Annex

To be published in official Gazette of Pakistan: Extraordinary

Government of Pakistan
Ministry of National Health Services, Regulations & Coordination,
****

Islamabad the15th March, 2017

NOTIFICAITON

SRO No.--- of 2017 WHERAS legal proceedings are pending before Honourable Supreme Court in HRC No.623 of 2017 wherein it was noticed by the Honourable Supreme Court that patients, medical practitioners and other stake-holders were facing difficulty in the use of unregistered medical devices.

2. AND WHEREAS the Honourable Supreme Court of Pakistan was pleased to issue directions through an order dated, 2.3.2017 that medical devices which had not so far been registered, their use were to be legalized for the purposes of medical use until those medical devices were registered in accordance with law.

3. Now therefore, in exercise of the powers conferred by section 36 and all other enabling provisions of the Drug Regulatory Authority of Pakistan Act, 2012, in order to remove difficulties in the public interest, the Federal Government is pleased to direct as under:

(1). That all medical devices, which were required to be registered under Medical Devices Rules, 2015 but had so far not been registered due to the exemption granted under Rule 128 of the afore-said Rules or otherwise shall be deemed to be registered subject to submission of application along with original free sale certificate, and allowed to be imported, sold or used for medical purposes throughout Pakistan if the said medical devices are approved for use and sale by the regulatory authorities of the reference countries as provided under Rule 142 of the Medical Devices Rules, 2015 or CE authorized based on the certificates issued by CABs notified by European Union Directive: 93/42/EEC medical devices, which may be amended by the Chief Executive Officer, Drug Regulatory Authority of Pakistan, from time to time, in accordance with revision by European Union authorities.

Nawaal Islam

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(2). SRO No.324(I)/94 dated 19th April, 1994, SRO No.957(I)/2009 dated 5th November 2009 and SRO No.349(I)/2010 dated 18th May, 2010 and SRO No.919(I)/10 dated 01.10.2010 are hereby repealed under rules 146 of Medical Devices Rules, 2015 and on issuance of this notification, all products registered under the provisions of aforementioned SROs, if qualify on above said criteria, shall be deemed to be registered as medical devices under the Medical Devices Rules, 2015.

(3) All Lifesaving medical devices as provided in schedule "A" hereof shall not be imported, sold or used in Pakistan except from above sources. Medical devices other than those provided in schedule A shall be exempted from the operation of the Medical Device Rules, 2015 for a period of 06 months from issuance of this notification. Schedule A hereof may be amended by Chief Executive Officer, Drug Regulatory Authority of Pakistan from time to time.

(4) On establishment license application as prescribed by Medical Device Board, from importers of above referred medical devices, Medical Device Board shall issue provisional establishment certificate for a period of 06 months, within seven (07) working days, to all importers on production of original valid authorized agency agreement.

(5) In order to facilitate the process and ensure quality and transparency the Drug Regulatory Authority of Pakistan shall develop an IT based national registry for cardiac stents and provide a mechanism for manufacturers / importers and Cath laboratories to compulsorily enter the data of manufacturing / importation and utilization of cardiac stents, respectively in national registry. All Cath laboratories shall be required to be registered with Society of Interventional Cardiologists.

4. This issues with the approval of the competent authority.

Sana ul Islam

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