Fixing the price of non-scheduled bulk drugs

Introduction

The pricing of drugs, formulations and medical devices is carried out by the National Pharmaceutical Pricing Authority (**"NPPA"**) which is the primary agency in India that regulates the prices of drugs and pharmaceutical products under the Drug Pricing Control Order, 1995 (**"DPCO"**). The NPPA, under the DPCO, is not restricted only to the fixation of the prices of the 75 bulk drugs mentioned under the First Schedule of the DPCO, but extends to non-scheduled drugs and formulations as well.

In this background, this newsletter will discuss the policy and methodology adopted by the NPPA in identifying the drugs outside the ambit of the First Schedule, and the methodology prescribed and applied by the NPPA while determining the prices of non-scheduled bulk drugs.

1. Power to fix prices non-scheduled bulk drug

At the outset, it is necessary to understand the definition of bulk drugs. Under the DPCO, a bulk drug is defined as a pharmaceutical, chemical, biological or plant product etc conforming to pharmacopoeial or other standards specified under the Second Schedule or other standards specified under the Second Schedule of the Drugs & Cosmetics Act, 1940 (**"DCA"**).[1] The definition of bulk drugs under the DPCO as well as the standards specified under the Second Schedule of the DCA are quite wide and cover more than just drugs used as medicines, and can include nutritional supplements as well. Due to this definition, the pricing of non-scheduled bulk drugs assumes significance not only for manufacturers of drugs for clinical and medicinal use but also manufacturers of nutracueticals.

Under paragraph 5 of the DPCO, the NPPA is provided with the discretionary power to fix or revise the prices of non-scheduled bulk drugs. This provision makes it mandatory for any manufacturer of a non-scheduled bulk drug, before commencing with production of any number of non-scheduled bulk drugs, to provide a detailed cost break-up of all such drugs to the NPPA in a prescribed form.[2] It is pertinent to note that at this stage, i.e. on providing the requisite information under paragraph 5 when commencing production, it is neither necessary for the manufacturer to seek approval of the price at which it intends to sell the drug, nor is it mandatory for the NPPA to fix or revise the price. This provision also gives NPPA the power to ask for further information from the manufacturer to assess whether it needs to fix or revise the price of the non-scheduled bulk drug. It is pertinent to note that once the relevant and complete information is provided to the NPPA, it has the sole discretion to either fix or revise the price. Interestingly, no conditions have been prescribed based on which the NPPA will ascertain whether or not to fix or revise the price.

[1] Paragraph 2(a).
[2] Form II under the DPCO.

The DPCO also empowers the NPPA to fix and revise the prices of the scheduled bulk drugs under the First Schedule.[3] However, under paragraph 10(c) of the DPCO, which is a non-obstante clause,[4] the NPPA can if it deems appropriate in public interest, include **any** bulk drug not presently under the First Schedule for the purpose of fixing or revising the price of the same. As such, the power of the NPPA to fix prices is unfettered and it can, solely on grounds of public interest, fix or revise the price of any drug.

Additionally, the NPPA monitors the prices of all non-scheduled bulk drugs through the "Retail Store Audit Reports" published by the IMS-ORG.[5] As per the NPPA,[6] it monitors the prices of all drugs through the IMS-ORG reports, scrutiny of price lists submitted by the manufacturers and any complaints or references received by the NPPA through official and non-official sources. On reviewing the data, the NPPA scrutinizes any price increase of a bulk drug in excess of 10% per annum. If the NPPA comes across such an increase in a bulk drug, it firstly asks the manufacturer to voluntarily reduce the price of the bulk drug below the 10% bench mark set by it. In case the manufacturer does not the NPPA, under paragraph 10(c), revises and fixes the price of the bulk drug. The usual course of action followed by the NPPA is to issue a show-cause notice to the manufacturer to provide reasons as to why the prices should not be revised of fixed. After hearing the manufacturer and satisfying itself, the NPPA either notifies the revised price or allows the manufacturer to continue selling at its prevailing rate (*the latter being a rare instance*).

2. Process for pricing non-scheduled bulk drug

Once the NPPA has short-listed a bulk drug, there are certain provisions under the DPCO which it needs to consider for arriving at the prices. Firstly, under paragraph 3, the NPPA must take into consideration the cost components provided by the manufacturer under Form II. These include the total cost of raw materials, cost of production and profit margin. In addition, the NPPA also must consider **(a)** a post-tax return of 14% on the net-worth of the manufacturer or **(b)** a return of 22% on the capital employed or 12% if it is a new company. The consideration for the post-tax return and return on capital employed increases to 18% and 26%, respectively in case the drug is being manufactured from the basic stage.[7]

Incidentally, the DPCO does not define "post-tax return" but defines "pre-tax return" as the profit before the payment of income tax, surcharge and incidental expenses which do not form part of the cost of production. Accordingly, it can be inferred that the post-tax return implies profit after deducting the aforementioned taxes and expenses. Further, "net-worth" under the DPCO implies the sum of the paid-up capital of the company and the free

[3] Paragraph 3.
[4] A non-obstante clause is a provision which overrides anything contrary to it in an enactment. As a result, the NPPA is not bound by any consideration under the DPCO while applying its power under paragraph 10(c).
[5] IMS-ORG is a private company (*ORG IMS Research Private Limited*) that provides statistical information and reports on movement of drugs by tracking stockists purchases.
[6] As mentioned by the Member Secretary in his message to the public posted on the NPPA's website dated July 7, 2009.
[7] What constitutes "basic stage" has not been defined under the DPCO and its determination is carried out by the NPPA on a case to case basis.

reserves of the manufacturer company which are freely available for operational activity.[8] Capital employed has also been defined as the sum of the net fixed assets and the working capital.[9]

Based on the above essential consideration, a manufacturer can independently assess the pricing evaluation the NPPA will arrive at once the price of the non-scheduled bulk drug being manufactured is to be fixed or revised. It is open for the manufacturer to choose between **(a)** the post-tax return rate and **(b)** the rate of return on the capital employed to be applied for the price fixation or revision. However, once the choice of the rate of return has been applied by the manufacturer, the same cannot be changed by the manufacturer without the permission of the NPPA.

3. Concerns

The NPPA has been quite proactive in the recent years, causing serious concern to several multinational drug manufacturers in India. With India being one of the largest markets for pharmaceutical products, not only in terms of domestic consumption but also in terms of production and export, pricing regulation is a serious concern both for the NPPA as well as the manufacturers.

While the NPPA's concern is focused on ensuring wide distribution, availability and affordability of drugs and medicines, the powers conferred to it under the DPCO are wider than its objective. The Pharmaceutical Policy 2002 (**"2002 Policy"**) takes into consideration the pricing regime to be followed in India and provides that the span of control over pricing of drugs and pharmaceuticals will be reduced drastically. This however does not appear to be the case as the NPPA has been quite proactive since 2002. For example, from April 1, 2008 till June 30, 2009, the NPPA had revised the price of 41 scheduled bulk drugs and 2058 formulations. It has also targeted major pharmaceutical companies such as GlaxoSmithKline, Wockhardt, Novartis, Lupin and many more, as recently as in 2010 where the prices of drugs to treat diabetes and TB are being considered to be fixed or revised.[10]

Under the 2002 Policy, the guiding principle provided for identification of specific bulk drugs for price regulation are **(a)** mass consumption nature of the drug and **(b)** absence of sufficient competition in such drugs. However, since the parameters provided are wide, and unqualified, the NPPA's power to fix and revise prices remains unfettered. As a result, drug manufacturers have the possibility of losing out on profitability, despite the intention of the government to increasingly de-regulate drug pricing under the 2002 Policy.

[8] Paragraph 2(n) of the DPCO.
[9] Paragraph 2(b) of the DPCO.
[10] The NPPA had conducted a study which depicted the difference between the same non-scheduled bulk drug being manufactured and sold by different manufacturers with a drastic difference in the prices.

Conclusion

While it is understandable and reasonable to require the price regulation of life-saving drugs, regulation of all drugs without any qualifying conditions will act counterproductive to the intention of the government to ensure wide accessibility of drugs to the Indian population. The NPPA has a tough task of regulating the prices of non-scheduled bulk drugs as, on the one hand, the directive under the 2002 Policy is to minimize regulation of prices but the NPPA has to also balance the public interest and ensure drug prices do not make them out of reach of the majority of the populace. The NPPA and the industry need to come together on a common platform to come to a common ground on drug pricing. Simply using its powers under the DPCO to fix the prices of non-scheduled bulk drugs to levels unacceptable to the manufacturer may drive out manufacturers in this sector, which invariably will lead to shortage of drugs.

Authored by:
Ashutosh Chandola