



GUIDELINES ON MINIMUM REQUIREMENTS FOR DIAGNOSTICS LIKELY

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Guidelines on minimum requirements for diagnostics likely

Industry Associations are in talks with the central government to establish minimum guidelines for the diagnostics industry. Due to the lack of regulation, the standards applied by public sector and private labs are quite drastically different and lacking in a few key areas. At present, accreditation is optional and not mandatory for laboratories. The sector is quite unregulated and considering the inflow of international tests being transferred to India for evaluation and diagnostics, there is a huge potential for error due to the lack of guidelines and regulations in this sector.

PSA view – The initiative of the industry associations is well founded, however, it will take considerable time to be formulated and implemented. That being said, in view of the tremendous potential for the diagnostics market in India, and the fact that most of the units in the diagnostic industry are involved in clinical trials, regulations of the government requiring minimum standards to be implemented will raise the quality of work emanating from India. This in turn would lead to more inflow of work, and consequently revenue. There is however some time before the guidelines are in place and can be implemented. On another note, most diagnostic centers catering to international work may also have to comply with additional international standards for work that flows from other jurisdictions, and having national guidelines in place will help them meet international requirements half-way, if not completely.

National vaccine policy finalized

In order to strengthen the UIP, the Health Ministry has finalized a Policy that aims to strengthen the institutional structure, processes and framework required for decision making for strengthening the UIP. While trying to streamline the decision-making process involved in introduction of new and under-utilized vaccine, the Policy also addresses the issues of vaccine security, regulatory guidelines, vaccine research and development and product development. It is to be noted that the date of implementation of this Policy is yet to be notified by the Health Ministry.

PSA view – The success of immunization program in any country depends more upon the effectiveness of its policies. Though, this Policy holds a lot of promises, what needs to be seen is how effectively will the Policy be implemented. As per a report published by the World health Organization in 2002, the main problem with the UIP was the delay in delivery of vaccination. Though, the Infrastructure in the health care

sector has improved since 2002, the question that needs to be answered is that will the Policy be able to reach out on time to the majority in need, if not all.

Reward Scheme for Whistle blowers

The FSSAI is in the process of drafting a reward scheme for whistle blowers information on cases of food adulteration. It is proposed to cover the following under the scheme:

- Information that will qualify for rewards under the scheme
- The rewards under the scheme
- Persons who can furnish information under the scheme
- Mechanism for receiving the information under the scheme and further processing of information
- Disbursement of the reward
- Fund allotment, monitoring and feedback

Draft Reward Scheme for Whistle Blowers for Information on Cases of Food Adulteration and Unsafe Food has been prepared. In this context, FSSAI has invited suggestions from all stakeholders including public by September 07, 2011.

PSA view – This is an interesting step towards curbing the menace of food adulteration and will involve public at large to have a say whenever they find out about adulteration in their vicinity and get a reward.

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