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October 10, 2019

N o t i f i c a t i o n PSEHB/MDED Notification No. 1010-1 PSEHB/PSD Notification No. 1010-1

To: Commissioner of Prefectural Health Department (Bureau)

Director of Medical Device Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare (MHLW)

Director of Pharmaceutical Safety Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare (MHLW)

## Revision of Precautions to the Package Inserts of Drug-eluting Coronary Stent or Drug-coated Balloon Dilatation Catheter for Coronary Angioplasty

Following the recent compilation of the JCS 2018 Guideline on Revascularization of Stable Coronary Artery Disease and the JCS 2018 Guideline on Diagnosis and Treatment of Acute Coronary Syndrome Guidelines by a joint research group organized by related academic societies, the following revision of the PRECAUTIONS in the package insert of drug-eluting coronary stent or drug-coated balloon dilatation catheter for coronary angioplasty has been instructed to the relevant marketing authorization holders (MAHs). Commissioners of the prefectural health bureaus and departments are requested to appropriately circulate the information among medical institutions or other concerned parties under your supervision.

- 1. The WARNINGS section of the package insert of drug-eluting coronary stent or drug-coated balloon dilatation catheter for coronary angioplasty should be revised according to the Appendix.
- The package inserts revised in line with the instruction as 1 above should be uploaded in the package insert information page for medical devices (only in Japanese) of the Pharmaceuticals and Medical Devices Agency (PMDA).
- 3. Responses to the instructions 1, 2, and dissemination to medical institutions and other related parties of the information on the revision of package insert should be completed within 3 months after the release of this notification and the completion should be notified to the Division of Safety for Medical Devices, Office of Manufacturing Quality and Vigilance for Medical Devices, PMDA.
- 4. Marketing authorization applicants for drug-eluting coronary stents or drug-coated balloon dilatation catheters for coronary angioplasty under review should notify the reviewing agency of their intention to revise the proposed package inserts submitted for the review.

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## (Appendix)

PRECAUTIONS in the package insert should be revised in line with the Table 1 and Table 2 below for drugeluting coronary stents and drug-coated balloon dilatation catheters for coronary angioplasty, respectively. Table 1

Current	Revised
(Deleted language is strike-through lined.)	(Added language is underlined.)
WARNINGS	WARNINGS
Dual antiplatelet therapy (DAPT) is recommended	Antiplatelet therapy (APT) after the operation
by the clinical studies for at least xx month(s) after	should be properly performed based on the latest
the operation (see the section of "CLINICAL	guidelines such as the JCS 2018 Guideline on
STUDY RESULTS") <sup>. Note 1)</sup> - Periodical follow-up	Revascularization of Stable Coronary Artery
should be performed as needed by the patient	Disease and the JCS 2018 Guideline on Diagnosis
conditions and whether administration of the	and Treatment of Acute Coronary Syndrome
antiplatelet drug should be prolonged or not is	Guidelines of the Japanese Circulation Society, as
determined in full consideration of risks of adverse	well as other relevant information. Periodical
reactions such as haemorrhage as well as the	follow-up should be performed as needed by the
background factors of the patient and the	patient conditions and whether administration of
anatomical features of the lesion, since there have	the antiplatelet drug should be prolonged or not is
been reports on late stent thrombosis – a critical	determined in full consideration of risks of adverse
malfunction – more than 1 year after stent	reactions such as haemorrhage as well as the
replacement. Meanwhile, it should be noted that	background factors of the patient and the
concomitant use of an antiplatelet drug or an	anatomical features of the lesion, since there have
anticoagulant drug may lead to a greater risk of	been reports on late stent thrombosis – a critical
haemorrhage.	malfunction – more than 1 year after stent
Note 1) Describe the rationale for the	replacement. Meanwhile, it should be noted that
recommended period in the CLINICAL	concomitant use of an antiplatelet drug or an
STUDY RESULTS section.	anticoagulant drug may lead to a greater risk of
	haemorrhage (see the CLINICAL STUDY
	RESULTS section for the period of dual
	antiplatelet therapy (DAPT) recommended by the
	clinical studies.)

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## Table 2

Current	Revised
(Deleted language is strike-through lined.)	(Added language is underlined.)
WARNINGS	WARNINGS
Dual antiplatelet therapy (DAPT) is	• Dual antiplatelet therapy (DAPT) is recommended
recommended by the clinical studies for at least xx	by the clinical studies for at least xx month(s) after
month(s) after the operation (see the section of	the operation (see the section of CLINICAL
CLINICAL STUDY RESULTS) Note 2). After the	STUDY RESULTS) Note 2). After the recommended
recommended period, DAPT should be performed	period by the clinical studies, DAPT should be
adequately after confirmation of the period	performed based on the latest guidelines such as
recommended by the stent placement. Periodical	the JCS 2018 Guideline on Revascularization of
follow-up should be performed as needed by the	Stable Coronary Artery Disease and the JCS 2018
patient conditions and whether administration of	Guideline on Diagnosis and Treatment of Acute
the antiplatelet drug should be prolonged or not is	Coronary Syndrome Guidelines of the Japanese
determined in full consideration of risks of adverse	Circulation Society, as well as other relevant
reactions such as haemorrhage as well as the	information. Periodical follow-up should be
background factors of the patient and the	performed as needed by the patient conditions
anatomical features of the lesion. Meanwhile, it	and whether administration of the antiplatelet drug
should be noted that concomitant use of an	should be extended or not is determined in full
antiplatelet drug and an anticoagulant drug may	consideration of risks of adverse reactions such as
lead to a greater risk of haemorrhage.	haemorrhage as well as the background factors of
Note 2) Describe the rationale for the	the patient and the anatomical features of the
recommended period in the CLINICAL STUDY	lesion. Meanwhile, it should be noted that
RESULTS section.	concomitant use of an antiplatelet drug and an
	anticoagulant drug may lead to a greater risk of
	haemorrhage.
	Note 2) Describe the rationale for the
	recommended period in the CLINICAL STUDY
Note 2) Describe the rationale for the recommended period in the CLINICAL STUDY	the patient and the anatomical features of the lesion. Meanwhile, it should be noted that concomitant use of an antiplatelet drug and an anticoagulant drug may lead to a greater risk of haemorrhage. Note 2) Describe the rationale for the

RESULTS section.