

# Pharma & Healthcare Update

June 16, 2011

## CLINICAL TRIAL RELATED INFORMATION EXEMPTED FROM DISCLOSURE

Clinical trial related information pertaining to patient identifiable data and trade secrets and intellectual property of the pharmaceutical companies may be exempted from disclosure under the Right to Information Act, 2005.

### BACKGROUND

The Right to Information Act, 2005 ("Act") was drafted to provide a platform for citizens to access information under the control of various public authorities to promote transparency and accountability in the public bodies. The Act casts important obligation on public authorities to facilitate the citizens in accessing information held under their control.

However, certain information as enlisted under Section 8 of the Act is exempted from disclosure. Information exempted from disclosure including those expressly forbidden to be published by any court of law or tribunal or the disclosure constituting contempt of court, commercial confidence, trade secrets or intellectual property, harming the competitive position of a third party; information available to a person in his fiduciary relationship; information impeding the process of investigation or apprehension or prosecution of offenders; cabinet papers including records of deliberations of the Council of Ministers, Secretaries and other officers among several others unless the same is necessitated under public interest.

But information that could be severed from exempted categories listed under Section 8 is required to be provided as per the provisions of Section 10 (1) of the Act.

### PROCEDURE FOR SEEKING INFORMATION

Section 6 of the Act allows the citizens requiring certain information to apply for the same in writing or through electronic means to the Central Public Information Officer ("CPIO") or State Public Information Officer ("SPIO"), or the Central Assistant Public Information Officer or State Assistant Public Information Officer, as the case may be, of the concerned public authority. The CPIO/SPIO is required to furnish the information within a period of 30 days and in cases involving life and liberty of individuals within 48 hours on payment of fees as per Section 7 of the Act. In case of refusal to provide information, the concerned officials are required to state the reasons and details of the appellate authority along with the duration of appeal.

Separate provisions have been enacted under the Act for revealing information held by third parties. The concerned officials within five days from the receipt of the request have to inform such third parties of their intention to disclose such information held in confidence. Further, the third parties are allowed to make submissions, written and oral against such disclosure within ten days from the receipt of the Notice. However, in case of trade or commercial secrets protected by law, disclosure may be allowed only in **public interest** as per the provisions of Section 11 of the Act.

The third parties are allowed to appeal under Section 19 of the Act before the Central Information Commission ("CIC")/State Information Commission ("SIC") if contrary decision taken by the CPIO/SPIO within thirty days from the date of the Order. Appeals are allowed even after the prescribed duration on sufficient cause being shown. Third parties are given reasonable opportunity for representations and the decisions are binding on the parties.

### LATEST CIC DECISION

The Central Information Commission ("CIC") recently in Ms. Deepa Venkatachalam & Anr. vs. Directorate General of Health Services<sup>1</sup> pertaining to disclosure of information on clinical trials held that pending Inquiry conducted by the Union Health Minister on the collaborative project between PATH, ICMR, Governments of Andhra Pradesh and Gujarat ("Inquiry") no information was required to be provided and only on final outcome of the Inquiry, information under Section 10 (1) of the Right to Information Act, 2005 ("Act") had to be furnished. Information disclosed should be severed from any patient related information as well as pertaining to exclusive intellectual property rights of the pharmaceutical companies as protected under the provisions of the Act.

In the present case, a RTI application was filed seeking information on post-licensure HPV vaccination observation study for usage of certain drugs "Gardasil" and "Cervatrix" in an age group outside the age group on whom they were tested. The information was sought from the Directorate General of Health Services. Detailed submissions were taken from third parties namely three pharmaceutical companies.

### CONTENTIONS OF THE PARTIES

The Applicants mainly contended that approvals obtained from Drugs Controller General of India ("DCGI") are for use in an age group outside the age group on whom they were tested during trial stage in India. The applicants' intention

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was to verify whether the licensing authorities had verified the data prior to approving the same. Further, it was submitted that for transparency and accountability purposes in biomedical research disclosure of information was essential.

The three pharmaceutical companies provided their detailed submissions for exemption of disclosure of such information as requested by the applicants.

§ M/s. PATH

It was contended that information sought under the RTI involved confidential data of the patients subjected to the clinical trial and are strictly confidential in nature in purview of the agreement entered between the companies and patients. Leakage of such information leads to breach of contract entered between patients and the companies. Patient confidentiality is of paramount importance and PATH in consultation with the Western Institutional Review Board ("WIRB") had adhered to protect patient confidentiality as required under Indian laws. PATH mainly contended that pending final report of the Inquiry and same being officially published no information was required to be disclosed in possession of DCGI claiming exemption under Section 8 (1) (h) and (j) of the Act. However, on completion of Inquiry, PATH agreed to furnish information except those relating to patient identifiable data.

§ M/s. MSD Pharmaceuticals

Further, M/s. MSD Pharmaceuticals invoking the provisions of Section 8 (1) (d) stated that confidential research methodologies, analysis methods, operational parameters developed are shared only with regulatory authorities as part of mandate in fiduciary capacity for approval and marketing. The said information constitutes commercial trade secret and exclusive intellectual property of the company and prohibited from disclosure to public under relevant laws in India. M/s. MSD Pharmaceuticals sought exemption under Section 8 (1) (d) & (e) of the Act as disclosure of such information would lead to irreparable commercial detriment to the company.

§ M/s. GlaxoSmithKline Pharmaceuticals Ltd.

The company objected to disclosure of information relating to technical, analytical, operational, clinical and scientific data and detailed manufacturing, research processes, methods of analysis, statistical data as it came within the ambit of commercial, confidential and proprietary information constituting trade secrets and intellectual property of the company. Disclosure of such information harms the competitive position of the Company and is under no obligation to disclose any such information to the general public. Clinical trial reports need not be disclosed as the Institution and Principal Investigator need to maintain confidentiality as per the terms of the Informed Consent Form signed by patients participating in a clinical trial.

DECISION AND RATIONALE

The CIC upheld the contentions of the pharmaceutical companies and held that no information was required to be disclosed as the marketing approval for the medicines as well as the approval documents contains substantial strategic, scientific data along with patient related information. The same are purely confidential in nature as per Schedule Y of Drugs and Cosmetics Act, 1945. The CIC relying on the provisions of Section 8 (1) (h) of the Act held that prior to completion of investigation and pending Inquiry no information had to be disclosed as clinical trial reports deals with patient related data and privacy and confidentiality of individuals need to be protected. Further, only information severing all and any patient related information and exclusive intellectual property rights of the pharmaceutical companies may be furnished under Section 10 (1) of the Act upon final outcome of the Inquiry.

CONCLUSION

The CIC with its latest decision has clearly spelled out what information can be exempted from disclosure in case of clinical trials. Transparency is essential in biomedical research however; such information may not be divulged in the public domain as it includes several substantial strategic, scientific data along with patient related information. Further disclosure of such information may harm the trade secrets and intellectual property of the pharmaceutical companies. The Act has specified that in cases where only part of the information would be provided in a matter, same needs to be explicitly stated with reasons. It is imperative to note that no such clear demarcation or guidelines have been laid down for such segregation of information other than those exempted under Section 8 of the Act. With regard to clinical trials, however, patient related data and trade secrets and intellectual property of the pharmaceutical companies may not be disclosed. The problem would persist wherein data are inter-linked and segregation is not possible making it a contesting issue for disclosure of information.

- Payel Chatterjee & Gowree Gokhale

1 File No. CIC/AD/A/2011/000115 & CIC/AD/A/2011/000116

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