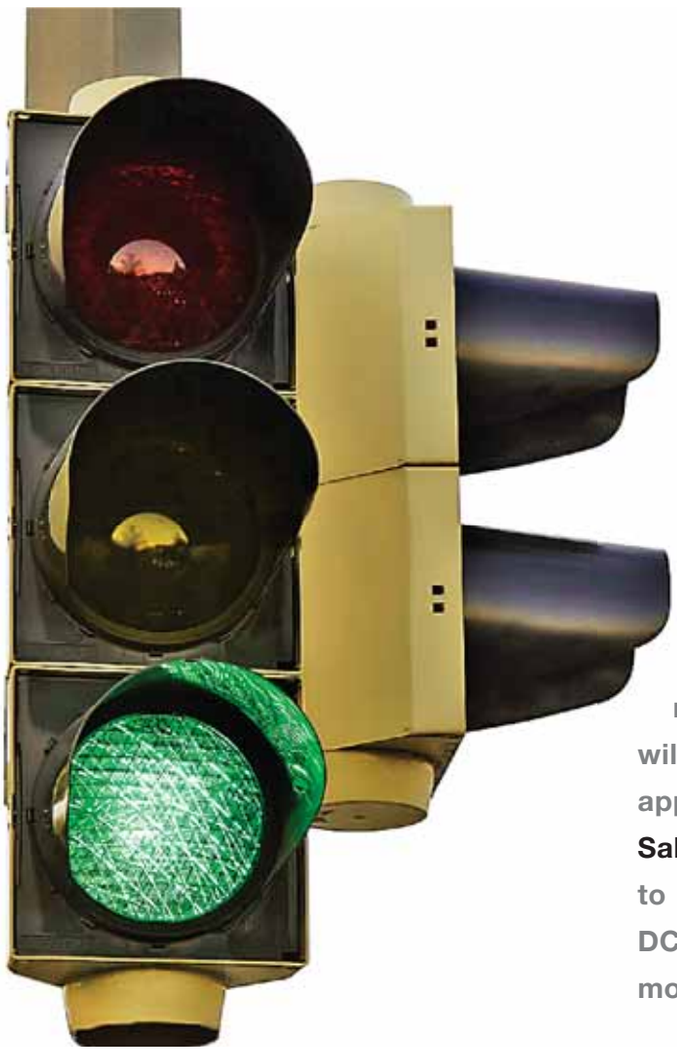

DCGI nod for pharma exports

Green signal or traffic stopper?

In accordance with a directive issued by the World Health Organization (WHO) to discourage multiple certifying authorities in one country, the Drug Controller General of India (DCGI) has passed a new regulation. Now, domestic pharma companies will have to export medicines only after receiving approval from a central authority, ie, the DCGI. Saloni Vora catches up with a few industry experts to know whether requiring a green signal from the DCGI is a move that will enable Indian exports to gain momentum or may act as a traffic stopper.

Dr M D Nair
consultant to the pharma industry

The recent decision of the Ministry of Health to centralise the issuance of certificates of pharmaceutical products (CoPP) through the offices of Central Drugs Standard Control Organisation (CDSCO) has alarmed pharma manufacturers, particularly export-oriented companies. Further, at a time when India has the potential to become one of the world leaders in this segment, any such action on the part of the government that is likely to create a roadblock to progress. Moreover, today, India is one of the major suppliers of generic bulk drugs to the global markets and has several FDA approved-facilities as well as abbreviated new drug application (ANDA) approvals outside the US. Considering all these developments, Indian exports are rapidly gaining momentum in present times. Also, other countries, especially China, continue to compete with India in this field. Hence, it is even more important for Indian exports to be regulated in an appropriate manner.

The mandatory issuance of CoPP by CDSCO was the result of recommendations from WHO to have a centralised system in place for monitoring the quality standards/aspects of exports. However, today, neither CDSCO nor the industry is prepared for such a change in a relatively short period of time. Hence, while the recent court interventions will definitely reverse or at least delay the implementation, a broader debate needs to be initiated to clearly demarcate the relative roles of various agencies, including those of the centre and the states along with the different ministries concerned with exports. Hence, any administrative action on the part of the government to change a prevailing system should be taken only after carefully considering the appropriate timeframe and the pros & cons of such actions. Any hurried action from the government's side on this matter is likely to adversely affect the export performance of the industry.

Ashwin Thacker
managing director,
Flamingo Pharmaceuticals Ltd

The new regulation mandating DCGI approval for the export of medicines by domestic pharma companies has its advantages and disadvantages. Its advantages include more uniformity and consistency in the approval process, with only a centralised agency inspecting manufacturing facilities and subsequently issuing certificates across the country. On the other hand, disadvantages include a delay in the entire procedure right from the inspection of facilities and issuing CoPPs to the final registration approval issued by the importing country. Moreover, this will seriously affect the availability of medicines and their prices in certain countries, ultimately affecting Indian exports.

Pharma companies, especially small & medium enterprises would face many hardships like the need for additional manpower for regular follow ups; pressure to match up to national standards along with investment of sufficient capital for infrastructure development; manufacturing standards; workforce training; and implementation of world-class processes. Further, any new development takes time to implement. Considering the fact that the human mind is not adept to accepting change, the entire process would have its challenges that would require a change in attitude as well as mindset to effectively deal with the same.

In order to ensure a smooth transformation, the DCGI would need to take adequate steps like training its workforce with respect to the requirements, procedures & processes, so as to complete the certification process effectively within the set time period. Further, this initiative needs to be carried out successfully at a national level for a smooth shift towards the new development.

Nayan Joshi
president – Supply Chain,
Inventia Healthcare Pvt Ltd

Today, the world is looking towards India for high-quality medicines at affordable prices. The Indian policy of decentralisation is meant to aid manufacturers and exporters in fulfilling their export commitments. By centralising the system of issuing licences, manufacturers will experience delays in getting the required permissions on time, leading to loss of business in this competitive world. Moreover, there are other Asian countries competing with India in the exports of medicines. Since most of these exports are time-bound, the inability to execute the export orders on time will be a loss to Indian export businesses.

In addition, the state regulatory administration has good infrastructure, qualified & well-trained officers and a full-fledged intelligence bureau that expedites export applications on a priority basis. Hence, the present system of licensing is favourable to the exports industry. If this notification is enforced where exports companies would require a DCGI nod before exporting their medicines into the international community, then the transition should take place in a gradual manner. For this, the DCGI should have adequate manpower to carry out the required functions efficiently & effectively so that the issuance of certificates to the export companies is not delayed and subsequently, their business is not lost.

Akkshay G Mehta
managing director,
Mission Vivacare Ltd

The recent notification issued by the DCGI is a good move, as it would ensure uniformity in the process of issuing certificates across the country, thereby serving as a common barometer for all exporting companies. But considering the fact that the Chennai High Court has recently issued a stay on this notification, its implementation is uncertain. Further, most CoPPs are already being issued by the DCGI. It is just a few state FDA offices that continue to issue these certifications. However, with the new ruling, pharma companies in these states will have to comply with the DCGI. Hence, initially these companies may face a temporary slowdown in their exports until they comply with the new notifications and get their CoPP released from the DCGI.

In a nutshell, the new regulation would harmonise the issuance process of WHO-GMP and COPPs. This would help in the immediate verification of these certifications and stop questionable manufacturers from offering products with similar brand names.

Tapan Ray
director general, Organisation of Pharmaceutical Producers of India (OPPI)

The Ministry of Health, Government of India, should be complimented on this important initiative, which has stemmed from a request made by the WHO. In April 2009, WHO informed the Ministry of Health, Government of India about the WHO logo being used in CoPPs, as the formats and guidelines laid down by the authority were not being followed appropriately by the various local CoPP issuing authorities in India. Further, the WHO requested Indian authorities to control such an important documentation procedure in a central manner to ensure uniformity and authenticity in the certificates being issued. Hence, taking into account these requests and concerns of the WHO, the new regulation was passed.

However, state drug authorities have expressed their unhappiness about this decision and challenged the power of the DCGI to effect such changes. According to them, the state would suffer from revenue losses with this procedural amendment. They also feel that since the manufacturing licences are issued by them to the exporters, the CoPP should also to be issued by the same authority, a practice being followed since ages. Further, in their opinion, the inadequate infrastructure available with CDSCO would hinder the effective implementation of the new system, resulting in unusual delays for issuing the certificate.

On the contrary, many stakeholders feel that the new ruling would help in strengthening the regulatory framework of the country. Besides, it would ensure that only high-quality generic drugs manufactured in India are moving into the international community, thereby having a positive impact on Indian pharma exports. Further, the new system would also assist the DCGI in providing up-to-date details on CoPP to the international regulators as and when required by them. Also, the infrastructural issue including the manpower need of CDSCO to handle this initiative is being addressed with adequate speed. Overall, this is a laudable move to ensure uniformity and consistency in the pharma products being exported from India.

D P Shrivastava
CEO – Zen Life Sciences, Unimark Remedies Ltd

The new regulation would result in the harmonisation of exports through unification and centralised quality approval of the medicines that are exported to foreign shores. Another advantage of this new ruling is that it would require all the companies to be equipped according to the required standards to deal in pharma exports. On the contrary, delay in obtaining certifications from the DCGI due to its inability to deal with a large number of applications would cause a lot of inconvenience to exporters. Moreover, hindrances will also be caused to small & medium-sized pharma companies, as they may incur losses during this period. Hence, rather than taking over the authority directly from the state FDA, the DCGI should have worked closely with them by appointing higher authorities who would work under the supervision & guidance of the DCGI to ensure the implementation of quality standards. By way of this, the seriousness with regard to certification & maintenance of quality standards could have been adopted at the state level, resulting in harmonisation between all states.

In order to ensure a smooth shift towards the new development, the DCGI should adequately train, guide, assist and supervise the process of CoPP certification by the state body through a dedicated team of DCGI officials. It should also inform small & medium-scale pharma companies regarding the process of quality certification and implement punitive actions with those companies that do not comply with the quality norms. In addition, the protocol and standard operating procedure (SOP) of this new move should be published on the DCGI website, which would serve as an informative & interactive medium and help in educating the concerned people regarding the process of certification. Also, the DCGI could initiate the process of filing an application for certification in an electronic manner, as it would assist in saving valuable time and ensure a more regulated manner of functioning.