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MSA2/75255/2018/DHS Dated:12/02/2019

From

The Director of Health Services.

To

The District Medical Officer of Health
Thiruvananthapuram/Kollam/Pathanamthitta/Alappuzha/
Kottayam/ Idukki/ Ernakulam/Thrissur/Palakkad/Malappuram
Kozhikode/Kannur/Wayanad/Kasaragod.

Sir,

Sub:- HSD- Reporting of Adverse Events due to the use of Medical Devices in Materiovigilance Programme of India (MvPI) – Reg.

Ref:- (1) Govt.Lr.No.HEALTH – F1/302/2018, dtd.07/09/2018, H&FW(F) Dept.
(2) Lr.No.DCG(I)/Misc/2017 (141) dtd.08/12/2017 of the Central Drugs Standard Control Organisation, Directorate General of Health Services, New Delhi.

Attention is invited to the above reference and Subject cited. The Guidance document in respect of Materiovigilance Programme of India (MvPI) is hosted in the website of DHS. You are requested to take all the necessary steps for the promotion of Materiovigilance Programme of India (MvPI).

Yours faithfully

For Director of Health Services

Materiovigilance Programme of India

Guidance Document

Materiovigilance Programme of India (MvPI)

(Reporting Medical Device Adverse Event)

(Version 1.1)

Chapter 5: Reporting of Medical Device Adverse Events

In the pilot phase, reporting by a prescribed form would be done by only research associates deputed at 10 Medical Device Event Monitoring Centres or voluntary medical device manufactures. The two-page format of the form is given at the end of chapter 5.

5.1 Scenario where an event or incident is noticed by manufacturer or healthcare service-provider or MDMC.

5.1.1 When an event or incident is noticed by medical device manufacturer

Currently the incident or event reporting is to be taken as a voluntary initiative by medical device manufactures in India. When the manufacturer is aware of information regarding an event which has occurred with their device, manufacturers are advised to initiate investigation root cause for failure and intimate IPC-NCC. IPC-NCC would send this information to research associates at MDMC located nearest to location of event or incident. The information obtained by performing device testing by the manufacturer, user or other party may include:

a) A malfunction or deterioration in the characteristics or performance of the Medical Device

b) An incorrect or out-of-specification test result

c) The discovery of a design flaw during design review

d) An inaccuracy in labelling, instructions for use and/or promotional materials. Inaccuracies include omissions and deficiencies. Omissions do not include the absence of information that should generally be known by the intended users

e) The discovery of a serious public health threat. This may include an event that is of significant and unexpected nature and is a potential public health hazard, e.g. human immunodeficiency virus (HIV) or Creutzfeldt-Jacob Disease (CJD).

f) Increase in user error or application error with the medical device

g) Any other information (Recall or field corrective notice) made available by medical device regulators in other countries for the same product

h) Information available by way of literature, scientific documentation, or increase in complaint trend.

It is possible that the manufacturer may not have enough information to decide definitively on the reporting of an event. In such a case, the manufacturer should make reasonable efforts to obtain additional information to decide upon reporting. Wherever appropriate, the manufacturer should consult the medical practitioner or healthcare professional involved, and try their utmost to retrieve the device concerned. As a general principle, there should be a pre-disposition to report rather than not to report in case of doubt on the reporting of an event.

5.1.2 When an event or incident noticed by Healthcare service-provider

The healthcare service-provider is aware of information regarding an event, which has occurred with their medical device. This information will be sent to research associates at the medical device event monitoring centres. The information may include:

a) A malfunction or deterioration in the characteristics or performance of the medical device

b) An incorrect or out-of-specification test result

c) An inaccuracy in labelling, instructions for use and/or promotional materials. Inaccuracies include omissions and deficiencies. Omissions do not include the absence of information that should generally be known by the intended users

d) The discovery of a serious public health threat. This may include an event that is of significant and unexpected nature and is a potential public health hazard, e.g. human immunodeficiency virus (HIV) or Creutzfeldt-Jacob Disease (CJD).

e) Increase in user error or application error with the medical device

f) Any other information made available by medical device regulators in other countries for the same product.

g) Information by way of literature, scientific documentation, or increase in complaint trend.

5.2 Assessing medical device associated with an event or incident

In assessing the link between the device and the event, the following parameters be followed:

- Opinion based on information made available by a healthcare professional
- Failure mode-effect and non-destructive root-cause analyses on the medical device