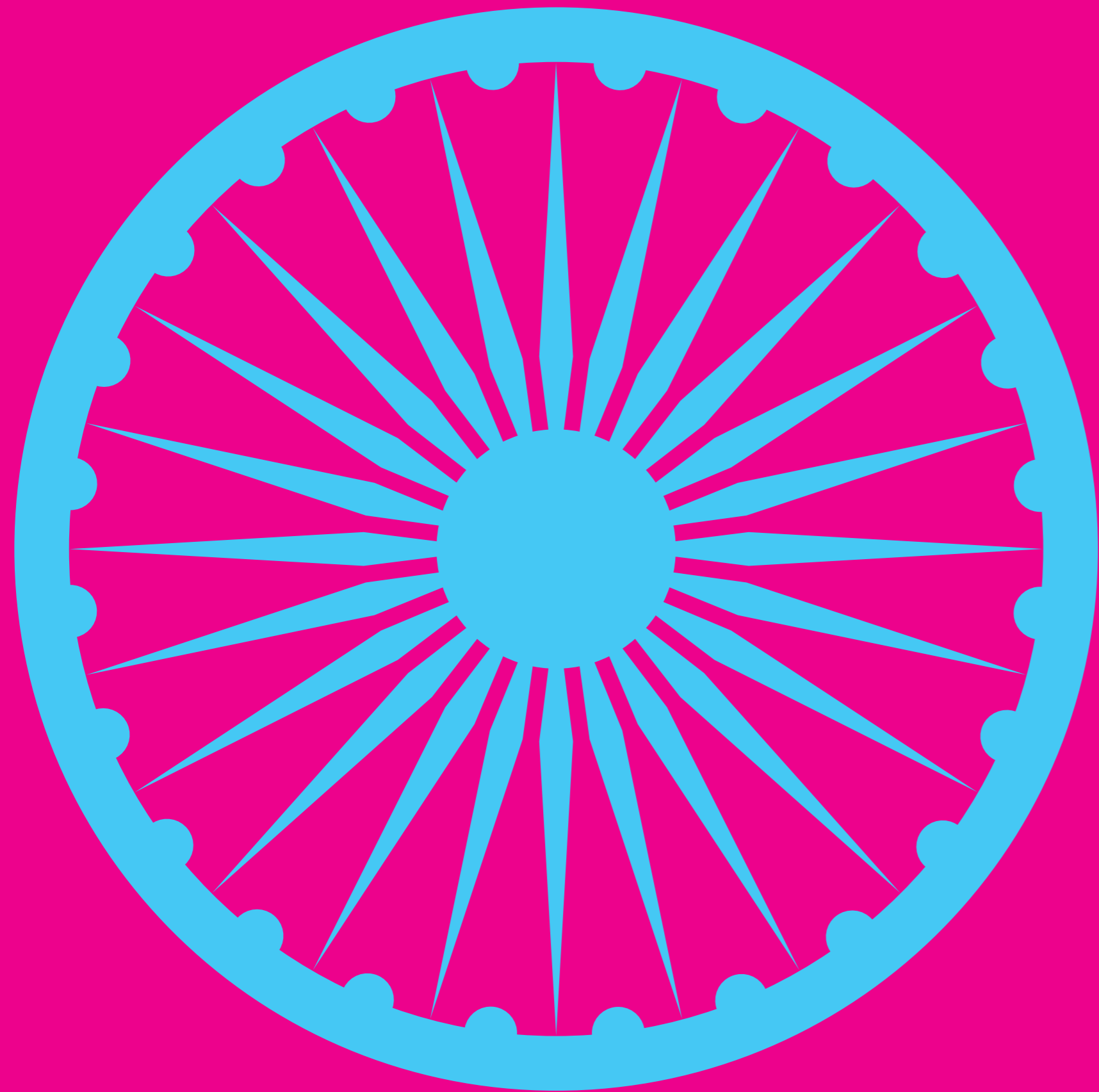


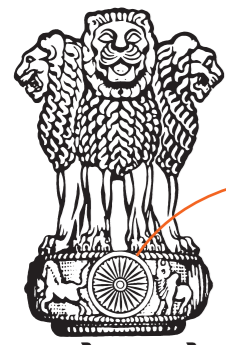


MAKE IN INDIA

BIOTECHNOLOGY



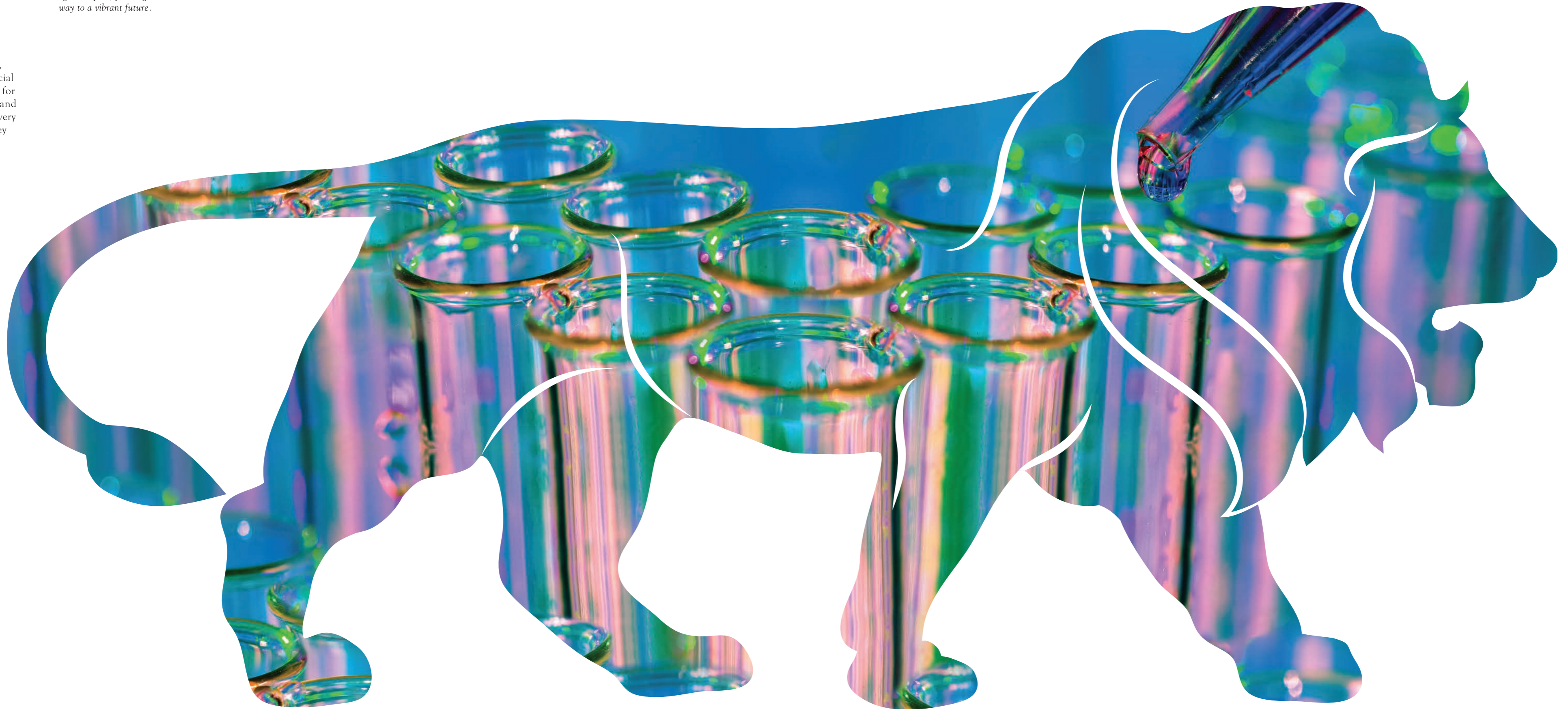
**FROM AGRICULTURE TO AUTOMOBILES
FROM HARDWARE TO SOFTWARE
FROM SATELLITES TO SUBMARINES
FROM TELEVISIONS TO MOVIES
FROM BRIDGES TO BIOTECHNOLOGY
FROM PAPER CLIPS TO POWER PLANTS
FROM ROADS TO CITIES
FROM FRIENDSHIP TO PARTNERSHIP
FROM PROFIT TO PROGRESS
WHATEVER YOU WANT TO MAKE:
MAKE IN INDIA**



The Ashoka Chakra is a central element in India's national emblem and also forms the centrepiece of India's national flag. The wheel denotes peaceful progress and dynamism – a sign from India's enlightened past, pointing the way to a vibrant future.

सत्यमेव जयते

Since time immemorial, the Lion has been the official emblem of India. It stands for strength, courage, tenacity and wisdom – values that are every bit as Indian today as they have ever been.





HEALTHY & WEALTHY

WITH USD 3.81 BILLION IN 2013 REVENUES, INDIA'S BIOTECH SECTOR IS A HEALTHY PROPOSITION.

3RD BIGGEST BIOTECH INDUSTRY IN THE ASIA-PACIFIC REGION

2ND HIGHEST NUMBER OF USFDA-APPROVED PLANTS

USD 3.7 BILLION TO BE SPENT ON BIOTECHNOLOGY FROM 2012-17

NO. 1 PRODUCER OF HEPATITIS B VACCINE RECOMBINANT

USD 4.3 BILLION BIO-ECONOMY BY THE END OF 2013

USD 100 BILLION INDUSTRY BY 2025

NEW INITIATIVES

THE MAKE IN INDIA PROGRAM INCLUDES MAJOR NEW INITIATIVES DESIGNED TO FACILITATE INVESTMENT, FOSTER INNOVATION, PROTECT INTELLECTUAL PROPERTY AND BUILD BEST-IN-CLASS MANUFACTURING INFRASTRUCTURE.

1 NEW PROCESSES

- SPECIAL FOCUS ON EASE OF DOING BUSINESS
- DE-LICENSING & DEREGULATION

2 NEW INFRASTRUCTURE

- INDUSTRIAL CORRIDORS
- INDUSTRIAL CLUSTERS
- SMART CITIES
- NURTURING INNOVATION
- SKILL DEVELOPMENT

3 NEW SECTORS

- OPENING OF CRITICAL SECTORS LIKE DEFENSE, CONSTRUCTION AND RAILWAYS FOR FDI

4 NEW MINDSET

- DEDICATED TEAMS THAT WILL GUIDE AND ASSIST FIRST-TIME INVESTORS FROM TIME OF ARRIVAL
- FOCUSED TARGETTING OF COMPANIES ACROSS SECTORS

FACTS + FIGURES

REASONS TO INVEST

- India is amongst the top 12 biotech destinations in the world and ranks third in the Asia-Pacific region.
- India has the second-highest number of USFDA-approved plants, after the USA.
- India adopted the product patent regime in 2005.
- Increasing government expenditure will augment the growth of the sector – the government aims to spend USD 3.7 Billion on biotechnology between 2012-17.
- India is the largest producer of recombinant Hepatitis B vaccine.
- India has the potential to become a major producer of transgenic rice and several genetically modified (GM) or engineered vegetables.

GROWTH DRIVERS

- The sector has seen high growth with a CAGR in excess of 20% and the key drivers for growth in the biotech sector are increasing investments, outsourcing activities, exports and the government's focus on the sector.
- A strong pool of scientists and engineers.
- Cost-effective manufacturing capabilities.
- The setting up of national research laboratories, centres of academic excellence in biosciences, several medical colleges, educational and training institutes offering degrees and diplomas in biotechnology, bio-informatics and biological sciences.
- For global companies looking to economise, outsourcing to lower cost economies results in a cost arbitrage of more than 50%.
- Fast-developing clinical capabilities with the country becoming a popular destination for clinical trials, contract research and manufacturing activities.

STATISTICS

- The Indian biotech industry will grow at an average growth rate of around 30% a year and reach USD 100 Billion by 2025.
- The Indian bio-economy grew to USD 4.3 Billion at the end of 2013, up from USD 530 Million in 2003.
- The Indian biotech industry grew by 15.1% in 2012-13, increasing the market's revenues from USD 3.31 Billion in 2011-12 to USD 3.81 Billion in 2012-13.
- The market size of the sector is expected to rise up to USD 11.6 Billion by 2017 due to a range of factors such as growing demand for healthcare services, intensive R&D activities and strong government initiatives.
- The Indian biotechnology sector is divided into five major segments – bio-pharma, bio-services, bio-agri, bio-industrial and bio-informatics.
- The bio-pharmaceutical sector accounts for the largest share of the biotech industry with a share of 64% in total revenues in 2013, followed by bio-services (18%), bio-agri (14%), bio-industrial (3%) and bio-informatics (1%).
- Revenue from bio-pharma exports reached USD 2.2 Billion in 2013, accounting for 51% of total revenues of the biotech industry.

INVESTMENT OPPORTUNITIES

- The Department of Biotechnology has established biotech parks in various parts of the country to facilitate product development, research and innovation, and the development of biotechnology industrial clusters.
- Operational biotech parks are located at Lucknow in Uttar Pradesh, Bangalore in Karnataka, Kalamassery and Kochi in Kerala, Guwahati in Assam and Chindwara in Madhya Pradesh.
- The parks offer investors incubator facilities, pilot plant facilities for solvent extraction and laboratory and office spaces.
- India constitutes around 8% of the total global generics market, by volume, indicating a huge untapped opportunity in the sector.
- Outsourcing to India is projected to spike up after the discovery and manufacture of formulations.
- Hybrid seeds, including GM seeds, represent new business opportunities in India based on yield improvement.



FDI POLICY

→ Foreign Direct Investment (FDI) up to 100% is permitted through the automatic route for greenfield and through the government route for brownfield, for pharmaceuticals.

FINANCIAL SUPPORT

PROVISIONS OF THE 2014-2015 UNION BUDGET:

→ Service tax exemption for services provided by operators of common bio-medical waste treatment facilities to a clinical establishment by way of treatment or disposal of bio-medical waste or processes incidental thereto.

→ Refund of customs duty paid at the time of import of scientific and technical instruments, apparatus, etc. by public funded and other research institutions, subject to submission of a certificate of registration from the Department of Scientific & Industrial Research.

OTHER INCENTIVES:

→ Depreciation allowance on plant and machinery has been raised to 40% from 25%.

→ Customs duty exemption on goods imported in certain cases for R&D.

→ Customs and excise duty exemption to recognised Scientific & Industrial Research Organisations (SIRO).

→ 150% weighted tax deduction on R&D expenditure.

→ A 3-year excise duty waiver on patented products.

→ 100% rebate on own R&D expenditure.

→ 125% rebate if research is contracted in publicly-funded R&D institutions.

→ Joint R&D projects are provided with special fiscal benefits.

→ The setting up of a venture capital fund to support small and medium enterprises.

→ Promoting innovations through BIPP, SBIRI, BIRAC and biotech parks.

SECTOR POLICY

NATIONAL GUIDELINES FOR STEM CELL RESEARCH 2013:

→ The guidelines have been laid down to ensure that research with human stem cells is conducted in a responsible and ethical manner and complies with all regulatory requirements pertaining to biomedical research in general and of stem cell research in particular.

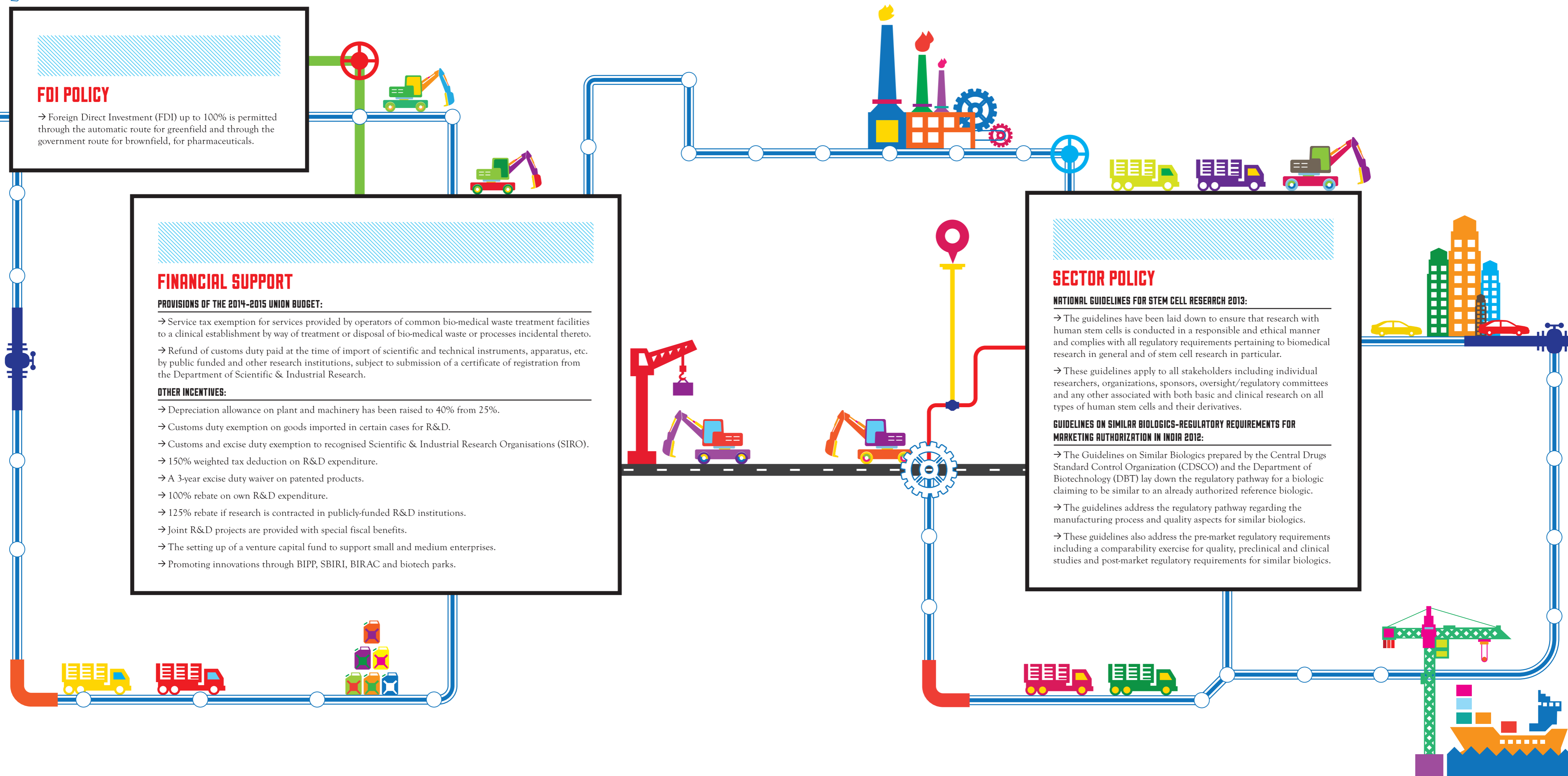
→ These guidelines apply to all stakeholders including individual researchers, organizations, sponsors, oversight/regulatory committees and any other associated with both basic and clinical research on all types of human stem cells and their derivatives.

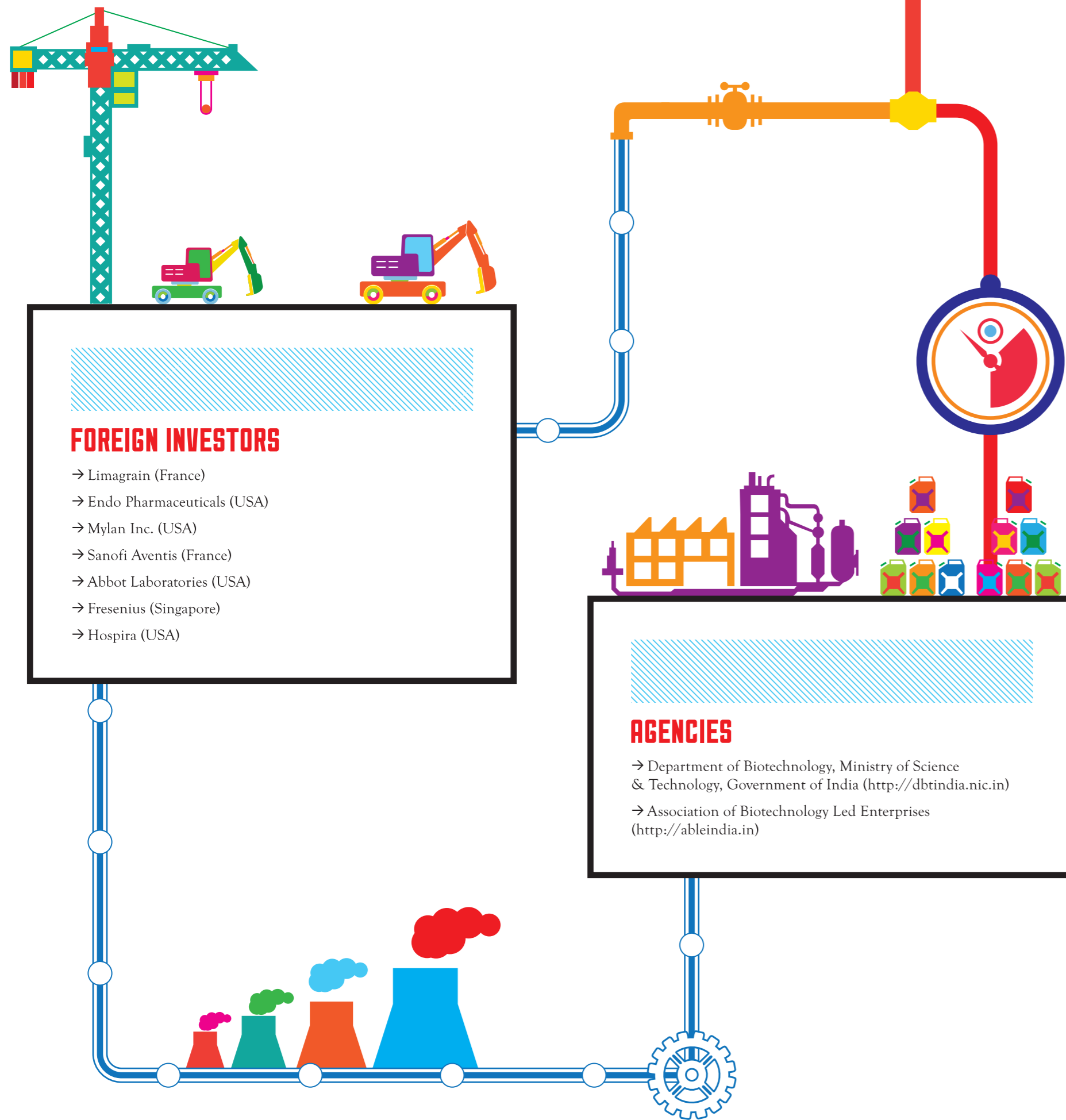
GUIDELINES ON SIMILAR BIOLOGICS-REGULATORY REQUIREMENTS FOR MARKETING AUTHORIZATION IN INDIA 2012:

→ The Guidelines on Similar Biologics prepared by the Central Drugs Standard Control Organization (CDSCO) and the Department of Biotechnology (DBT) lay down the regulatory pathway for a biologic claiming to be similar to an already authorized reference biologic.

→ The guidelines address the regulatory pathway regarding the manufacturing process and quality aspects for similar biologics.

→ These guidelines also address the pre-market regulatory requirements including a comparability exercise for quality, preclinical and clinical studies and post-market regulatory requirements for similar biologics.





FOREIGN INVESTORS

- Limagrain (France)
- Endo Pharmaceuticals (USA)
- Mylan Inc. (USA)
- Sanofi Aventis (France)
- Abbot Laboratories (USA)
- Fresenius (Singapore)
- Hospira (USA)

AGENCIES

- Department of Biotechnology, Ministry of Science & Technology, Government of India (<http://dbtindia.nic.in>)
- Association of Biotechnology Led Enterprises (<http://ableindia.in>)



GOVERNMENT OF INDIA

Department of Industrial Policy & Promotion
Ministry of Commerce & Industry
Investor Facilitation Cell
Tel: +91-11-23487411

