Pharma & Healthcare Update

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LAUNCH NEW DRUG IN 6 MONTHS OR FACE CANCELLATION OF THE LICENSE

INTRODUCTION

As per a recent circular[1] issued by Drugs Controller General of India ("**DCGI**") on January 10, 2013 ("**Circular Date**"), all manufacturers of 'new drug' (explained later) are required to launch the new drug within six months from the date of the grant of the permission by the DCGI, failing which the permission received from the DCGI will be cancelled. Manufacturing of new drug after cancellation of permission would constitute violation of the Drugs and Cosmetics Act, 1940[2] ("**The Act**"), and those who deal with new drug produced after cancellation of such permission would be liable to be punished under the Act.[3]

By imposing such a condition, the Indian drug regulator intends to ensure that the manufacturers do not evade the compulsory requirement of submission of Periodic Safety Update Report ("**PSUR**") in relation to new drugs. A PSUR usually comprises of, inter alia, information on patient exposure to the new drug and is employed as a post-marketing surveillance tool by the drug regulator. Under the present regime, submission of PSUR is mandatory only for a period of four years from date of permission to manufacture, since a new drug ceases to be 'new' after four years from the date of first approval by DCGI. As per DCGI, many manufacturers of new drugs were evading the requirement of filing PSUR by stalling manufacture for four years post approval. Therefore, all manufacturers of new drugs are now obligated to launch the new drug within six months of being permitted to manufacture and are consequently required to make regular PSUR submission.

LEGISLATIVE FRAMEWORK

Under the Drugs and Cosmetics Rules, 1945 ("**Rules**"), a new drug is defined as a drug which is yet to be approved by DCGI, or a new drug which has received approval from DCGI for certain claims, but now is proposed to be marketed for different claims (indication, dosage, dosage form etc.), or a fixed dose combination of two or more drugs, which have been individually approved by DCGI earlier for certain claims, but now are being proposed to be combined for the first time in a fixed ratio or if the ratio of ingredients in an already marketed combination is proposed to be changed, with certain claims. As already mentioned, once a new drug gets approval from DCGI, it continues to be considered a new drug for a period of four years from the date of its first approval or its inclusion in the Indian Pharmacopoeia, whichever is earlier.[4]

The approval system for manufacture of drug is usually one- tier (that is, only a license from State Licensing Authorities ("**SLA**"), is required)[5], but in case of manufacture of new drug, permission from DCGI[6] is the first step followed by license from the SLA[7].

Once permission to manufacture is received, the Rules mandate that PSUR must be submitted every six months for the first two years after receipt of marketing approval, and should be submitted annually for the subsequent two years. PSURs must be submitted within 30 calendar days of the last day of the previous reporting period. The ingredients and structure of a PSUR has been specified under Schedule Y of the Rules.[8]

ANALYSIS

There is uncertainty surrounding the applicability of the Circular. While it is clear that the Circular will have prospective effect, i.e. in relation approvals granted post the Circular Date, it is unclear whether the same would be applicable in relation to approvals granted before the Circular Date. For example, it is unclear whether a manufacturer, who has not launched its new drug for over 6 months after receiving DCGI approval but before the Circular Date, will face cancellation immediately.

Moreover, the Circular appears to be disconnected from commercial realities of the day. The pharmaceutical companies have to bear significant cost to go through the entire process of clinical trials before a new drug is approved for marketing. There may be several commercial reasons, including strategic reasons, for not launching a new drug immediately upon receiving approval. It is unreasonable for the DCGI to cancel approvals on the ground that the new drug has not been marketed within 6 months.

While discussing the impact and short comings of the Circular, one must not lose track of the real issue at hand, which is the importance of submission of the PSURs. You may recollect that in August last year, the DCGI had issued an office order which directed all manufacturers who had not submitted PSUR, to submit the report within a short time- limit or face suspension / cancellation of permission to manufacture.[9] You may read more about the said office order in our piece here.

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Now, this additional Circular, as discussed above, is issued to cover the situation where the new drug no longer remains a new drug due to the way it is defined upon expiry of 4 years from the date of first approval. However, it should be appreciated that filing of PSUR is an independent obligation and the same can be made applicable from the date on which the drug has been actually launched. In fact, Schedule Y does have a provision which states that if the marketing of the new drug is delayed by the applicant after obtaining approval to market, such data (PSUR) will have to be provided on the deferred basis beginning from the time the new drug is marketed.[10] The DCGI could have taken the benefit of this provision and issued a Circular clarifying that irrespective of when the new drug is marketed post- approval, the PSUR requirement will be applicable for 4 years from the date of marketing.

From a legal point of view, the direction given through the Circular to SLAs may be argued to lack competence since the Rules do not obligate manufacturers to launch their products immediately or within a certain time frame. The decision to stipulate a time frame may be construed as creation of a new rule, which under law, can only be done by a Central Government by notification in the Official Gazette[11]. From a plain reading of the Rules, it does not appear that there is legislative intent to provide DCGI with the power to determine time frame for launch of products.

CONCLUSION

It will be beneficial for the industry as well as the Regulator if a more balanced approached in dealing with newer issues is adopted. Instead of by- passing the due process by issuing circulars and notifications to add a provision of law, the existing rules may be examined thoroughly and implemented with vigor to ensure meeting of larger public interest.

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You can direct your queries or comments to the authors

[1] DCGI Circular F. No. 12-01/12- DC Pt- 127 dated January 10, 2013, available at http://cdsco.nic.in/cancellation_of_permission.pdf (last viewed on 17.01.13).

[2] S. 18 of the Act.

[3] S. 27 (d) r/ w S. 18 of the Act.

[4] R. 122E of the Rules.

[5] R. 69(1) of the Rules.

[6] R. 122A (1) (a) r/w R. 21(b) of the Rules.

[7] R. 69(1) of the Rules.

[8] Schedule Y (3) (4) of the Rules.

[9] DCGI Office Order dated August 28, 2012, available at http://cdsco.nic.in/Submission%20of%20PSUR.pdf (last accessed 17.01.13

[10] Schedule Y (3) (4) (iii) of the Rules reads, ".¦ If marketing of the new drug is delayed by the applicant after obtaining approval to market, such data will have to be provided on the deferred basis beginning from the time the new drug is marketed."

[11] S. 33 of the Act. It reads, "33. Power of Central Government to make rules. ."(1)The Central Government may after consultation with, or on the recommendation of, the Board and after previous publication by notification in the Official Gazette, make rules for the purposes of giving effect to the provisions of this chapter: Provided that consultation with the Board may be dispensed with if the Central Government is of opinion that circumstances have arisen which render it necessary to make rules without such consultation, but in such a case the Board shall be consulted within six months of making of the rules and the Central Government shall take into consideration any suggestions which the Board may make in relation to the amendment of the said rules¦"

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