IAF TO CHALLENGE THMPD

May 2011

IAF to challenge THMPD

By the THMPD, EU has banned all ayurvedic products in EU. Miffed over this step, the IAF is all geared up to initiate legal proceedings under Article 234 EC in the Courts of the UK challenging the legality of the THMPD. The basic arguments are as to how does the directive become a law since it is in contravention with lots of existing laws in EU, how EU is violating the European human rights legislation, and how EU is violating the existing protocol of WTO treaty through this directive.

PSA view – It is crucial to challenge THMPD because if it remains unchallenged, chances of other countries replicating the same move may follow suit. The existing global ayurveda industry is estimated to be US$ 5 billion and THMPD like directives could be a disaster for the industry. The chances that such directives will lead to illegal use of ayurvedic products.

Ministry to notify the Drugs and Cosmetics (First Amendment) Rules, 2011

The Ministry is all set to notify the Drugs and Cosmetics (First Amendment) Rules, 2011 which seeks to insert requirements and guidelines for registration of clinical research organizations under a new Schedule called Schedule Y-1 to the Act. Draft rules were circulated for comments from stakeholders in January this year and Ministry has already reviewed and considered the comments received. The most crucial feature of this proposed amendment is the insertion of Schedule Y1 which covers all organizations, individuals, institutions, and companies that take the responsibility of conducting clinical trials including those who seek permission for clinical trial from licensing authority. The Drugs Technical Advisory Board has given approval to the amendment paving way for the Ministry to announce the draft of the amendment.

PSA view – It is important to note that the draft guidelines are not stand alone guidelines and will be used together with Schedule Y of the Drugs and Cosmetics Rules, Indian Good Clinical Practice guidelines and ethical guidelines for bio-medical research on human participants by the Indian Council of Medical Research which are applicable to clinical researches in India. The amendment also lays down criteria for registration and functioning of Clinical Research Organizations. Ensuring transparency and accessibility in conduct of clinical trials, the registration of trials in the clinical trial registry of the ICMR, has been made mandatory since June 15, 2009. The amendment is now eagerly awaited.

Clarification on Service Tax on Short Term Accommodation and Restaurants

The Department has vide Circular No. 139/8/2011-TRU, dated May 10, 2011 (“Circular”) provided

clarifications on the levy of service tax on services provided by way of short-term accommodation and by specified restaurants. The clarification is in response to various queries raised by the general public and the potential tax payers. The Circular (a) defines the term Declared Tariff, (b) clarifies whether tax is to be paid on the declared tariff or on the actual amount charged, (c) defines the scope of declared tariff and (d) clarifies the services provided by a restaurant that are liable for taxation.

PSA view – The clarifications have been welcomed and have cleared the ambiguity surrounding applicability of service tax on services provided by restaurants and by way of short-term accommodation. Further, the Circular has clarified whether in case of service provided by way of short-term accommodation, service tax is to be levied on the “declared tariff” or “actual amount charged”.

By:

Neeraj Dubey
Divij Kumar