

Terms of reference

General Industry

- 1) Generic industry's size by value, volume and percentage wise of the total industry size (By value & Volume). Percentage of Prescriptions generated for generics visa-vis the total number of prescriptions.
- 2) Local pharma companies numbers (API manufacturers, Formulation manufacturers and integrated manufacturers). Both in Public and private sector.
- 3) What percentage of NLEM (National list of essential medicines) manufactured in the country? Russia has 600 products listed under this category. What products under this category are not being manufactured?
- 4) Progress of 2020 self-sufficiency. Soon they are rolling out Plans for 2030 which mainly concentrates on developing Research facilities and to increase exports. What can be anticipated from the 2030 plan?
- 5) What vaccines Russia imports? Does it manufacture essential (Immunisation scheduled) vaccines? What Vaccines can India offer?(India is strong in essential vaccines)
- 6) Russia imports Veterinary vaccines from other countries and not from India. What exactly are they looking for in these vaccines(Price, Quality or any other barrier)
- 7) What percentage of their APIs requirement is manufactured in the country and how much is imported. What APIs are imported?
- 8) Largest type of imports and source for Russia imports and pharmaceutical goods and reasons for choosing the particular country.
- 9) Most viable areas for Indian companies to enter into the Russian market in the backdrop of changing and competition

Health care & medical Insurance

- 1) Government health care expenditure is rising. Is Government prepared to absorb or is there any move to shift this burden to private sector?
- 2) Role of medical insurance. What sort of Insurance policies are followed? Is it akin to Indian style or this insurance companies like US companies influence patients in choosing products? Are co-payments made by patients? If so does the percentage of Co-payments vary depending on the products patient prefers. Do Insurance companies have any contracts with Pharma companies regarding supplies?

Regulatory

Latest regulatory features for especially generic market authorisations for a foreign company. Current thinking regarding restrictions on Imports of generics. Time taken for a registration of a generic. Number of years of marketing permission granted at the time of First registration and subsequent extensions.

Does current Restrictions on import of NLEM medicines (Especially of those manufactured in Customs Union countries) also apply to Retail trade or only for Government procurement?

What percentage of manufacturing in Russia qualifies a product for a locally produced status?

Current status on Bioavailability tests requirements.

What sort of generic products (Ex: Insulins, Derma etc) are to undergo clinical trials for establishing Bioavailability?

Does the regulatory authority accept clinical trials results conducted in USFDA/EMA specified labs in India? If not does any Indian centres for clinical trials are recognised in Russia?

What are the factors taken into account while granting prices to imported generics? Do they differentiate in pricing between an imported generic and locally made generic?

FDI

Basic structure in Pharma industry. Risk/Reward Ratio region wise.

Regions marked for FDI status, if any.

Are FDI companies treated on par with Local companies.(In Tenders, Supply of energy and costing).

Other issues like granting of Visa, repatriation of earnings.

What are the possible ways of protecting current India's market share in Russia's Pharma market? Especially in Government's procurement? In lieu of their 2020 program and their regulations on customs union.

Procedure for registration of herbal, Ayurveda and homeopathy products. Whether the market exists for this kind of products, how best to exploit it.