GNH INDIA

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BUSTING - MYTHS IN COMPARATOR SOURCING

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IN THIS PRESENTATION

- Why do we need Comparators ?
- Common myths, common assumptions
- Regulatory facts for Drug registration in India
- Costly sourcing mistakes - increasing trial cost and time
- Take an informed decision - Based on facts
- Role of specialised wholesalers

Why do we need Comparators

- WMA (World Medical Association) Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects - 1st adopted in June 1964

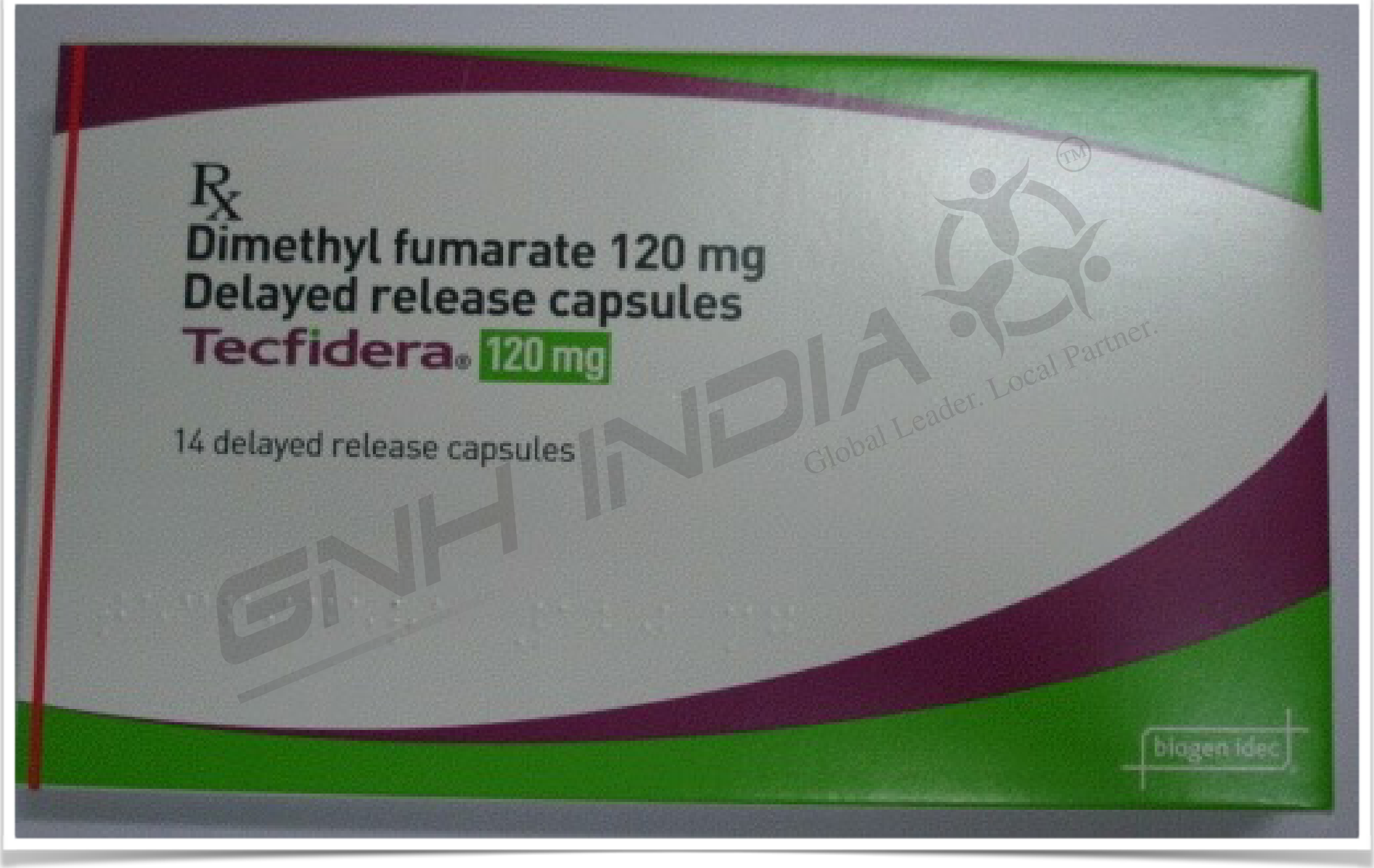
- There can be 1000s of other marketing or regulatory answer, but the core change started from Helsinki Declaration

- It will be a good for all RnD units, CROs to maintain a copy of this declaration as it will add to your compliance value.

Common myths - Common Assumptions

- Common Comparators - Innovators, Pre Qualified Generic, Bio Similar,
- Focus of this presentation will be mainly on **Innovators**
- **Common myths:**
  - Comparators (Innovators) are available only in US / Europe
  - Products with NDC number or PZN or POM numbers can only be called comparators
  - Comparators are not available in India and need to be imported
  - If available in India - they cannot be called comparators

Comparator Example



Common myths - Common Assumptions

Common Assumptions:

- Trial will be invalid if comparators are sourced from India
- The formulation in India is not same as US / EU or is different from the original marketed in US / EU

No one is above suspicion - let see how

Regulatory facts for drug registration in India

- CDSCO - link for new product registrations:
  - http://www.cdsco.nic.in/writereaddata/Guidance%20documents.pdf
  - CoPP a must - Certificate of Pharmaceutical Product (CoPP : The certificate of pharmaceutical product (abbreviated: CPP or CoPP) is a certificate issued in the format recommended by the World Health Organisation (WHO), which establishes the status of the pharmaceutical product and of the applicant for this certificate in the exporting country)
  - FSC a must - Free Sale certificate (A document required in certain countries or for certain commodities (such as pharmaceuticals), certifying that the specified imported goods are normally and freely sold in the exporting country's open markets and are approved for export).
  - Do you think CDSCO will register imported product without these to important documents ?
  - What do these documents prove or demonstrate ?
  - Why is CDSCO or any registration authority in the world wants these two documents ?

Time consuming - Imports

Costly Mistakes

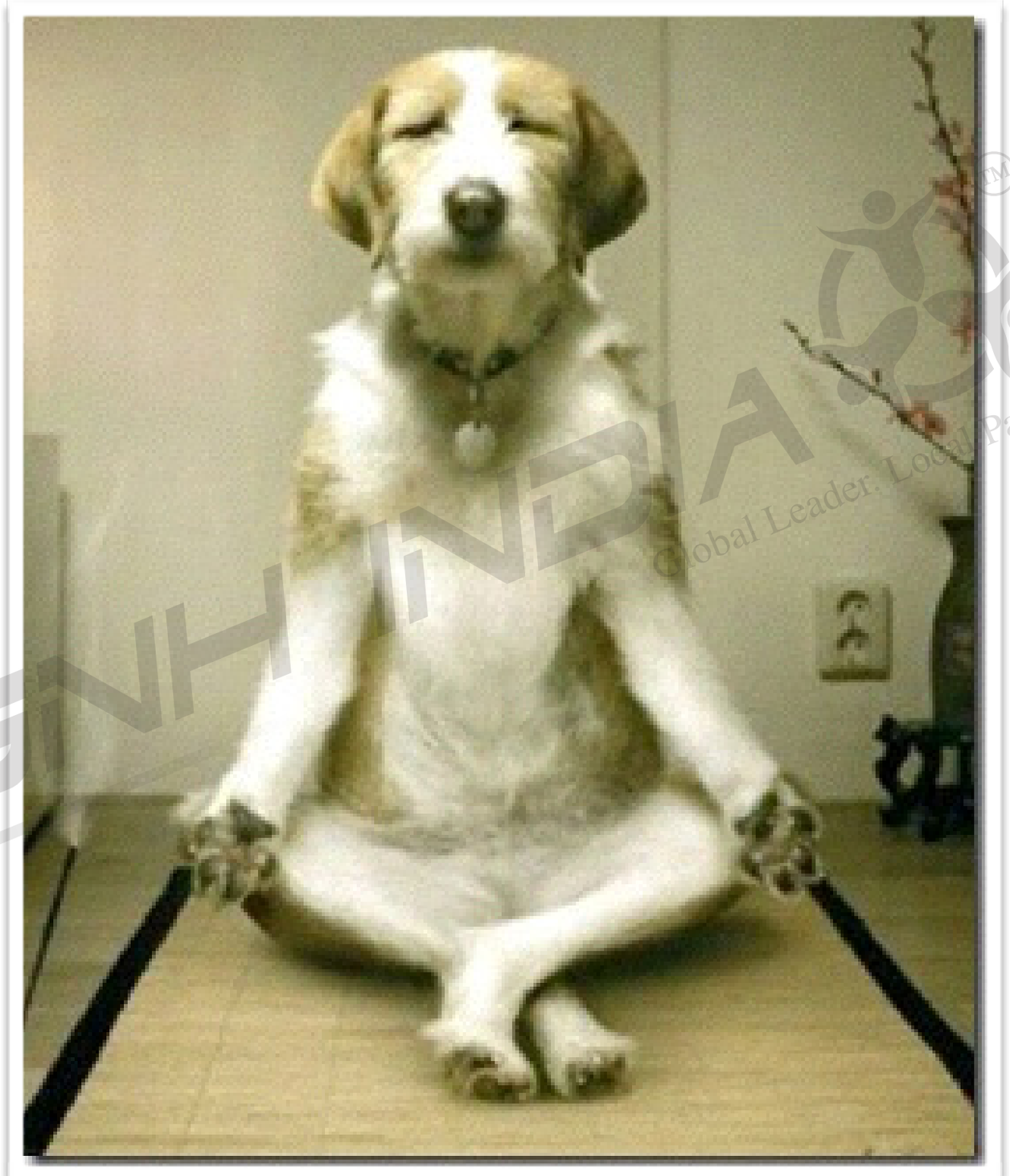
- Importing: Most of Comparators get imported into India even though they are locally available many a time.

- Most comparators are priced at half the price in India as compared to US / EU

- Import process, logistics, Import clearance, ADC clearance require tremendous amount of time, effort and money

- In our experience pharma companies, RnD units, CROs are paying about 4X the cost and time for comparator imports as against local sourcing

Take an informed decision



Take an informed decision

- Think local : Most Comparators available in India
- We supply Comparators to over 60 countries globally
- Large quantities available with ease in India
- Most Comparators in India have been duly registered and licensed in India by CDSCO after taking CoPP and FSC on record
- This ensures that exact same formulation marketed in CoO is marketed in India too
- Cold chain maintenance, Storage, Handling is done under Manufacturer's supervision for official imports.
- Cost effective, Cost Competitive, Economical and Fast

Role of specialised Wholesalers

- GNH India is a specialised Wholesaler in Clinical trial arena
- WHO cGDP complaint warehouse operations
- Qualified QP on site
- Storage, handling, packing and dispatch done under direct supervision of QP
- Mapped storage area, calibrated warehouse equipments
- Validated shipping systems, reports on file
- Complete traceability, audit trail and archiving of all purchases and sale transactions for a period of 7 years

Myths - Busted !!