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Will India's new drug pricing policy create problems for the industry?

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India's union cabinet has given its nod for the implementation of the National Pharmaceutical Pricing Policy (NPPA). The policy aims to put in place a regulatory framework for pricing of drugs to ensure that they are available at reasonable prices. The Indian government has also stated that it will consider providing sufficient opportunity for innovation and competition to support the growth of the pharma industry.

Under the new policy, a new formula is likely to be used for calculating the ceiling price, which will be a simple average of all brands with one percent market share cut-off, as against the earlier announcement made on September 27, 2012, by a group of ministers (GoM) headed by India's union agriculture minister, Mr Sharad Pawar, with the ceiling-price formula as the Weighted Average Price (WAP) of all brands with one percent market share. This formula was opposed by the finance minister (who favored a cost-based approach) during an earlier cabinet meeting.

In a memorandum to Mr P Chidambaram, India's union finance minister, the Associated Chambers of Commerce and Industry in India (ASSOCHAM) said, "The weighted average price of all brands, having greater than one percent market share formula recommended by the GoM, will result in over 20 percent price reduction in 60 percent of the National List of Essential Medicines (NLEM). The WAP mechanism to control the price of essential medicines will achieve twin objectives of public health and industrial growth."

The chamber further said that the existing cost-based policy reveals its lack of relevance in current market conditions, significant limitations and adverse impact on the industry and patient access. For one, it has shifted bulk drug production out of India to countries like China, escalated prices for select medicines, scaled down the number of industry players, lessened innovation in cost control medicines and limited new introductions, and above all, failed to help medicines reach patients located in rural areas.

The cost-based policy has created an inefficient and inconsistent mechanism of price calculation that is not aligned with India's needs. A drug price control policy must be carefully calibrated to avoid adverse trade-offs in achieving key drug policy objectives for striking a balance between ensuring quality, affordability and reasonably priced to patients and enabling development within the industry. The ASSOCHAM memorandum said, "Given the severe handicaps of cost-based pricing, a market-based pricing policy would best suit India's needs as it would not only improve affordability but also the availability and encourage competition, innovation, and growth and help harness the export potential."
The pharmaceutical industry understands that, the access to essential medicines is a critical component of an effective health system, and it is imperative that good quality and safe medicines remain accessible, available and affordable to beneficiaries.

Sharing his thoughts on NPPA, Mr KV Balasubramaniam, managing director, Indian Immunologicals, said, "The cost-based price control mechanism might create problems for the industry instead of offering essential medicines at reasonable price. However, market-based pricing, as it would be based on widely available market information would result in transparency and fair pricing and would also encourage more investment in innovation."

This new policy will also ensure continuous availability of price-controlled medicines by preventing drugs from going off the market on account of an non-viable manufacturing environment which happened in the case of cost-based pricing. This methodology will allow patients to benefit from access to innovation and introduction of new medicines, as the players will continue investing in research and development (R&D) which ultimately helps to provide the patients with advanced and more effective medicines, as opposed to cost-based pricing which is not a factor in the R&D and innovation efforts and costs undertaken by pharmaceutical players and patient access to good quality medicines and will significantly improve as manufacturers will be encouraged to invest in quality raw material and processes.

Biologicals listed in NLEM
With the cabinet approval of NPPA, 348 essential drugs listed in the NLEM 2011will come under the scope of price control, leading to reduction in prices. The Government of India is keen on using NLEM as one of the key instruments in balanced healthcare delivery system, which inter alia includes accessible, affordable and quality medicine at all the primary (P), secondary (S), and tertiary (T) levels of healthcare.

The NLEM was prepared after many rounds of workshops and meetings of the core committee headed by Dr YK Gupta, professor and head, Department of Pharmacology, All India Institute of Medical Sciences (AIIMS), New Delhi and taking the views of 87 experts of different disciplines from leading medical and pharmacy institutions of the country.

In comparison to NLEM 2003, the 2011 list has added 43 new medicines by removing 47 medicines. In NELM 2011, 181 medicines fall under the category of P, S and T, 106 medicines fall under the category of S and T while 61 medicines are categorized as T only.

Of the 348 drugs listed in NLEM, about 30 are biologicals namely alpha interferon, filgrastim, dextran-40 and 70, fresh frozen plasma, factor VIII concentrate, factor IX complex, streptokinase, urokinase, atorvastatin, insulin injection (soluble), anti-D immunoglobin (human), polyvalent anti-snake venom, rabies immunoglobin and many vaccines like BCG, DPT, Hep B, rabies and so on, used in different therapy areas such as cytotoxic medicines, medicines used in palliative care, plasma substitutes, plasma fractions for specific use, antithrombotic medicines, hypolipidemic medicines, insulins and other anti-diabetic agents, immunologicals (diagnostic agents), sera and immunoglobins, and vaccines (for universal immunization).

Surprised with the names of biologicals included in the list, an industry veteran, who wished not be quoted said, "I do not see intravenous immunoglobulins (IVIG) among the plasma derived or immunological drugs category. Although filgrastim is not used for treating cancer, it is still in the supportive therapy. It is of course very useful, I just wonder if it is "essential". He further said, "Erythropoietin, used in kidney failure patients, is quite widely used, and I am surprised that it is not in the list and alfa interferon is in the list, but it is now hardly used, since its use in cancer was superseded by other drugs, and its use in hep-C was superseded by pegylated-interferon, which is not listed."

Sharing his thoughts about the biologicals listed in NLEM, Dr Ashok Kumar, president, Research and Development, Ipca Laboratories, said, "There could be several drugs used for life-threatening diseases that could be included, however, possibly, the expert committee who prepared this list could have omitted them because these drugs are not available in India.

We need to note that the development of these biological drugs requires not only higher development cost but also very huge initial set-up costs for manufacturing these complicated molecules. This is not only due to complexity of manufacturing these biological, but also its quality requirements to match with innovator products in the market."

He further said, "This is a major hurdle for these biologicals to become commodity drug, and applying the Drugs Price Control Order (DPCO) policy when the drug is marketed in India does not justify the return for investment made by the developer. This is something the government needs to address. Therefore, the government should bring in funds to partly bear or cover the cost for development and set-up of manufacturing facilities by way of soft loans or other funding options for mass production of biologicals. Or we may need to bring in suitable mechanism for adequately covering the cost of development and setting up manufacturing facility for biologicals by Indian manufacturers. My opinion is that, this is the right time to take proper action in indigenous development of biological, as most of the essential biological drugs are going off-patent in coming years and promoting the development of these drugs would be beneficial to bring in all essential medicines for the Indians at large."

Reacting on the impact of the biologicals listing in NLEM on local companies, who have been manufacturing and offering the biologicals at an affordable price, Dr Ashok Kumar said, "The list contains biological that are well established in Indian market. So I do not consider a heavy impact on those manufactures currently marketing them. As and when the competition increases in the market, we do expect further price reduction in the biologicals area."

Having the same views, the industry expert said that due to competition many of the biologicals are already priced quite low, so the impact of drug pricing policy will not make much difference to Indian biological manufacturing companies.

On the contrary, sharing her views Dr Kiran Mazumdar-Shaw, chairman and managing director, Biocon, asserted, "The new Price ceiling order that NPPA has issued, has one price for indigenous manufacturers and one for multinationals (MNCs) and importers which is at a 20-40 percent premium. It is clearly pro MNC's who get to enjoy better margins than domestic players. Domestic players like Wockhardt and Biocon have been instrumental in bringing down the cost of insulins for the patients, however it's the MNC's who are being favored by the government."

Continuing, Ms Shaw pointed out that the MNC's (in case of insulin market) are well entrenched players with almost 80 percent market share in India. It is incorrect to assume that lower price will boost volumes, as it is not an over-the-counter product but a prescription product, where doctors make the decision and not the patients. Secondly and more importantly, MNCs, are using their price advantage to support aggressive marketing initiatives including free distribution of devices.

She further said, "We have been requesting the government to provide a level playing field for all players in the market, domestic as well as MNCs, and do away with a dual pricing mechanism for insulins. We have suggested to have a common ceiling price for insulin products to ensure affordability for the patients. This new ruling with two ceiling prices one for domestic product and the other for imported ones defies the purpose and fails to address the basic issue raised a few years ago. No country favors foreign companies and puts domestic companies at a commercial disadvantage. This is against national interest and implies that government would prefer to import insulin rather than manufacture it in the country which suggests that Biocon should shut shop in Bangalore and import from its Malaysian plant. We will be approaching the Prime Minister's Office, concerned ministries and the NPPA to have them correct this anomaly."

Welcoming the government's move to make essential drugs more affordable and accessible to the society, Mr Arun Sawhney, chairman, National Committee on Pharmaceuticals, Confederation of Indian Industries (CII) said, "The new policy recommends a shift from cost-based to market-based pricing which is a fair approach and it will help improve the availability of essential medicines. While the industry welcomes this move, it would also be pertinent to note that the proposed policy will expand the span of price control to around 30 percent of the domestic pharmaceutical market and impact revenues of the industry which is already facing increased input costs, inflation and a variety of regulatory challenges."

All India Drug Action Network (AIDAN), an independent network of several non-government organizations (NGOs) has challenged the cabinet approval of drug price controls based on market-based pricing at the Supreme Court, which has deferred the case for hearing on December 12, as government of India is seeking time so that it can place the drug pricing policy before the Supreme Court. It may be noted that AIADN besides other NGOs has been working hard to increase access and improve the rational use of essential medicines, for which the government has plans in place to start an initiative for free supply of essential medicines in public health facilities in the country aiming to provide affordable health care to the people by reducing out of pocket expenses of medicines.