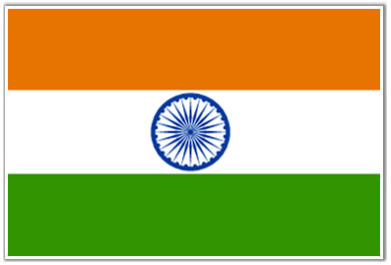
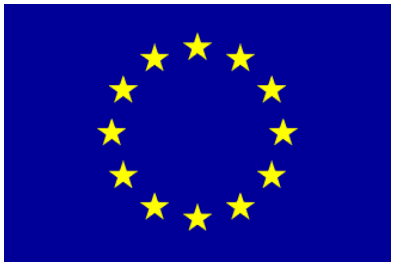
A solution to your regulatory needs for the European markets





# Towards a partnership with Europe for the Indian ayurvedic industy

# A solution to your regulatory needs for the European markets

## Trading in / exporting to Europe : many regulatory challenges / opportunities

- Growth & geographic spread, particularly in the EU, generates a wider interface with regulators/policy-makers at all levels
- The business environment is constantly changing and regulation must evolve to remain effective and relevant

# A solution to your regulatory needs for the European markets

## The European Union ….

- 27 member states
- 3 principal EU institutions with which we must interact
  - European Commission
  - Council of Ministers
  - European Parliament
- Plus other EU-related, influential bodies / institutions relevant to your company – e.g. European and national medicines agencies

# A solution to your regulatory needs for the European markets

## Trading in / exporting to Europe : some of the regulatory challenges / opportunities

*State aid*

*Product registration / Market authorisation*

*Discrimination*

*R&D initiatives*

*Anti-trust*

**Many issues, often complex, often interrelated**

*Environment*

*Trade defence*

*Customs*

*Investment protection*

# A solution to your regulatory needs for the European markets

## In the pharmaceutical industry, complexity takes specific forms:

- High cost of compliance with numerous bureaucratic rules & regulations, esp. pharmaceutical registration and authorisations
- EU Internal Market freedoms sometimes seem mythical
- National enforcement leads to differences in interpretation
- Member states can & do erect own trade barriers – often illegal
- Very difficult to navigate without insider knowledge
- Effective solutions take time, insight & local presence

## Allopathic & ayurvedic medicines in the EU: Indian concerns

- Lack of an EU-wide system of registration and market authorisation
- No recognition of export controls or certifications as equivalent to EU standards
- Non-acceptance of Indian monographs
- High cost of securing EU registration and market authorisation
- Different national interpretations of ‘food supplement’, ‘prescription medicine’, ‘cosmetic’

## Allopathic & ayurvedic medicines in the EU: additional Indian concerns

- Pharmaceutical regulation in the Single Market currently under review
- Herbal medicines Directive 2004/24/EC currently under review
- Exclusion of animal & mineral products from 'herbal' medicine definition
- Overburdening requirements to demonstrate efficacy, safety, GMP compliance, traceability and absence of toxins in ayurvedic preparations
- Differing national policies on reimbursal of prescription costs

## Ayurvedic medicines in the EU: Indian concerns

- No recognition of ayurveda as a branch of medicine
- No registration system for ayurveda practitioners
- No recognition of an ayurveda pharmacopoeia
- 15-year safe use intra-EU / 30-year extra-EU for ayurvedic & herbals
- No ayurveda-specific legislation – square peg into a round (allopathic) hole

## Ayurvedic medicines in the EU: some issues for Indian manufacturers

- Sustainability of ayurvedic plants grown in wild – a likely future concern
- Weak coordination among national ayurvedic associations
- Lack of defined a medium/long-term strategy to effect change in EU
- Are expectations of EU market-access too high / is EU position fully understood by all ?
- Current EU regulatory reviews might only provide an opportunity to lay a solid foundation for major progress at the next review

# A solution to your regulatory needs for the European markets

## Manufacturers of ayurvedic medicine need EU experts to:

- Identify, defend and promote …
  - … the most appropriate regulatory options …
  - … to facilitate the development of the ayurvedic market in Europe …
- Help get substantive penetration of Indian ayurvedic products on the EU market 5-10 years earlier than might otherwise occur

## A solution to your regulatory needs for the European markets

**Brussels-based EU experts should:**

- Be Indian ayurvedic industry's 'eyes and ears' in Brussels
  - e.g. monitoring and informing you about developments on the herbal medicines Directive and the review of the Single Market in pharmaceuticals
- Help your industry contribute to the EU process, develop and present your position directly:
  - To key players in the EU institutions
  - To other stakeholders (e.g. via seminars, press relations, etc.)
- Work with and in parallel to GoI activity
- And also…

# A solution to your regulatory needs for the European markets

## Brussels-based EU experts should also:

- Identify sympathetic and unsympathetic stakeholders
- Coordinate EU public affairs activity among exporters and national associations
- Help promote local 'in-house' regulatory clean-up and enforcement in India
- Share experience and develop strategies

➔ Establish realistic expectations of what it is possible to achieve within a given timeframe

# A solution to your regulatory needs for the European markets

## Seven priority targets for next twelve months:

- Coalition-building
- Anticipate opposition & counter-arguments
- Ascertain direction of EU regulatory review processes
- Lobby key EU players
- Organise seminar in Brussels aimed at key EU opinion leaders
- Coordinate EU activity of national ayurveda associations
- Investigate cooperation with manufacturers of Chinese medicine

# A solution to your regulatory needs for the European markets

**In conclusion, Indian ayurvedic/allopathic exporters to benefit from expert assistance to:**

- Better understand regulatory hurdles faced in Europe
- Develop long- & short-term strategies to cope with & effect changes to EU regulatory issues
- Monitor and contribute to ongoing regulatory reviews in order to influence their outcome
- Promote the understanding of ayurveda by key EU policy- and decision-makers and influencers
- Facilitate and establish coordination of activities by national ayurvedic associations
- Secure a regulatory situation which allows business growth

# A solution to your regulatory needs for the European markets

## ONE MOTTO FOR A SUCCESSFUL EU PUBLIC AFFAIRS INITIATIVE

- Indian Ayurvedic medicines in the 21st century…
  - **At the intersection of tradition and modernity**…
    - For the benefit of citizens from India and from the world…
      - And from Europe as well !