ANNOUNCEMENT 12/10/MDS-AN001

SUBJECT: Update of the Implementing Rule on the *Validation of Documents to be provided to the SFDA by Manufacturers for Marketing Authorization* (MDS-IR6) and in particular its application dates.

ADDRESSEES: Manufacturers of medical devices (both local and overseas) and authorised representatives for both local and overseas manufacturers.

Articles Six, Ten and Eleven of Version 1 of Implementing Rule 6 (MDS-IR6) has been modified as follows:

Article Six: General information

A. Contact details for the manufacturer.

B. Where the manufacturer is established within the KSA, his establishment National Registry Number.

C. Where the applicant is an authorised representative of a manufacturer established outside the KSA, his contact details and establishment National Registry Number.

D. The name and contact details of the person responsible for completing the application form.

E. Information on the medical device the manufacturer wishes to supply to the market.

F. An indication of whether or not the device that is the subject of the application complies with the relevant medical device regulations of one or more of the GHTF Founding Member jurisdictions (namely Australia, Canada, Japan, USA or the EU).

G. A copy, in electronic form, of the labelling associated with the medical device that will be placed on the market of the KSA, i.e. both the labels affixed to the device and the instructions for use, and show that the text of the different elements of the labelling and their content take appropriate account of the intended use of the devices and the qualifications of the users in the KSA.

H. Where the device is connected to an a/c power supply, confirm it is designed to operate with a 60 Hertz supply at nominal values of either 127 or 220 or 380 volts and is fitted

with the appropriate a/c power connector and provides the required electrical safety conditions. Also, ensure that the device shall perform as intended when subject to the other environmental factors encountered within the KSA.

I. A copy, in electronic form, of the manufacturer's instructions to ensure that the medical devices intended to be placed on the KSA market will be correctly stored, transported, installed, maintained & disposed of; and to provide information that allows users and other persons, as appropriate, to be trained in their proper handling, storage, use and maintenance,

J. A copy, in electronic form, of the advertising and marketing materials that will be used in the KSA, if any.

K. An undertaking by the manufacturer to inform the SFDA of all measures and actions taken , either within or outside the KSA, which may affect the medical devices supplied to the KSA, as specified in Implementing Rule MDS-IR 7 on post- marketing surveillance.

L. Where the applicant is an authorised representative, the License Number assigned to him by the SFDA.

Article Ten: Marketing authorisation

A. When satisfied that the manufacturer or his authorised representative has provided all the information required, the SFDA shall issue:

1. A marketing authorisation in writing to the manufacturer that permits the relevant medical devices to be placed on the market of the KSA. The SFDA shall copy the authorisation to the relevant customs authorities within the KSA and assist these authorities to implement appropriate border controls. The marketing authorisation shall incorporate the dates of both its issue and expiry, taking into account, among other factors, the conditions of validity of the original authorizations, if any.

2. A Listing National Registry Number for each medical device that is included in the marketing authorization.

B. The authorisation issued by the SFDA that permits the medical device to be marketed within the KSA shall be in both the Arabic and English languages.

Article Eleven: Application Dates:

A. The Implementing Rule and the electronic application form referred to in Article Five shall be published and made available on the SFDA website.

B. The application date of this Implementing Rule and the provisions of the Medical Devices Interim Regulation to which this relates is 14th February 2011.

C. Applications for a marketing authorization for medical devices may be made to the SFDA from the date referred to in paragraph B of this Article.

D. From 14th February 2011 medical devices that have a SFDA marketing authorization may be placed on the market within the KSA.

E. After 14th August 2011 only medical devices that have a SFDA marketing authorization may be placed on the market within the KSA.

F. After 31st December 2011 only medical devices that have a SFDA marketing authorization may be put into service within the KSA.

The revised Implementing Rule MDS-IR 6 will be posted on the SFDA website on January 20th, 2011 as Version 2.

NOTE: *The updated version of MDMA forms are published on the SFDA website for reference only. Submission will be done electronically through MDMA electronic system.*