

The Times of India**Title : Key diabetes, cardiac drugs to get cheaper****Author : Rupali.Mukherjee****Location :****Mumbai:****Article Date : 07/14/2014**

Coping with the inflation demon will become a tad easier for the burdened consumer. In a move that has surprised and shaken the industry, prices of widely-used expensive antidiabetic and cardiac medicines will reduce over the next few weeks by as much as 35% with the drug pricing regulator, National Pharmaceutical Pricing Authority (NPPA), deciding to bring them under price control.

In a rare invocation of a lesser-used provision in the Drug Price Control Order (DPCO), NPPA has fixed the prices of 108 formulation packs of 50 anti-diabetic and cardiovascular medicines.

What makes the development significant is that NPPA has fixed prices of those medicines which are not listed under the national list of essential medicines (NLEM). (Prices of 652 drugs under NLEM were fixed by the government last year under DPCO 2013) The move will mean savings for patients prescribed expensive chronic therapies, including drugs like Gliclazide, Glimepiride, Sitagliptin, Voglibose, Amlodipine, Telmisartan and Rosuvastatin, Heparin and Ramipril.

With this list, the total market of cardiac medicines under price control, including the earlier ones, stands at 58%, while 21% of the anti-diabetic market comes under the purview. Around Rs 5,500 crore of the pharma market will be impacted, with the range of prices being reduced from 10-15% to as high as 35%, with the average reduction around 12%.

The provision, Paragraph 19 of DPCO, 2013, authorizes the NPPA "in extraordinary circumstances, if it considers necessary so to do in public interest, fix the ceiling price or retail price of any drug for such period as it deems fit". The notification to fix prices of these medicines, which are non-scheduled formulations, was issued on July 10: "...wherever the maximum retail price (MRP) of the brand of a particular formulation exceeds 25% of the simple average price, the same will be capped at the 25% level".

Simply put, if the price of a drug brand exceeds the simple average price in that therapy group by 25%, or the price at which a new drug is launched for the first time is higher than the most expensive brand existing in the group, NPPA would initiate the process of fixing a price cap.

The move which surprised many in the pharma industry, has "shaken its confidence" and it is "examining all options". When contacted, the industry body Indian Pharma Alliance's secretary general D G Shah said the NPPA has "gone beyond essentiality as a criterion, and into policy-making and price fixation, making the NLEM redundant". According to the notification, NPPA has also acted on drugs where there is a "huge inter-brand price difference in branded-generics/off-patent drugs, which is indicative of a severe market failure, as different brands of the same drug formulation, including the off-patent drug, which are identical to each other in terms of active ingredient(s), strength, dosage, route of administration, quality, product characteristics, and intended use, vary disproportionately in terms of price".

"And whereas market failure alone may not constitute sufficient grounds for government intervention, but when such failure is considered in the context of the essential role that pharmaceuticals play in the area of public health, which is a social right, such intervention becomes necessary, especially when exploitative pricing makes

7/14/2014

medicines unaffordable and beyond the reach of most and also puts huge financial burden in terms of out-of-pocket expenditure on healthcare“, the notification says.