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

PMDA/CSO No.60
February 17, 2023

To (to be described in Note)

Chief Safety Officer,
Pharmaceuticals and Medical Devices Agency

Points to Consider, etc. for Consultation Associated With Revision, etc. of Package Inserts, etc.

Regarding the safety of drugs, medical devices, regenerative medical products, in vitro diagnostics, quasi-pharmaceutical products, and cosmetics, the Office of Pharmacovigilance I, Office of Pharmacovigilance II, and Office of Manufacturing Quality and Vigilance for Medical Devices, Pharmaceuticals and Medical Devices Agency (hereinafter referred to as "PMDA") accept a consultation associated with revision, etc. of electronic package inserts (hereinafter referred to as "e-PI"), documents attached to products, information on their containers or wrappings, or information leaflets for patients (including instructions for use) (hereinafter referred to as "package inserts, etc.") [revision consultation] and a consultation concerning other safety measure plans (including product improvement and development) [other consultation] for marketing authorization holders.

With the enforcement of the notification “Points to Consider for Describing the Results of Investigation Using the Medical Information Database in Electronic Package Inserts” (PSEHB/PSD Notification No. 0217-1 by the Director of Pharmaceutical Safety Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare, dated February 17, 2023) for prescription drugs (excluding in vitro diagnostics) and regenerative medical products, the Office of Pharmacovigilance I, Office of Pharmacovigilance II, and Office of Medical Informatics and Science, PMDA accept, as [other consultation], a consultation regarding the plan for investigations using the medical information database to be conducted as an effort to enhance the provision of information through e-PI in accordance with

this notification. As a result of that, the consultation application forms concerning other safety measure plans were changed as shown in the appendixes.

Furthermore, specific matters concerning a consultation associated with revision, etc. of package inserts, etc. were determined as follows (the same as before, except for the addition of a note on quasi-pharmaceutical products and cosmetics in the General considerations section).

This notification will come into effect from February 17, 2023. Please inform relevant organizations under your jurisdiction of these matters. With the enforcement of this notification, "Points to Consider, etc. for Consultation Associated with Revision, etc. of Descriptions of Package Inserts, etc." (PMDA/OIMS Notification No. 0729001, PMDA/OPI Notification No. 0729001, PMDA/OPII Notification No. 0729001 and PMDA/OMQVMD Notification No. 0729001, Joint Notification by the Directors of Office of Informatics and Management of Safety, Office of Pharmacovigilance I, Office of Pharmacovigilance II, and Office of Manufacturing Quality and Vigilance for Medical Devices, dated July 29, 2022) will be abolished.

1. General considerations

For a consultation, fill out the attached consultation application form and submit the form for a consultation by e-mail or FAX. If you wish to have a meeting at the time of the consultation, enter the requested date and time in the "Requested date of meeting" of the consultation application form. In the case of revision of package inserts, etc. requiring notification as shown in "Considerations for Notification, etc. of Information on Precautions, etc." (PSEHB/SD Notification No. 0219-2 by the Director of Safety Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare, dated February 19, 2021, hereinafter referred to as "Director Notification") for prescription drugs, guidance-mandatory drugs, class IV medical devices, and regenerative medical products, the "consultation application form (for revision, etc. of package inserts)" should be used for a prior consultation because a prior consultation needs to be applied before the notification (except the cases in which a prior consultation is not required, such as correction of errors in writing). If the applicant wishes to consult about matters other than those described in the "Consultation application form (revision, etc. of package inserts)," the "Consultation application form (consultations for other safety measures)" should be used. For quasi-pharmaceutical products and cosmetics, the consultation application form for drugs (excluding in vitro

diagnostics) shall be used.

(Contact information for consultation) * Submit the forms via e-mail whenever possible.

- For medical devices and in vitro diagnostics:

Division of Medical Device Safety and Vigilance, Office of Manufacturing Quality and Vigilance for Medical Devices

e-mail:anzen1-menkai@pmda.go.jp FAX:03-3506-9514

- For drugs (excluding in vitro diagnostics):

Office of Pharmacovigilance I, Office of Pharmacovigilance II

e-mail:anzen2-menkai@pmda.go.jp FAX:03-3506-9441

- For regenerative medical products:

Office of Pharmacovigilance II

e-mail:anzen3-menkai@pmda.go.jp FAX:03-3506-9441

2. Consultation concerning class IV medical devices and regenerative medical products

When package inserts, etc. are revised in association with the submission of adverse event reports, reports on measures taken in foreign countries, and research reports (hereinafter referred to as “adverse event reports, etc.”), the prior consultation is regarded as being held by indicating their draft revisions in the adverse event reports, etc., but since a consultation reference number needs to be obtained for notification, a separate consultation application form shall be submitted. At the time of submission, it is acceptable to describe in the column of "Details of consultation" in the consultation application form that a consultation was held in the adverse event reports, etc.

3. Consultation concerning class I to III medical devices

"Q & A on Guidelines for Package Inserts for Medical Devices" (Administrative Notice by the Safety Division, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare, dated October 31, 2014, hereinafter referred to as "Administrative Notice") states that regarding class I to III medical devices, a prior consultation is required for revision of matters that may have a significant impact. A prior consultation is required for the following items.

- Class II-III medical devices:

"Warnings," "Contraindications," "Indications for Use or Precautions Concerning Indications," "Precautions (Caution is necessary for the following

patients.)," "Contraindications for Concomitant Use (Concomitant use is prohibited with the following medical devices.)" and "Clinically Significant Malfunctions/adverse Events"

- Class I medical devices:

"Warnings," "Contraindications," "Contraindications for Concomitant Use (Concomitant use is prohibited with the following medical devices.)"

However, prior consultations are not required in the following cases.

(1) When the case corresponds to “(a) Revision made based on the Director Notification which instructs or directs revisions, for which the ‘consultation reference number’ is shared with the company that consulted with PMDA in advance” in “3. Cases where prior consultation is not required” in “Points to Consider for Notification and Publication of Information on Precautions, etc.” (PMDA/OIMS Notification No. 0219001, PMDA/OPI Notification No. 0219001, PMDA/OPII Notification No. 0219001, and PMDA/OMQVMD Notification No. 0219001, Joint Notification by the Directors of Office of Informatics and Management for Safety, Office of Pharmacovigilance I, Office of Pharmacovigilance II, Office of Manufacturing Quality and Vigilance for Medical Devices, PMDA, dated February 19, 2021)

(2) When revision is made regarding descriptions on "Examples of matters that are considered to have already been taken care of by healthcare professionals to perform a medical action," which is shown in Appendix 1 of the Administrative Notice as an example of descriptions that are not necessary in package inserts, etc.

(3) When revision is made regarding descriptions on "Precautions to Be Described in Package Inserts for Medical Electrical Equipment" (PAB Notification No. 495 by the Director of Pharmaceutical Affairs Bureau, Ministry of Health and Welfare, dated June 1, 1972), which was abolished by "Revision of Instructions for Package Inserts for Medical Devices" (PFSB Notification No. 1002-8 by the Director-General of Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare, dated October 2, 2014) and was specified in the Administrative Notice as matters no longer necessary in package inserts, etc.

When package inserts, etc. are revised in association with the submission of adverse event reports, etc., the prior consultation is regarded as being held by indicating their draft revisions in the adverse event reports, etc., but a separate consultation application form shall be submitted. At the time of submission, it is

acceptable to describe in the column of "Details of consultation" in the consultation application form that a consultation was held in the adverse event reports, etc.

4. Consultation concerning combination products

For a consultation concerning revision of package inserts, etc. for drugs, etc. that make up a combination product (e.g., machinery/equipment or processed cells, etc. that make up a combination product classified as a drug, drugs or processed cells, etc. that make up a combination product regarded as a medical device, and drugs or machinery/equipment, etc. that make up a combination product regarded as a regenerative medical product), the consultation application form corresponding to the category of approval, etc. for the final combination product should be used.

5. Consultation concerning in vitro diagnostics

Any revision of matters that may have a significant impact should be consulted about in advance. For items requiring a prior consultation, refer to the Administrative Notice by the Office of Manufacturing Quality and Vigilance for Medical Devices, PMDA, dated July 29, 2022.

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

Appendix 1

Consultation application form (revision, etc. of package inserts for drugs [excluding in vitro diagnostics])

To: Office of Pharmacovigilance I and Office of Pharmacovigilance II, Pharmaceuticals and Medical Devices Agency
[FAX :03-3506-9441] [e-mail: anzen2-menkai@pmda.go.jp]

Company name		Name of person in charge	
Brand name		TEL	
Nonproprietary name		FAX	
		e-mail	
Therapeutic category number, etc. Note)			

Note) Format: Therapeutic category number (3 digits) + therapeutic category name

<Details of consultation>

1. Items of revision, etc.

(1) "Package Insert"
- ☐ Warnings
- ☐ Contraindications
- ☐ Relative Contraindications
- ☐ Precautions Concerning Indications
- ☐ Precautions Concerning Dosage and Administration
- ☐ Careful Administration
- ☐ Important Precautions
- ☐ Interactions
- ☐ Adverse Reactions (Clinically Significant Adverse Reactions)
- ☐ Adverse Reactions (Other Adverse Reactions)
- ☐ Geriatric Use
- ☐ Use in Pregnant, Parturient and Nursing Women
- ☐ Pediatric Use
- ☐ Influence on Laboratory Tests
- ☐ Overdosage
- ☐ Precautions Concerning Use
- ☐ Other Precautions
- ☐ Precautions for Handling
- ☐ Matters you should not do
- ☐ Consultation
- ☐ Precautions for Storage and Handling
- ☐ Other Items

(2) "Patient Medication Guide" and "Guide for Persons Receiving Vaccination"
- ☐ Present (Necessity of revision: ☐ Yes ☐ No)
- ☐ Absent (Necessity of new preparation: ☐ Yes ☐ No)

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

(3) "Risk Management Plan (RMP)"
☐ Present (Necessity of revision: ☐ Yes ☐ No)
☐ Absent (Necessity of new preparation: ☐ Yes ☐ No)

2. Description of revision (give specific details)

* If the revised drafted "package insert", "patient medication guide", "guide for persons receiving vaccination" and "risk management plan" have already been prepared, enter "See Attachment." in the following column and attach the "revised drafts" and "revised materials explaining 'Precautions and Precautions for handling.' "

<Requests>

Requested date of meeting (if you would like to have a meeting)

First choice:	MM DD	YYYY	AM or PM
Second choice:	MM DD	YYYY	AM or PM
Third choice:	MM DD	YYYY	AM or PM

---- <Processing field for Pharmaceuticals and Medical Devices Agency>

*** Not necessary to fill in the following fields. ----**

< Response status >

1. Date of consultation Responder [ ]

☐ Date of consultation [MM DD YYYY HH MM]
☐ Others (consultation not required)

2. Consultation results, etc.

[

]

Pharmaceuticals and Medical Devices Agency

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

Consultation application form (revision, etc. of package inserts for drugs [excluding in vitro diagnostics], etc.)

To: Office of Pharmacovigilance I and Office of Pharmacovigilance II, Pharmaceuticals and Medical Devices Agency
[FAX :03-3506-9441] [e-mail: anzen2-menkai@pmda.go.jp]

Company name		Name of person in charge	
Brand name		TEL	
Nonproprietary name		FAX	
Therapeutic category number, etc. Note)			

Note) Format: Therapeutic category number (3 digits) + therapeutic category name

<Details of consultation>

1. Items of revision, etc.

(1) "Package Insert"
☐ Warnings ☐ Contraindications ☐ Precautions Concerning Indications
☐ Precautions Concerning Dosage and Administration ☐ Important Precautions
☐ Precautions Concerning Patients with Specific Backgrounds
[ ]
☐ Interactions [ ]
☐ Adverse Reactions [ ]
☐ Matters you should not do ☐ Matters you should consult about
☐ Precautions for Storage and Handling
☐ Other items [ ]

(2) "Patient medication guide" and "Guide for Persons Receiving Vaccination"
☐ Present (Necessity of revision: ☐ Yes ☐ No)
☐ Absent (Necessity of new preparation: ☐ Yes ☐ No)
(3) "Risk Management Plan (RMP)"
☐ Present (Necessity of revision: ☐ Yes ☐ No)
☐ Absent (Necessity of new preparation: ☐ Yes ☐ No)

2. Description of revision (please specify)

* If the revised "package insert", "patient medication guide", "guide for persons receiving vaccination" and "risk management plan" (draft) have already been prepared, enter "See Attachment" in the following column and attach the "revised drafts" and "revised materials explaining Precautions and Precautions for handling.'
"

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

<Requests>

Requested date of meeting (if you would like to have a meeting)

First choice:	MM DD YYYY	AM or PM
Second choice:	MM DD YYYY	AM or PM
Third choice:	MM DD YYYY	AM or PM

---- <Processing field for Pharmaceuticals and Medical Devices Agency >

*** No necessary to fill in the following fields. ----**

< Response status >

1. Date of consultation Responder [ ]

☐ Date of consultation [MM DD YYYY HH MM]
☐ Others (consultation not required)

2. Consultation results, etc.

[

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

Appendix 2

Consultation application form (revision, etc. of package inserts for medical devices)

To: Division of Medical Device Safety and Vigilance, Office of Manufacturing Quality and Vigilance for Medical Devices, Pharmaceuticals and Medical Devices Agency
[FAX :03-3506-9514] [e-mail: anzen1-menkai@pmda.go.jp]

Company name		Name of person in charge	
Brand name Note)		TEL	
Nonproprietary name Note)		FAX	
Approval number, Certification number, Notification number Note)		e-mail	

Note) If the content of the consultation is common to multiple products, list all applicable products.

<Details of consultation>

1. Items of revision, etc.

(1) "Package Insert"
- ☐ Warnings
- ☐ Contraindications
- ☐ Precautions Concerning Indications or Intended Use
- ☐ Precautions Concerning Directions for Use
- ☐ Precautions
- ☐ Important Precautions
- ☐ Interactions
- ☐ Medical device Malfunctions/Adverse Events
- ☐ Geriatric Use
- ☐ Use in Pregnant, Parturient and Nursing Women, or Pediatric Use
- ☐ Influence on laboratory tests
- ☐ Overuse
- ☐ Other precautions
- ☐ Precautions Concerning Handling
- ☐ Maintenance and Inspections
- ☐ Other Items

(2) "Instruction for Use" etc. and "Information Leaflets for Patients"

(3) "Information documents"

2. Description of revision (give specific details)

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

* Provide specific details such as the background and circumstances of the consultation (the basis for the revision in the case of revision).
* If a draft version of revision of the "package insert," "instruction for Use," or "Instruction for use for patients," or "information document," etc., has already been prepared, indicate "See Attachment." at the bottom and attach it as an appendix. When preparing the Appendix, the content of the consultation should be presented in an easy-to-understand manner, for example, by using an old/new comparison table.

<Requests>

Requested date of meeting (if you would like to have a meeting)

First choice:	MM DD YYYY	AM or PM
Second choice:	MM DD YYYY	AM or PM
Third choice:	MM DD YYYY	AM or PM

---- <Processing field for Pharmaceuticals and Medical Devices Agency>

*** Not necessary to fill in the following fields. ----**

< Response status >

1. Date of consultation Responder [ ]

☐ Date of consultation [MM DD YYYY HH MM]
☐ Consultation method [☐ face to face ☐ consultations via telephone ☐ others ( )]
☐ Others (consultation not required)

2. Consultation results, etc.

3. Consultation reference number

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

Appendix 3

Consultation application form (revision, etc. of package inserts for in vitro diagnostics)

To: Division of Medical Device Safety and Vigilance, Office of Manufacturing Quality and Vigilance for Medical Devices, Pharmaceuticals and Medical Devices Agency
[FAX :03-3506-9514] [e-mail: anzen1-menkai@pmda.go.jp]

Company name		Name of person in charge	
Brand name Note)		TEL	
Nonproprietary name Note)		FAX	
Approval number, Certification number, Notification number Note)		e-mail	

Note) If the content of the consultation is common to multiple products, list all applicable products.

<Details of consultation>

1. Items of revision, etc.

(1) "Package Insert"
- ☐ Warnings
- ☐ Important Precautions
- ☐ General Precautions
- ☐ Shape, structures, etc. (Kit Components)
- ☐ Principle of Measurement
- ☐ Precautions Concerning Procedure
- ☐ Dosage and Administration (Method of Operation)
- ☐ Methods for Determining Measurement Results
- ☐ Clinical Importance
- ☐ Performance
- ☐ Precautions Concerning Use or Handling
- ☐ Other Items

(2) "Instruction for Use" and "Information Leaflets for Patients"

(3) "Information documents

2. Description of revision (give specific details)

* Provide specific details such as the background and circumstances of the consultation (the basis for the revision in the case of revision).

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

* If a draft version of revision of the "package insert," "instruction for Use," or "Instruction for use for patients," or "information document," etc. has already been prepared, indicate "See Attachment." at the bottom and attach it as an appendix. When preparing the Appendix, the content of the consultation should be presented in an easy-to-understand manner, for example, by using an old/new comparison table.

<Requests>

Requested date of meeting (if you would like to have a meeting)

First choice:	MM DD YYYY	AM or PM
Second choice:	MM DD YYYY	AM or PM
Third choice:	MM DD YYYY	AM or PM

---- <Processing field for Pharmaceuticals and Medical Devices Agency>

*** Not necessary to fill in the following fields. ----**

< Response status >

1. Date of consultation Responder [ ]

☐ Date of consultation [MM DD YYYY HH MM]
☐ Consultation method [☐ face to face ☐ consultations via telephone ☐ others( )]
☐ Others (consultation not required)

2. Consultation results, etc.

3. Consultation reference number

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

Appendix 4

Consultation application form (revision, etc. of package inserts for regenerative medical products)

To: Office of Pharmacovigilance II, Pharmaceuticals and Medical Devices Agency
[FAX :03-3506-9441] [e-mail: anzen3-menkai@pmda.go.jp]

Company name		Name of person in charge	
Brand name Note)		TEL	
Nonproprietary name Note)		FAX	
Approval number Note)		e-mail	

Note) If the content of the consultation is common to multiple products, list all applicable products.

<Details of consultation>

1. Items of revision, etc.

(1) "Package Insert"
- ☐ Warnings
- ☐ Contraindications
- ☐ Precautions Concerning Indications or Performance
- ☐ Precautions Concerning Dosage and Administration, or Method of Use
- ☐ Precautions
- ☐ Important Precautions
- ☐ Interactions
- ☐ Defects/Adverse reactions
- ☐ Geriatric Use
- ☐ Use in Pregnant, Parturient and Nursing Women, or Pediatric Use
- ☐ Influence on laboratory tests
- ☐ Overuse
- ☐ Other Precautions
- ☐ Precautions for Handling
- ☐ Other Items

(2) "Instruction for Use " and "Information Leaflets for Patients"

(3) "Information documents

2. Description of revision (give specific details)

* Provide specific details such as the background and circumstances of the consultation (the basis for the revision in the case of revision).

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

* If a draft version of revision of the "package insert," "instruction for Use," or "Instruction for use for patients," or "information document," etc., has already been prepared, indicate "See Attachment." at the bottom and attach it as an appendix. When preparing the Appendix, the content of the consultation should be presented in an easy-to-understand manner, for example, by using an old/new comparison table.

<Requests>

Requested date of meeting (if you would like to have a meeting)

First choice:	MM	DD	YYYY	AM or PM
Second choice:	MM	DD	YYYY	AM or PM
Third choice:	MM	DD	YYYY	AM or PM

---- <Processing field for Pharmaceuticals and Medical Devices Agency>

*** Not necessary to fill in the following fields. ----**

< Response status >

1. Date of consultation Responder [ ]

☐ Date of consultation [MM DD YYYY HH MM]
☐ Consultation method [☐ face to face ☐ consultations via telephone ☐ others( )]
☐ Others (consultation not required)

2. Consultation results, etc.

3. Consultation reference number

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

Appendix 5

Consultation application form (consultations for other safety measures (for drugs [excluding in vitro diagnostics])

To: Office of Pharmacovigilance I and Office of Pharmacovigilance II, Pharmaceuticals and Medical Devices Agency

[FAX :03-3506-9441] [e-mail: anzen2-menkai@pmda.go.jp]

Company name		Name of person in charge	
Brand name		TEL	
Nonproprietary name		FAX	
Therapeutic category number, etc. Note)		e-mail	

Note) Format: Therapeutic class number (3 digits) + therapeutic category name

<Details of consultation>

<Requests>

Requested date of meeting (if you would like to have a meeting)

First choice:	MM DD	YYYY	AM or PM
Second choice:	MM DD	YYYY	AM or PM
Third choice:	MM DD	YYYY	AM or PM

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

---- <Processing field for Pharmaceuticals and Medical Devices Agency>

*** Not necessary to fill in the following fields. ----**

< Response status >

1. Date of consultation Responder [ ]

Corresponding Offices :

☐ Office of Pharmacovigilance I and Office of Pharmacovigilance II
☐ Risk Communication Promotion Division, Office of Informatics and Management for Safety, Pharmaceuticals and Medical Devices Agency

Date of consultation [MM DD YYYY HH MM]
Consultation method [☐ face to face ☐ telephone ☐ others ( )]

2. Consultation results, etc.

[ ]

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

Appendix 6

Consultation application form (consultations for other safety measures) (for medical devices, in vitro diagnostics)

To: Division of Medical Device Safety and Vigilance, Office of Manufacturing Quality and Vigilance for Medical Devices, Pharmaceuticals and Medical Devices Agency
[FAX :03-3506-9514] [e-mail: anzen1-menkai@pmda.go.jp]

Company name		Name of person in charge	
Brand name Note)		TEL	
Nonproprietary name Note)		FAX	
Approval number, Certification number, Notification number Note)		e-mail	

Note) If the content of the consultation is common to multiple products, list all applicable products.

<Details of consultation>

<Requests>

Requested date of meeting (if you would like to have a meeting)

First choice:	MM DD YYYY	AM or PM
Second choice:	MM DD YYYY	AM or PM
Third choice:	MM DD YYYY	AM or PM

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

---- <Processing field for Pharmaceuticals and Medical Devices Agency>

*** Not necessary to fill in the following fields. ----**

< Response status >

1. Date of consultation Responder [ ]

Corresponding Offices :

☐ Division of Medical Device Safety and Vigilance, Office of Manufacturing Quality and Vigilance for Medical Devices
☐ Risk Communication Promotion Division, Office of Informatics and Management for Safety

Date of consultation [MM DD YYYY HH MM]
Consultation method [☐ face to face ☐ telephone ☐ others ( )]

2. Consultation results, etc.

[ ]

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

Appendix 7

Consultation application form (consultations for other safety measures (for regenerative medical products))

To: Office of Pharmacovigilance II, Pharmaceuticals and Medical Devices Agency
[FAX :03-3506-9441] [e-mail: anzen3-menkai@pmda.go.jp]

Company name		Name of person in charge	
Brand name Note)		TEL	
Nonproprietary name Note)		FAX	
Approval number Note)		e-mail	

Note) If the content of the consultation is common to multiple products, list all applicable products.

<Details of consultation>

<Requests>

Requested date of meeting (if you would like to have a meeting)

First choice:	MM DD YYYY	AM or PM
Second choice:	MM DD YYYY	AM or PM
Third choice:	MM DD YYYY	AM or PM

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

---- <Processing field for Pharmaceuticals and Medical Devices Agency>

*** Not necessary to fill in the following fields. ----**

< Response status >

1. Date of consultation Responder [ ]

Corresponding Offices :

☐ Office of Pharmacovigilance II,
☐ Risk Communication Promotion Division, Office of Informatics and Management for Safety

Date of consultation [MM DD YYYY HH MM]
Consultation method [☐ face to face ☐ telephone ☐ others ( )]

2. Consultation results, etc.

[ ]

(Note) In the order of Japanese syllabary

President, Japan Association of Clinical Reagents Industries
Chairperson, American Medical Devices and Diagnostics Manufacturers' Association
Representative Organizer, Association of Registered Certification Bodies under PMD Act.
Chair, European Federation of Pharmaceutical Industries and Associations
Chair, EBC Medical Equipment and Diagnostics Committee
Chairperson, Forum for Innovative Regenerative Medicine
Chairman, Japan Federation of Medical Devices Associations
Chairperson, Japan Household Insecticide Industry Association
President, Japan Cosmetic Industry Association
Chairperson, Japan Dentifrice Manufactures Association
President, Japan Pharmaceutical Manufacturers Association
President, Federation of Pharmaceutical Manufacturers' Associations of Japan
Chairperson, Japan Permanent Wave Lotion Industry Association
Chairperson, Japan Hair Color Industry Association
Chairperson, Hygienic Insecticide Association of Japan
Chairperson, Japan Bath additive Industry Association
Chairman, Japan-Based Executive Committee, Pharmaceutical Research and Manufacturers of America (PhRMA)