," the approximate age range of newborns, babies, infants, or children means as mentioned below. However, if the specific age is clear, "less than X years old," "X years old or older, less than X years old" shall be also indicated. It is also acceptable to use age categories other than:

[1] Newborns are aged less than 4 weeks.

[2] Babies are aged 4 weeks to less than 1 year.

[3] Infants are aged 1 to less than 7 years.

[4] Children are aged 7 to less than 15 years.

(6) When describing information in the Section "9.8 Geriatric Use," the approximate age of the elderly shall be defined as 65 years or older, and as necessary, information on the age group of 75 years or older shall be also included. However, if the specific age is clear, "X years old or older" shall be also indicated. It is also acceptable to use age groups other than this.

(7) When describing information in the Sections "9.2 Patients with Renal Impairment," "9.3 Patients with Hepatic Impairment," and "9.7 Pediatric Use," if risks are assumed but there are no sufficient data on them because the applicable patients were excluded from clinical studies, such a fact shall be stated.

(8) When describing information in the Sections "9.5 Pregnant Women" and "9.6 Breast-feeding Women," if data from clinical use experience, epidemiological surveys, or other relevant sources are clinically beneficial, they shall be provided as information on appropriate use.

10. INTERACTIONS

(1) Information shall be presented in a manner that makes it as easily understandable as possible such as in table format. Precautions for co-administration can be provided in a descriptive manner depending on cases.

(2) The Section "10. Contraindications for Co-administration (Do not co-administer with the following.)" shall be entered into a table with a red frame, but the text shall not be written in red.

(3) When indicating the names of drugs, names of bio-similar products shall be represented by the non-proprietary name of the reference biological product as "XXXX product"

11. ADVERSE REACTIONS

(1) For the frequency of adverse reactions, in principle, the incidence shall be indicated as a percentage to one decimal place, and if the incidence is less than 0.1%, such a fact shall be stated on the basis of the results of pooled clinical studies to investigate efficacy and safety of the drug within the scope of approved indications and dosage and administration.

(2) In cases of adverse reactions were accumulated from spontaneous reports and Post-marketing Surveillance, etc. and the frequency is unknown, "frequency unknown" shall be added. However, when clinical study data are quite limited for orphan drugs for example, and only when it is particularly useful to present the frequency of adverse reactions based on Post-marketing Surveillance, etc., the frequency shall be indicated by specifying the sources of references.

(3) When adding the frequency of adverse reactions for generic drugs and bio-similar products, if there are results from clinical studies that were accurately and objectively conducted using the generic drugs or bio-similar products themselves, the frequency shall be described on the basis of the said results. When the frequency for the concerned generic drugs or bio-similar products is unknown, in principle, the frequency of the reference drug or reference biological product shall be included.

(4) When clinically significant adverse reactions are known for similar drugs and the same caution may be necessary for the drug concerned, they shall be presented in the same manner as those that are known for the concerned drug without mentioning "similar drugs."

(5) Information in the Section "11.2 Other Adverse Reactions" shall be provided in table format.

(6) Precautions for infections associated with drugs shall be presented as specified for adverse reactions.

12. INFLUENCE ON LABORATORY TESTS

When the use of the drug causes apparent changes in laboratory data, conditions, effects, reasons, and other relevant matters associated with such changes shall be briefly described.

13. OVERDOSAGE

It shall not be necessary to present information in this section if there is no case of an intoxication symptom or a typical intoxication symptom is unknown.

14. PRECAUTIONS CONCERNING USE

(1) "Precautions Concerning the Preparation of the Drug" shall include precautions when preparing the drug. The use of protectors (such as eyeglasses, gloves, and a mask) by persons preparing the drug for avoiding exposure shall be included in this section.

(2) "Precautions Concerning Administration of the Drug" shall include precautions for the route of administration, dosage form, injection rate, site of administration, and other relevant matters.

(3) "Precautions Concerning the Dispensing of the Drug" shall provide instructions to patients. Precautions for the storage of the drug by patients shall be included in this section.

(4) When there are precautions when making a diagnosis for diagnostics, they shall be presented by adding a section "Precautions for diagnosis."

15. OTHER PRECAUTIONS

(1) When providing information in the Section "15.1 Information Based on Clinical Use," even if evaluation has not been established on data such as carcinogenicity and mortality, it shall be stated as objectively as possible preceded by a phrase that "it has been reported that…" on the basis of epidemiological studies, etc.

(2) Information in the Section "15.2 Information Based on Nonclinical Studies" shall be described while considering the safety margin as compared with clinical exposure.

16. PHARMACOKINETICS

(1) The pharmacokinetics shall be separated into those of healthy individuals and those of patients, and if necessary, a description of the condition of the patients shall be added. When data are from non-Japanese populations, such a fact shall be stated.

(2) When providing the results of a population analysis or simulation, such a fact shall be stated and they shall be differentiated from actual results.

(3) If the studied dosage and administration are different from those approved, such a fact shall be also mentioned as a note.

17. CLINICAL STUDIES

(1) "17.1 Clinical Studies for Efficacy and Safety"

[1] Information shall be described by adding an appropriate section so that the positioning of studies (e.g., the phase of development and study design) can be understood.

[2] When the results from a global study or data from a non-Japanese population are provided, such a fact shall be clearly stated. For a global study, the number of Japanese subjects shall also be included.

[3] Safety results shall be described on the basis of adverse reactions or adverse events. However, it shall be specified whether the results are based on adverse reactions or adverse events.

(2) "17.3 Others"

If results using dosage and administration that are different from those approved are described such a fact shall also be mentioned as a note.

18. PHARMACOLOGY

(1) For a combination drug, when explaining the pharmacological action of each active ingredient, expressions that give the impression that the drug can be used for indications other than the approved indications (or, in drugs exempt from approval, for indications outside the recognized medical and pharmaceutical range) shall not be used. For a combination drug, synergistic effects shall be included only when sufficiently objective data are available.

(2) For diagnostics, the Section "18.1 Mechanism of Action" shall be replaced with "18.1 Measurement Method," and measurement principles supporting approved indications shall be described.

19. PHYSICOCHEMICAL PROPERTIES

A non-proprietary name shall be mentioned in Japanese followed by its English name in parentheses.

20. PRECAUTIONS FOR HANDLING

In addition to precautions for handling that are stipulated in the JP or the standards pursuant to the provisions of Article 42, Paragraph 12 of the PMD Act, regulations for drug management such as avoiding fire shall be described, if any.

21. APPROVAL CONDITIONS

(No points to consider)

22. PACKAGING

(1) The packaging form such as an ampule, vial, syringe, bottle, or bag shall be included. The materials or characteristics of the container shall be, as necessary, described. If a desiccant is contained in the package, such a fact shall be stated.

(2) The packaging unit such as the number of products, weight, and volume per unit according to the packaging form shall be included. If the product is individually packed, such a fact shall be stated. For sheet packaging, the number of products per sheet and the number of sheets shall be clearly indicated.

(3) When describing information on tools and instruments, the number of gauges shall also be mentioned for an injection needle. When describing information on a solution, the volume and other information shall be indicated together.

23. REFERENCES

(1) Parts quoted from the references shall have the reference number attached so that the reader can locate the reference.

(2) The Vancouver style (the name of the author (s), name of the journal, year of publication, volume number, and the first to last pages) shall be used for listing references.

(3) If in-house documents are cited, the details of the documents shall be described clearly and as concretely as possible to facilitate users' requests for literature. If a summary of approval application documents is published, the date of the corresponding approval and document number shall also be indicated.

(4) For generic drugs and bio-similar products, the same published literature as that for their reference drugs and reference biological products shall be listed, as a rule. However, this is not applicable to the case where it is necessary to provide different information according to product differences.

24. REFERENCE REQUEST AND CONTACT INFORMATION

(No points to consider)

25. PRECAUTION CONCERNING HEALTH INSURANCE BENEFITS

(No points to consider)

26. MARKETING AUTHORIZATION HOLDER, etc.

(1) If the names of the distributor, licenser company, etc. are indicated, they shall be mentioned after the marketing authorization holder.

(2) For foreign special approval drugs, in addition to the name and address of the appointed marketing authorization holder, the name of the foreign special approval holder and the country where it is residing shall be provided.

(Appendix 1)

Standard Commodity Classification Number of Japan

*Revised: Month 20XX (XXth version, XX)

Storage:
Expiration date:

Therapeutic Category
Non-proprietary Name, Standard Name, or Name Specified in the Japanese Pharmacopoeia

	● mg	▲ mg
Approval Number		
Initial Marketing in Japan	Month 20XX	Month 20XX

Regulatory Classification

Prescription-only drug[Note)]

Brand Name

Name of Product

Note) Caution - Use only pursuant to the prescription of a physician, etc.

1. WARNINGS

2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.)

3. COMPOSITION AND PRODUCT DESCRIPTION
3.1 Composition
<Table format>
3.2 Product Description
<Table format>
4. INDICATIONS

5. PRECAUTIONS CONCERNING INDICATIONS

6. DOSAGE AND ADMINISTRATION

7. PRECAUTIONS CONCERNING DOSAGE AND ADMINISTRATION

8. IMPORTANT PRECAUTIONS

9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS
9.1 Patients with Complication or History of Diseases, etc.

9.2 Patients with Renal Impairment

9.3 Patients with Hepatic Impairment

9.4 Persons with Reproductive Potential

9.5 Pregnant Women

9.6 Breast-feeding Women

9.7 Pediatric Use

9.8 Geriatric Use

10. INTERACTIONS
10.1 Contraindications for Co-administration (Do not co-administer with the following.)

Drugs	Signs, symptoms, and measures	Mechanism and risk factors

10.2 Precautions for Co-administration (This drug should be administered with caution when co-administered with the following.)

Drugs	Signs, symptoms, and measures	Mechanism and risk factors

11. ADVERSE REACTIONS
11.1 Clinically Significant Adverse Reactions
11.1.1 XX

11.2 Other Adverse Reactions

	≥X%	0.1 to <X%	<0.1%	Frequency unknown

12. INFLUENCE ON LABORATORY TESTS

13. OVERDOSAGE

14. PRECAUTIONS CONCERNING USE

15. OTHER PRECAUTIONS
15.1 Information Based on Clinical Use

15.2 Information Based on Nonclinical Studies

16. PHARMACOKINETICS
16.1 Blood Level

16.2 Absorption

16.3 Distribution

16.4 Metabolism

16.5 Excretion

16.6 Patients with Specific Backgrounds

16.7 Drug-Drug Interactions

16.8 Others

17. CLINICAL STUDIES
17.1 Clinical Studies for Efficacy and Safety

17.2 Post-marketing Surveillance, etc.

17.3 Others

18. PHARMACOLOGY
18.1 Mechanism of Action

18.2 XX Effect

19. PHYSICOCHEMICAL PROPERTIES

20. PRECAUTIONS FOR HANDLING

21. APPROVAL CONDITIONS

22. PACKAGING

23. REFERENCES

24. REFERENCE REQUEST AND CONTACT INFORMATION

25. PRECAUTION CONCERNING HEALTH INSURANCE BENEFITS

26. MARKETING AUTHORIZATION HOLDER, etc.

(Appendix 2)

Drug type	drug excipients
Injections (including body fluids, artificial perfusion agents and powders for injection)	1. Calcium chloride 2. Potassium chloride 3. Sodium chloride 4. Hydrochloric acid 5. Citric acid 6. Sodium citrate 7. Succinic acid 8. Acetic acid (Note 1) 9. Potassium acetate 10. Sodium acetate 11. Tartaric acid 12. Potassium hydroxide 13. Sodium hydroxide 14. Water for injection 15. Physiological saline 16. Sodium carbonate 17. Sodium bicarbonate 18. Lactic acid 19. Sodium lactate 20. Maleic acid 21. Sulfuric acid 22. Phosphoric acid 23. Potassium phosphate 24. Dibasic sodium phosphate 25. Potassium hydrogenphosphate 26. Dibasic calcium phosphate 27. Potassium dihydrogenphosphate 28. Dibasic sodium phosphate 29. Disodium hydrogenphosphate
External agents used for mucous membrane (ophthalmic instillations, ophthalmic ointments, eyewashes, nasal sprays, ear drops, suppositories [for the anus, vagina, or urethra], intra-anal injections, inhalants, buccal agents [sublingual tablets], troches, oral cavity patches, oral cavity applications, gargles, and mucosally delivered dental drugs)	1. Calcium chloride 2. Potassium chloride 3. Sodium chloride 4. Hydrochloric acid 5. Citric acid 6. Sodium citrate 7. Succinic acid 8. Acetic acid (Note 1) 9. Potassium acetate 10. Sodium acetate 11. Tartaric acid 12. Potassium hydroxide 13. Sodium hydroxide 14. Purified water (Note 2) 15. Physiological saline 16. Sodium carbonate 17. Sodium bicarbonate 18. Lactic acid 19. Sodium lactate 20. Maleic acid 21. Sulfuric acid

	22. Phosphoric acid 23. Potassium phosphate 24. Dibasic sodium phosphate 25. Potassium hydrogenphosphate 26. Dibasic calcium phosphate 27. Potassium dihydrogenphosphate 28. Dibasic sodium phosphate 29. Disodium hydrogenphosphate

Note 1: Including glacial acetic acid and acetic acid anhydride
Note 2: Including water for injection and sterile purified water

(Appended list)

Japan Medical Association

Japan Dental Association

Japan Pharmaceutical Association

Japanese Society of Hospital Pharmacists

Federation of the Pharmaceutical Manufacturers' Association of Japan

Japan Pharmaceutical Manufacturers Association

Japan-Based Executive Committee, Pharmaceutical Research and Manufacturers of America

European Federation of Pharmaceutical Industries and Associations

Japan Generic Medicines Association

Japan Kampo Medicines Manufacturers Association

Japan Medicinal Plant Federation

Japan CRO Association

Office of Safety I of the Pharmaceuticals and Medical Devices Agency

Office of Safety II of the Pharmaceuticals and Medical Devices Agency

Version:
1.0 (23-January-2018)
1.1(1-May-2019)

Document History

Version	Release Date	Sections revised	Brief Summary of Changes
1.1	1-May-2019	II.F.(4) II.2. II.10. (2) II.14. (1) II.14. (2) II.14. (3) Appendix 1 Regulatory Classification Appendix 1 2. Appendix 1 10.1. Appendix 1 10.2. Appendix 1 16.7.	Updated for consistency with the English translation guidance (PSEHB/SD Notification No. 0329-8 dated March 29, 2019)

Reference:
Points to Consider for the Instructions for Package Inserts of Prescription Drugs
http://www.pmda.go.jp/files/000218448.pdf
(Japanese original text)