Pharma & Healthcare Update

January 30, 2013

CLINICAL TRIALS ON TRIAL

INTRODUCTION

The Drugs Controller General of India ("**DCGI**"), the executive arm of Central Drug Standards Control Organization ("**CDSCO**") under the Ministry of Health and Family Welfare, which is responsible for regulation of drugs in India, has reportedly announced ("**Announcement**") that new clinical trials will not be granted permission for at least next two months, until a new regulatory regime for conducting clinical trials ("**New Regime**") is put in place.[1] The Announcement comes in the wake of a remark of the Supreme Court of India, made while hearing a public interest litigation[2] filed by a non-governmental organization (on the ground that "**illegal clinical trials must be stayed**").[3]

Since the Announcement has roots in the aforementioned public interest litigation, we have examined the facts in some detail before analyzing the repercussions of the Announcement.

BACKGROUND

In January, 2012, a writ petition was filed before the Supreme Court of India ("**the Court**") by Swasthya Adhikar Manch ("**SAM**"), a non-governmental organization ("**NGO**")[4], against the Ministry of Health and Family Welfare ("**MoHFW**"), Government of India, alleging several flaws in the regulatory framework surrounding clinical trials in India. The writ petition was later joined with a separate writ petition filed by Bhopal Gas Peedit Mahila Udyog Sangathan ("**BGPMUS**"), another NGO, alleging that flaws in the regulatory framework connected to clinical trials had led to exploitation of the civilian population. The two petitions are now being heard together (the petition filed by SAM and by BGPMUS collectively referred to as the "**Petition**"). The aforementioned remark of the Supreme Court was made in the fifth hearing of the case. The following table summarizes the important developments in the case till date:

Sr. No.	Date	Development
1	February 6, 2012	The Court hears the Petition for the first time. Time is granted to the Respondents- MoHFW, CDSCO and others to submit a counter-affidavit.
2	March 26, 2012	The Court grants extension of time to the Respondents to submit the counter-affidavit.
3	July 16, 2012	The Court grants further extension of time, to submit counter-affidavit, to the Respondents.
4	October 8, 2012	The Court orders the Secretary, MoHFW and / or CDSCO, through DCGI, to provide the following information to the Court within four weeks of the hearing: ▪ The number of experimental New Clinical Entities ("NCEs") approved for clinical trials by the DCGI from January 1, 2005 to June 30, 2012. ▪ Whether deaths were suffered by subjects of the clinical trials. If yes, the number of deaths occurred. ▪ Whether serious side effects were suffered by the subjects of clinical trials. If yes, the number of the subjects and the nature of side effects. ▪ The details of compensation paid to the subjects who suffered side effects or paid to the family of the subjects who died.
5	January 3, 2013	The Court observes that the information, as directed, is not submitted by the Secretary, MoHFW or the CDSCO. Instead, an additional affidavit is filed by the Deputy DCGI providing the requested information. The Court notes non-compliance of the Order dated October 8, 2012 and decides to ignore the additional affidavit. It re-directs the Secretary, MoHFW or CDSCO through the DCGI as well as the Chief Secretary of all States to file an affidavit providing the requested information within four weeks from the date of hearing. It takes note of the statement of the Additional Solicitor General of India that until further order of the Court, clinical trials of new chemical entities will be conducted strictly in accordance with the procedure described in Schedule Y of the Drugs and Cosmetics Rules, 1945[5]under the direct supervision of the Secretary, MoHFW. The Court directs the case to be listed in four weeks. It is noteworthy that this matter case coincided with the publication of the Department-related Parliamentary Standing Committee on Health and Family Welfare's Report on the Functioning of the CDSCO on May 8, 2012, which made scathing remarks on regulatory control over the conduct of clinical trials in India, especially in the case of new drugs. It had, inter alia, found that the approvals to clinical trials had been granted without adhering to the provisions of Schedule Y of the Drugs and Cosmetics Rules, 1945 (the "**Rules**").

IMPACT

As per the Announcement, no new clinical trials will be permitted to be conducted in India for at least two months

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from January 22, 2013 ("**Effective Date**").

To begin with, such an announcement has further paralyzed already crippled clinical trials industry in India as a whole, which showed a radical attempt at tightening the surveillance over clinical trials over the past couple of years. In the following table, we have captured important regulatory developments connected with clinical trials in the past couple of years.

Publication Date	Regulatory Developments
19.01.2011	Draft Rules to include provisions pertaining to the registration of contract research organizations ("**CROs**") under the Rules, and to include a Schedule Y-1 which covered the 'requirements and guidelines for registration of CROs'. Stakeholder comments were invited for these proposed rules and the Schedule Y-1, however, they continue to be in the draft form as no further action was taken by the authorities and the Notification yet remains to be implemented
18.11.2011	Draft Rules to include provisions to award compensation to study subjects, by Sponsors of trials, in case of clinical trials related injury or death and consequences of non-compliance
21.12.2011	Guidelines for requirement of chemical and pharmaceutical information including stability study data before approval of clinical trials / Bio- Equivalence studies
17.07.2012	Draft Rules which outline the required conditions to be met in order to issue a permission to conduct clinical trials, thereby amending Rule 122 of the Rules
17.07.2012	Draft Rules to include provisions for registration of the Ethics Committees with the licensing authority prior to approving clinical trials, and to include, as part of Schedule Y-1, requirements and guidelines for registration of the Ethics Committe
03.08.2012	Draft Guidelines for determining quantum of compensation
16.08.2012	DCGI Order directing Ethics Committee to conduct surprise visit and keep vigil to see whether clinical trials are being undertaken as per Schedule Y / GCP Guidelines
16.08.2012	DCGI Notice drawing out a check list of essential elements in the informed consent document to be obtained from the study subjects and the format of the said informed consent document
28.08.2012	DCGI Order directing importers and manufacturers of 'New Drugs' to submit pending Periodic Safety Update Reports immediatel
12.12.2012	DCGI Order directing sites of sponsors/CROs and Ethics Committees to remain open for inspection in order to ensure that subjects of clinical trials are safe, and that data generated is scientifically and ethically sound
12.12.2012	DCGI Order directing the Ethics Committees to mandatorily operate according to Good Clinical Practice guidelines issued by CDSCO Since the Announcement does not cover suspension of the existing clinical trials, it appears that such trials will continue to be conducted as per the existing rules. However, the Announcement could bring the existing clinical trials under cloud as these developments may raise concerns about adequacy of existing rules and regulations and the uncertainty on proposed new rules being made applicable to the ongoing trials. As it is, the constant activity at the drugs regulators' end to publish draft amendments to the existing legislation with no certainty on when they will be implemented, has raised several concerns in the industry. Streamlining the entire process in a balanced manner (that is, creating a fine balance between the sponsors and the CROs/institutions in India) and bringing further clarity to the existing legislation may, perhaps, lead to better implementation and adherence to the laws/rules/guidelines while conducting clinical trials

1. Impact on Local Manufacturers: The Announcement is likely to hit Indian domestic manufacturers of new drugs who intend to begin conducting clinical trials in India. This may lead to severe economic costs such as cost of delay on payment made to third parties in expectation of the permission to manufacture or delay in recouping all the costs incurred for manufacturing the drugs etc.
2. Impact on Foreign Manufacturers of new drugs: The impact of the Announcement on local manufacturers of new drugs applies equally to foreign manufacturers of new drugs who intend to launch their drugs in India. All new drugs intended to be launched in India have to mandatorily undergo Phase III trials in India. If the DCGI does not approve Phase III clinical trials for the announced duration, then the foreign manufacturers may not be able to apply for permission to market and sell the new drug in India
3. Impact on contractual parties in a clinical trial: All CROs, Sites (Hospitals) and Principal Investigators ("**Parties**") carrying out clinical research in India on behalf of a manufacturer (commonly called Sponsor) may have to revisit their contracts and arrangements with the Sponsor

SILVER LINING ON A DARK CLOUD

This is a testing time for the Indian clinical trial industry. One way to look at the Announcement is to view it as possibly the final nail on the coffin for the clinical trials industry. The other way is to look at it as the final frontier. Once the DCGI comes up with the New Regime and the regime gets an approval of the Supreme Court of India, it will bring a great amount of public confidence and stability to the industry with the clarity in law which it has been yearning for a long time.

– Anay Shukla & Khushboo Baxi
You can direct your queries or comments to the authors

[1] "Ministry gets 2 months to define clinical trials regulatory regime", livemint, dt. January 22, 2013, available at http://www.livemint.com/Industry/JTitha6MKC0Q1UdZToidFK/Ministry-gets-2-months-to-define-clinical-trials-regulatory.html (last accessed on January 24, 2013

[2] Swasthya Adhikar Manch, Indore & Anr vs. Min. of Health and Family Welf. &Ors, W.P. No. 33 of 2012 (Supreme Court).

[3] "Illegal clinical trials must be stayed", The Hindu, dt. January 3, 2013, available at http://www.thehindu.com/news/national/illegal-clinical-trials-creating-havoc-supreme-court/article4268671.ece (last accessed on January 24, 2013).

[4] It is a network of various organizations which provides a platform to deal with various issues related to health & related rights.

[5] As framed under the Drugs and Cosmetics Act, 1940.

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