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PART II

Statutory Notifications (S.R.O.)

GOVERNMENT OF PAKISTAN
MINISTRY OF NATIONAL HEALTH SERVICES, REGULATIONS AND
COORDINATION
(Drug Regulatory Authority of Pakistan)

NOTIFICATION

Islamabad, the 18th August, 2022

S. R. O. 1559(I)/2022.— In pursuance to the honorable Supreme Court Order dated 20th March, 2018 and subsequent orders dated 10th January, 2020 & 04th January, 2022 passed in Human Rights Case No.623-P of 2017, and its Notification No.S.R.O.849(I)/2020 dated 8th September, 2020, the Federal Government is pleased to notify mechanism for fixation of maximum retail prices of cardiac stents in paragraph-2 of this notification. The Federal Government is further pleased to notify maximum retail prices of cardiac stents specified in column-7 of the schedule below on which the cardiac stents specified in columns-2 to 6 thereof, shall be sold.

2. The maximum retail prices (MRPs) of cardiac stents for private sector hospitals/ cath labs shall be fixed on the basis of following mechanism; namely:—

(3577)

Price : Rs. 20.00

[9075(2022)/Ex. Gaz.]

- i. Average procurement prices of leading hospitals / cath labs in the country for each category of stent with addition of markup @5% to cover administrative, storage and financial charges incurred by private hospitals / cath labs will form the basis to calculate maximum retail prices of stents.
- ii. The status of approval by the FDA, EU and other countries.
- iii. Available scientific data of different randomized controlled trials (RCTs) as validated by National Interventional Cardiology Board (NICB).
- iv. Inclusion or exclusion of particular type/ make of stents as per advice by the NICB.
- v. Exchange rate parity of Pak Rupee vs US \$ be considered to fix prices of stents as directed by the Honorable Supreme Court of Pakistan.
- vi. MRPs of 15 categories of cardiac stents specified in Schedule, recommended by the committee, will be considered as base prices and will be notified after approval of the Federal Government.
- vii. Whenever a new research stent after its approval by NICB is marketed, its recommended MRP (base price) by the Committee will be forwarded to seek approval of the Federal Government.
- viii. The National Price Fixation Committee will hold its meeting after every three months in compliance of Supreme Court order dated 02-08-2018 to review base MRPs and calculate / issue MRPs considering variation in USD exchange rate against Pak Rupee. Subsequently, approval of the Federal Government will not be required for issuance of revised (upward & downward) MRPs due to variation in exchange rate.
- ix. The National Price Fixation Committee may adjust and issue MRPs, if variation (increase/decrease) in USD exchange rate against Pak Rupee is more than 10%, even before lapse of three months period.

SCHEDULE

S. No	Category / Type of stent	BMS/ DES	Country of Origin	Certification (US FDA Approved/ European CE Mark /, etc.	Manufacturer Company name	Maximum retail price
(1)	(2)	(3)	(4)	(5)	(6)	(7)
1	Xience Xpedition	DES	USA	US FDA	Abbott Vascular	Rs.116,843
2	Xience Prime	DES	USA	US FDA	Abbott Vascular	Rs.75,453

3	Resolute Onyx	DES	USA	US FDA	Medtronic	Rs.108,395
4	Resolute Integrity	DES	USA	US FDA	Medtronic USA	Rs.51,175
5	Promus Premier	DES	USA	US FDA	Boston Scientific	Rs.65,953
6	Promus Elite	DES	USA	US FDA	Boston Scientific	Rs.89,159
7	Promus Element Plus	DES	USA	US FDA	Boston Scientific	Rs.56,386
8	Orsiro	DES	Switzerland	US FDA	Biotronic	Rs.107,480
9	ISAR Neo	DES	Germany	CE Mark	B.Braun	Rs.74,503
10	Firehawk	DES	China	European CE Mark	Microport	Rs.54,961
11	BMS Integrity	BMS	USA	US FDA	Medtronic USA	Rs.21,374
12	Xlimus	DES	Germany	European CE Mark	Cardionovum Poland	Rs.70,025
13	Bio matrix Alpha Stent	DES	Switzerland	CE Mark	Biosensor Europe, Switzerland	Rs.103,816
14	Biomatrix Flex / Neoflex Stent	DES	Switzerland	CE Mark	Biosensor Europe, Switzerland	Rs.74,910
15	Stent Yukon	DES	Germany	CE Mark	Transmulinia, Germany	Rs.51,297

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