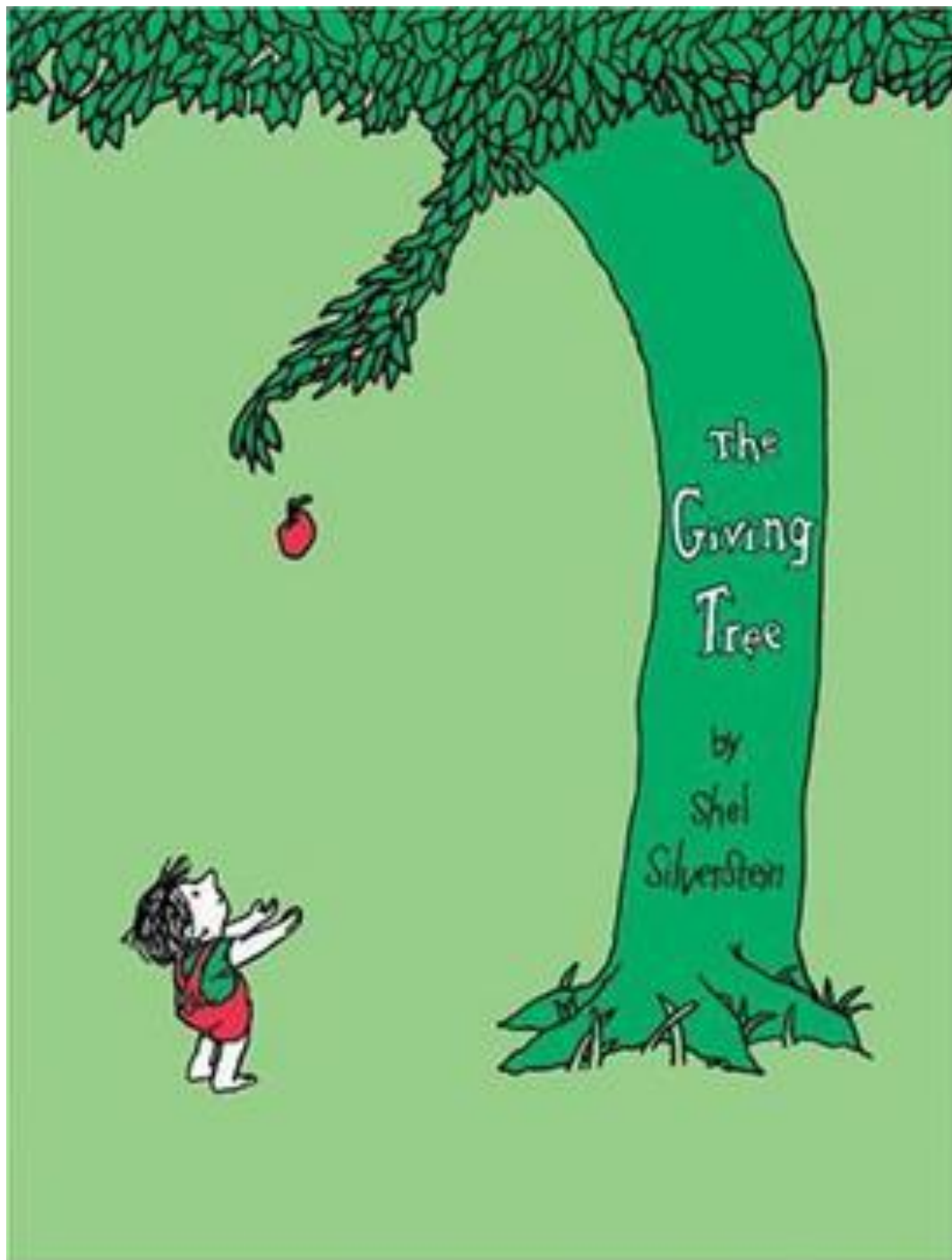


جایگاه مفردات گیاهی پزشکی در درمان بیماری ها

زهرا معماریانی
استادیار داروسازی سنتی
عضو هیات علمی دانشگاه علوم پزشکی بابل
خرداد 1403





NDC 55390-114-20
16.7 mL Multiple-Dose Vial

PACLITAXEL
INJECTION

6 mg/mL

**MUST BE DILUTED PRIOR TO
IV USE. Read enclosed
package insert.**

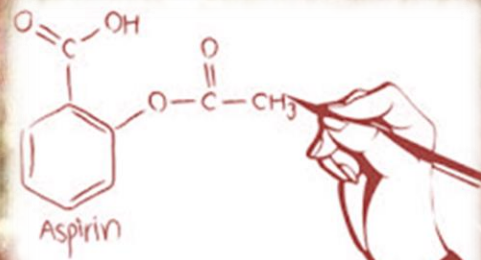
BEDEORD
LABORATORIES™

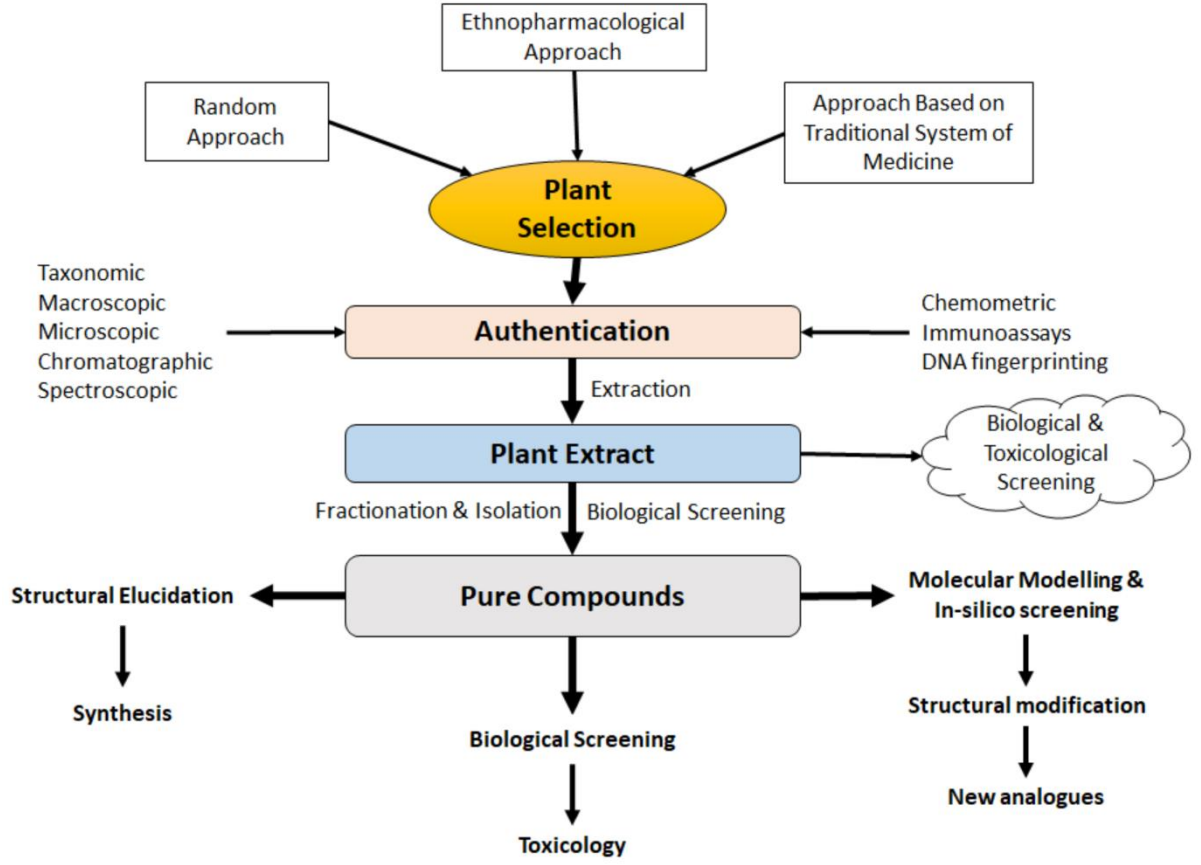
PACLITAXEL
INJECTION

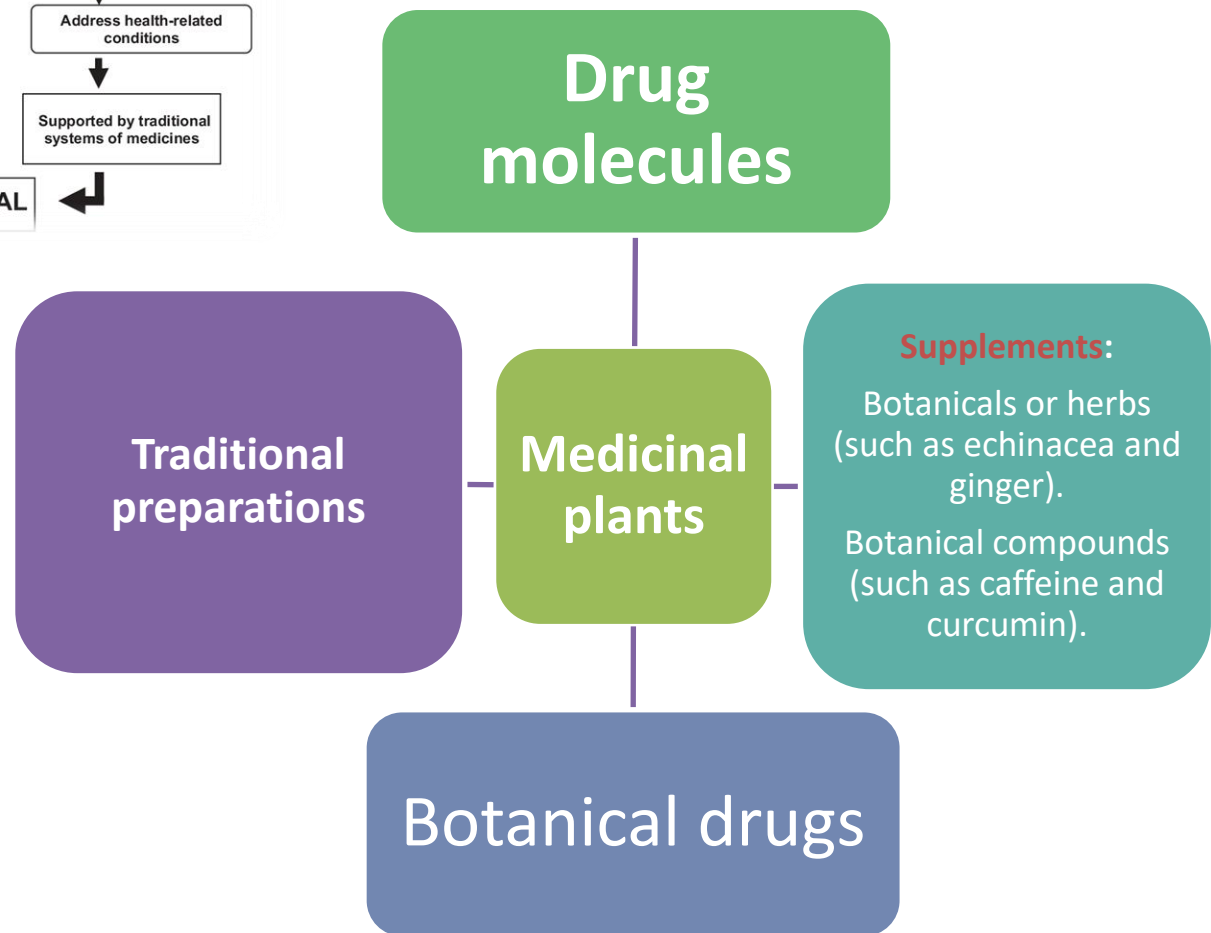
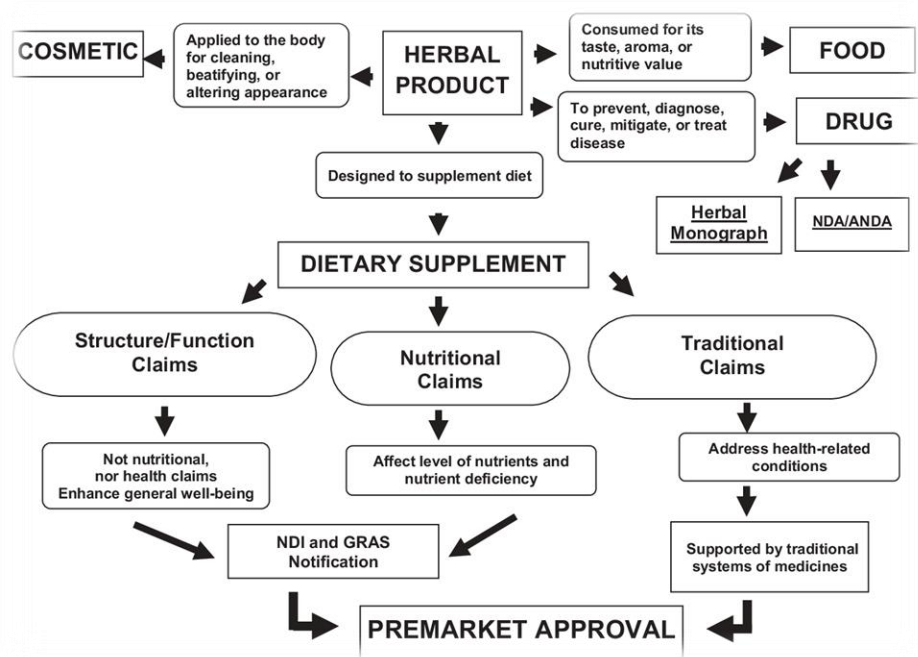
6 mg/mL

**MUST BE DILUTED PRIOR TO IV USE.
Read enclosed package insert.**

Rx ONLY







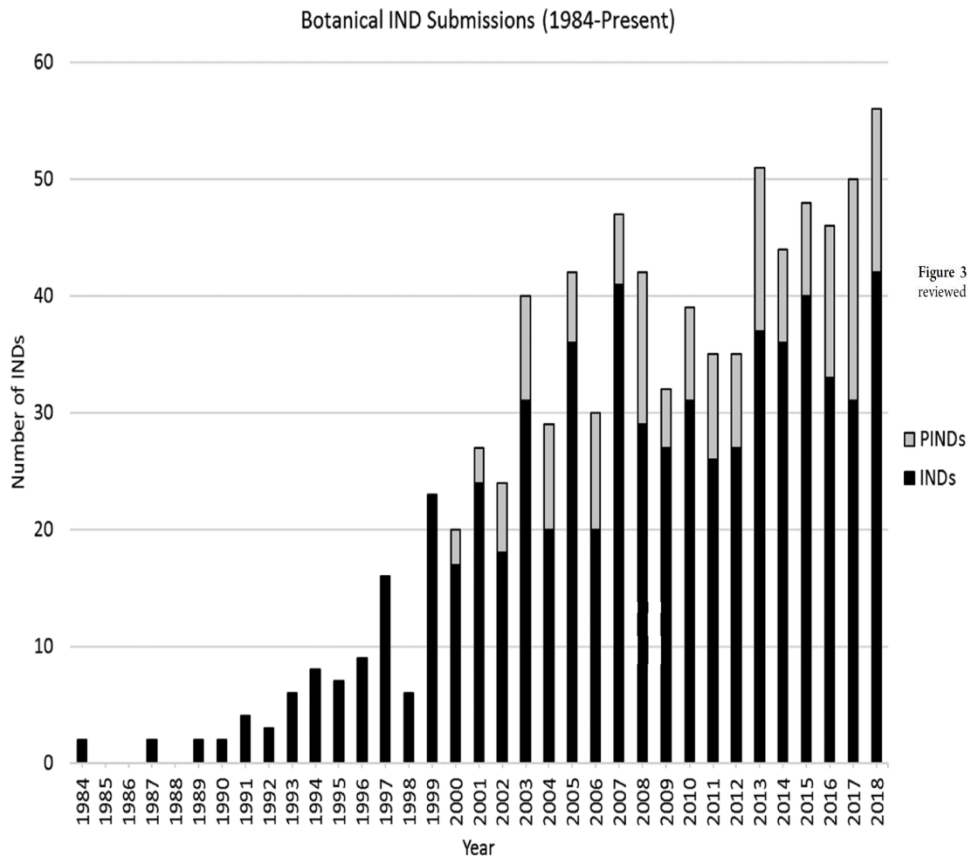


Figure 1. Annual PIND (open bar) and IND (solid bar) submissions reviewed by the Botanical Review Team from 1984 to 2018. More than 800 botanical pre-INDs/INDs have been received and reviewed by the FDA, and two NDAs have been approved by the FDA (Veregen and Mytesi) in 2006 and 2012, respectively.

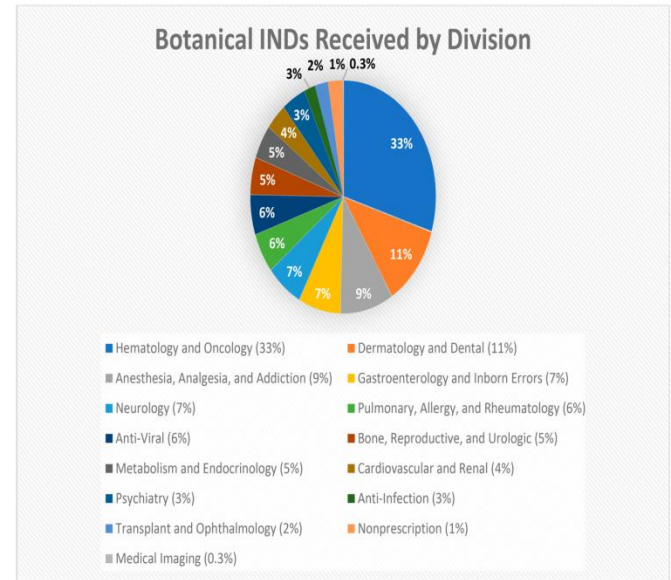
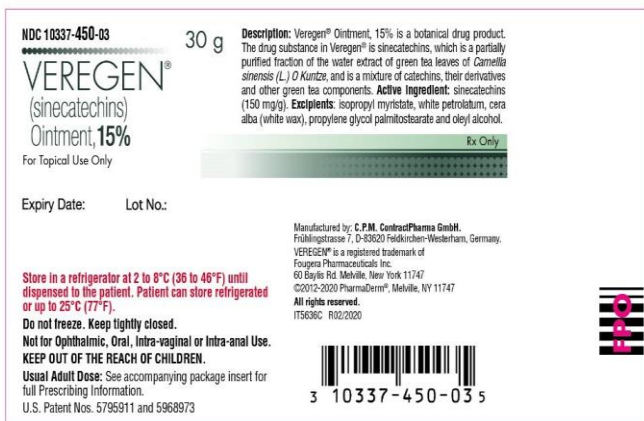


Figure 3. Therapeutic areas of received botanical INDs and NDAs by the FDA from 1984 to 2018. Each botanical submission is assigned and reviewed by a specific review division based on the indication of the botanical drug product.

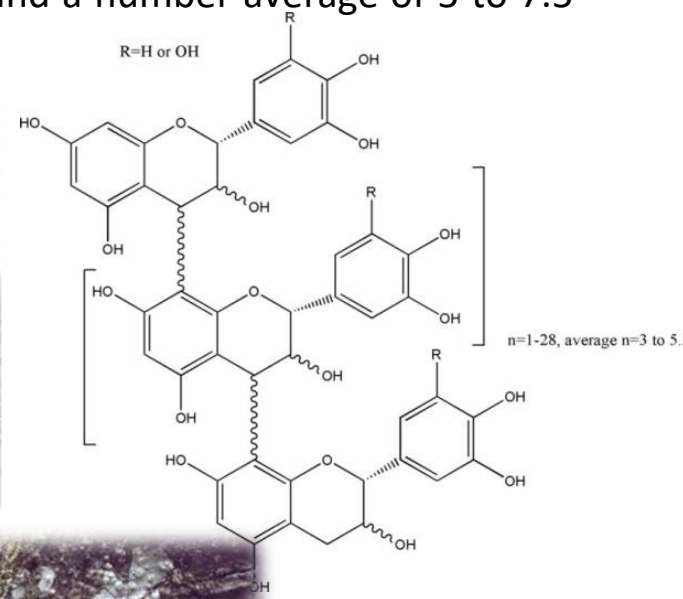
The first botanical drug approved by the FDA

- Veregen FDA Approval History
 - FDA Approved: Yes (First approved October 31, 2006)
- Brand name:** Veregen
Generic name: Sinecatechins
Dosage form: Ointment
Previous Name: Polyphenon E
Company: MediGene AG
Treatment for: [*Condylomata acuminata*](#)



Date	Article
Oct 31, 2006	Approval Polyphenon E MediGene AG - Treatment for Genital and Perianal Warts
Jun 30, 2006	FDA Extends PDUFA Date for Polyphenon E Ointment to October 31, 2006
Dec 1, 2005	MediGene Announces FDA Acceptance of New Drug Application for Polyphenon E Ointment for the Treatment of Genital Warts

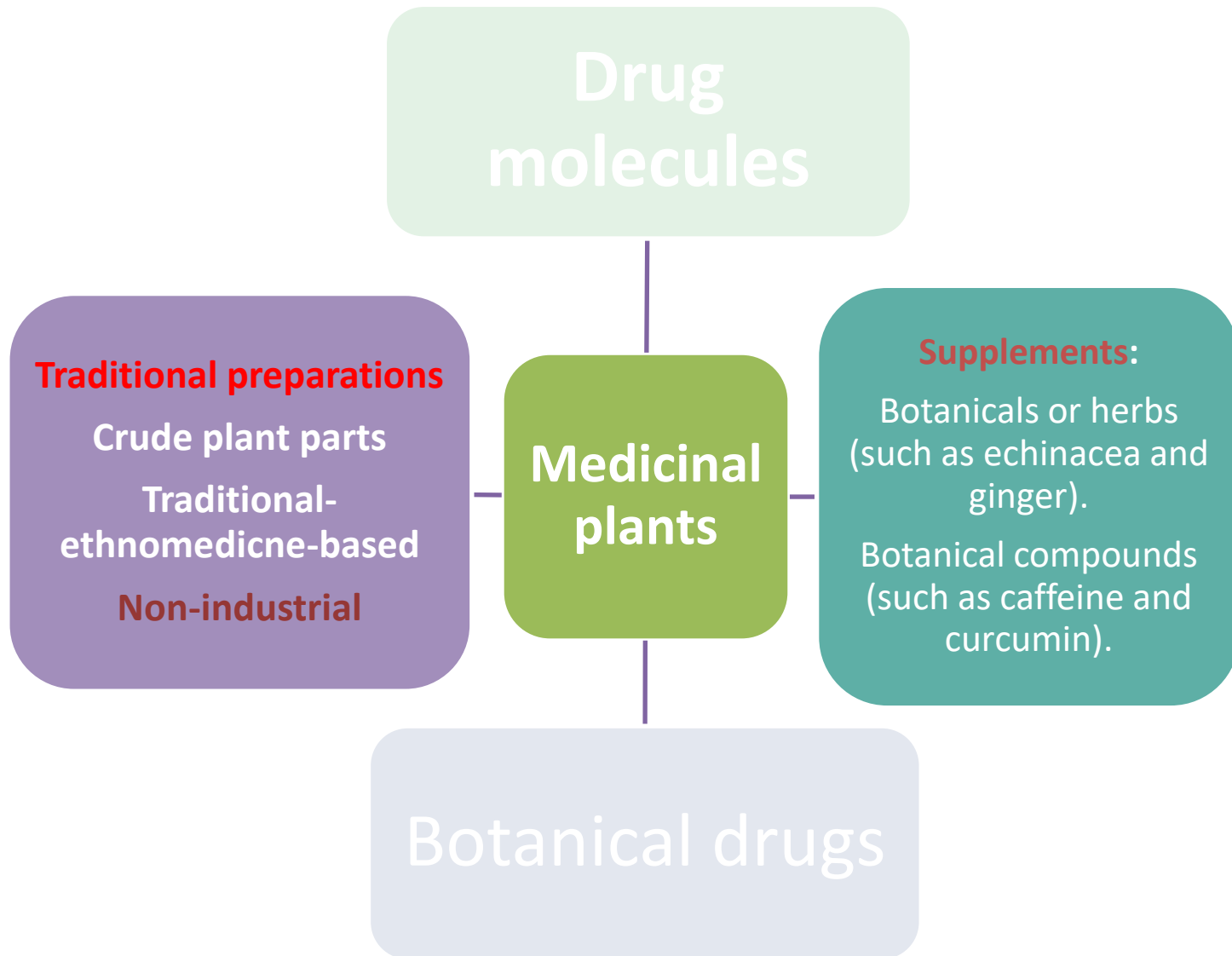
A random, linear sequence of (+)-catechin, (+)-gallocatechin, (-)-epicatechin, and (-)-epigallocatechin units. Polymer chains contain 1 to 28 repeating units and a number average of 5 to 7.5 units



Nabiximols /Sativex

- A whole plant *Cannabis* **extract** containing an ~1:1 combination of Δ^9 -THC:CBD as well as a lesser but controlled/known percentage of other minor cannabinoid and noncannabinoid components, including fatty acids, terpenoids, flavonoids, and sterols
- Nabiximols is not currently approved for any indications in the US but is approved in over 25 other countries, including Canada, the United Kingdom, France, and Poland for spasticity associated with MS, and cancer associated pain (GWpharm.com).
- Trials in the US are however ongoing





Bringing herbal medicinal products to market within the EU

Companies seeking to bring herbal medicinal products to the market in EU Member States should follow the national procedures overseen by [national competent authorities](#).

There are three main regulatory pathways for bringing a herbal medicinal product to market in EU Member State

Regulatory pathway	Main requirements on safety and efficacy	Where to apply
Traditional use registration (Article 16a(1) of Directive 2001/83/EC ↗)	<ul style="list-style-type: none">• No clinical tests and trials on safety and efficacy are required as long as sufficient safety data and plausible efficacy are demonstrated• Involves assessment of mostly bibliographic safety and efficacy data• Must have been used for at least 30 years, including at least 15 years within the EU• Are intended to be used without the supervision of a medical practitioner and are not administered by injection	<ul style="list-style-type: none">• National competent authority of a Member State for national, mutual recognition and decentralised procedures
Well-established use marketing authorisation (Article 10a of Directive 2001/83/EC ↗)	<ul style="list-style-type: none">• Scientific literature establishing that the active substances of the medicinal products have been in well-established medicinal use within the EU for at least ten years, with recognised efficacy and an acceptable level of safety• Involves assessment of mostly bibliographic safety and efficacy data	<ul style="list-style-type: none">• National competent authority of a Member State for national, mutual recognition and decentralised procedures• EMA if centralised procedure applies
Stand-alone or mixed application (Article 8(3) of Directive 2001/83/EC	<ul style="list-style-type: none">• Safety and efficacy data from the company's own development or a combination of own studies and bibliographic data	<ul style="list-style-type: none">• National competent authority of a Member State for national, mutual recognition



Hypericum perforatum

 More than 40 clinical trials

- Comparisons with:

Tricyclic antidepressants → Equivalent to low dose

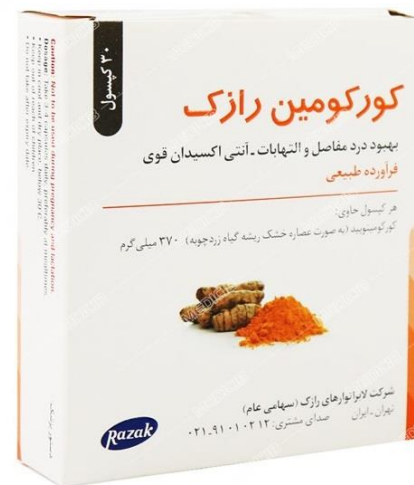
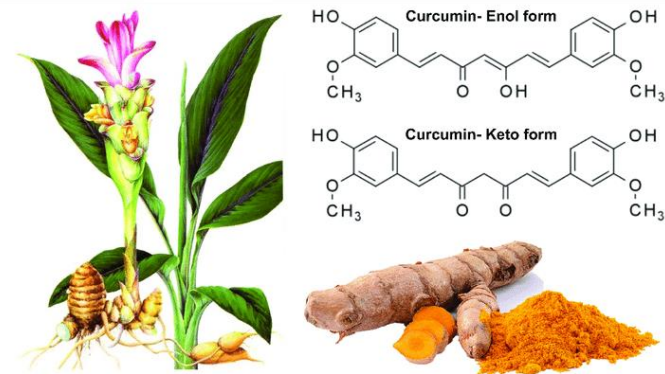
Serotonin reuptake inhibitors → Standard doses

- More effective than placebo
- For mild to moderate depression



- A meta-analysis of 15 RCTs involving 1621 participants

- *Curcuma longa* extract and curcumin can:
- Relieve pain and joint stiffness in patients with OA,
- Improve joint function,
- Would not increase the occurrence of adverse events.
- It is recommended to use *Curcuma longa* extract and curcumin supplement for OA patients for more than 12 weeks.



Meta-analysis: 14 randomized trials
with a total of 1,506 patients

The results of demonstrate that **ginger** can reduce
postoperative nausea



Ginger powder
capsules have been
shown to reduce
anesthesia-triggered
nausea following
surgery.

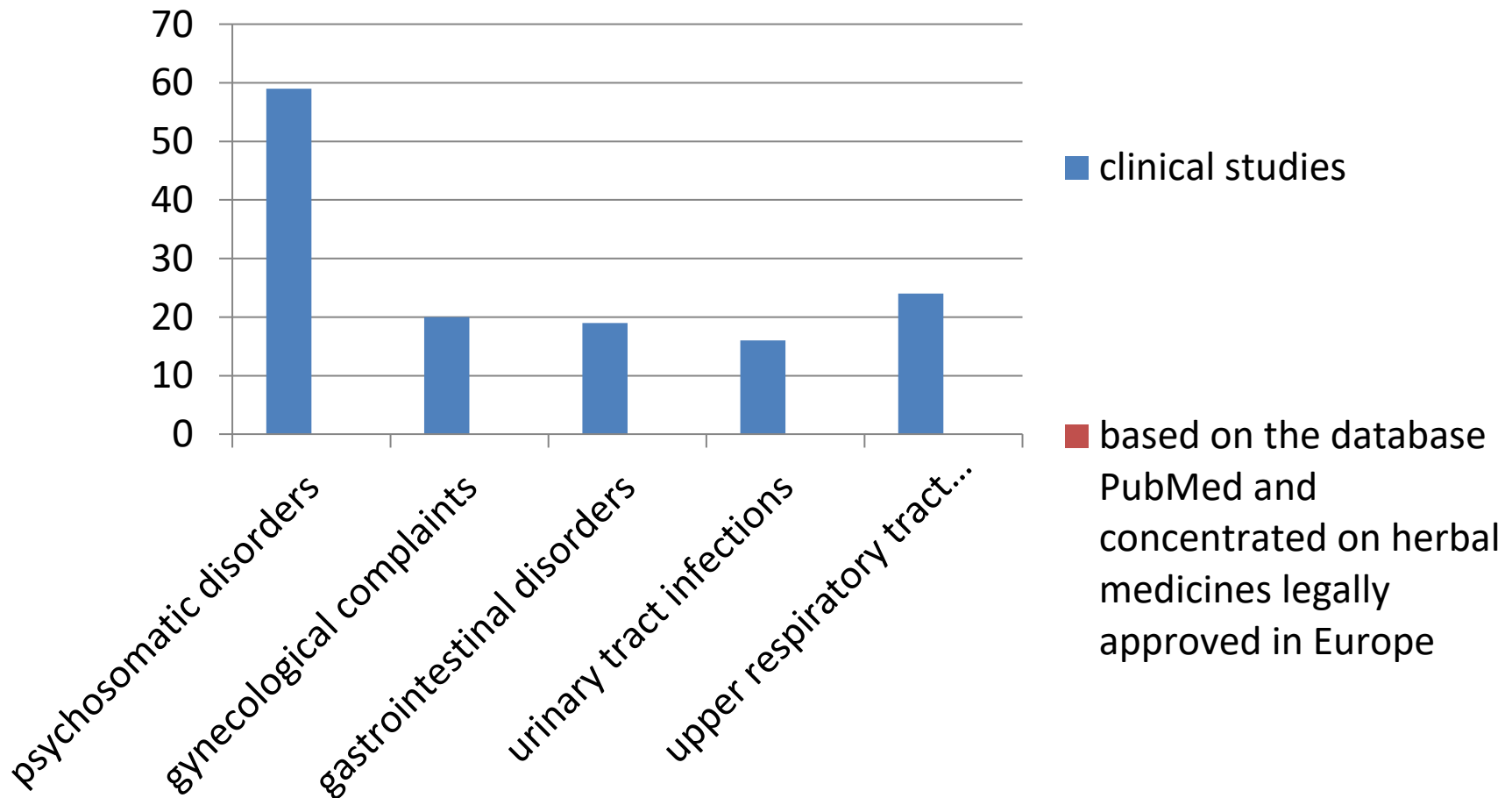


Peppermint oil

- Met-analysis of 11 studies in 684 people: peppermint oil is a safe and effective treatment for global IBS symptoms over the short term.
- Clinical practice guidelines published in 2021 by the American College of Gastroenterology, include peppermint oil as one of several approaches that may be helpful for relieving IBS symptoms.
- Peppermint oil shouldn't be taken by people with a hernia or gastroesophageal reflux disease (GERD), especially at high doses.



Current state of research on the clinical benefits of herbal medicines for non-life-threatening ailments (2023)



- *H. perforatum* L. for depressive disorder,
- *V. agnus castus* L. for menstrual complaints,
- *Cimicifuga racemose* (L.) for menopausal symptoms,
- *I. amara* L., *M. chamomilla* L., *Mentha ×piperita* L., *C. carvi* L., *G. glabra* L. and *M. officinalis* L., for functional dyspepsia,
- *C. erythraea*, *Levisticum officinale* W.D.J.Koch and *Rosmarinus officinalis* L. for uncomplicated urinary tract infections,
- *P. sidoides* DC. for bronchitis and sinusitis
- *H. helix* for cough

سیاس از توجه شما



E-mail: memarianiz@gmail.com