PRESS INFORMATION BUREAU
पत्र सूचना कार्यालय
GOVERNMENT OF INDIA
भारत सरकार

Business Line, Delhi
Monday, 11th June 2012, Page: 7
Width: 12.49 cms Height: 11.94 cms, Ref: pmin.2012-06-11.33.47

US body to bring out drug reference standards for biologics

G. Naga Sridhar
Hyderabad, June 10

The United States Pharmacopeial Convention is working on developing reference standards for biologics, an emerging class of drugs.

"Developing reference standards for biologics is a very complex process and we will collaborate with many countries, including India in this regard," Dr Srini Srinivasan, Executive Vice-President, International Sites and Standards, USP, told *Business Line* here.

(Biologics are medicinal preparation made from living organisms and their products. The United States Pharmacopeial Convention (usually also called the USP) is a non-profit organisation that owns the trademark and copyright to the book on the list of medicines in the US that is published every year.)

Mr Srinivasan refused to give any time line by saying "we just started coordinated efforts."

"There is big future for biologics as drugs worth $490 billion will be coming out of patent regime in next three to four years," he said. At present, China, Korea, the US and India have strong research and development strengths in this segment.

Biologics are officially approved subsequent versions of innovator biopharmaceutical products made by another company following patent and exclusivity expiry.

The USP was also working on bringing out standards for chemicals, vaccines and monoclonal antibodies, Mr Srinivasan said.

EXPANSION

The USP is expanding its Indian operations based out of Hyderabad. "The expansion of our facility here will be continuous. As bulk drug capital of India, Hyderabad is very important for us," he said.

From 101 research professionals now, the USP lab strength will be increased to 141 by next month.

On the increasing regulatory issues with US FDA for Indian drug majors, Mr Srinivasan said: "The Red Flag started in India now while only China had problems earlier. The industry will have to figure it out as far good manufacturing practices are concerned."

The USP sets standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements manufactured, distributed and consumed worldwide. They are enforceable in the US by the FDA.

nagsridhu@thehindu.co.in

Miscellaneous.