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**Bayerisches
Staatsministerium
für Wirtschaft, Infrastruktur,
Verkehr und Technologie**

DIN



Herbal medicine a much under-estimated therapy opportunity

What are the problems?

- # Europe has a millennia-old experience and tradition in the use of specific medicinal herbs and their use as “**phyto-medicine**”.
- # The European countries primarily in the German-speaking area have always maintained their “**phyto-tradition**” alongside the Western chemically defined modern medicine and did intensive scientific research on it.
- # South-east Asia such as China, Japan, Korea and neighboring countries have an equally long “**phyto-tradition**”
- # Asian countries have also maintained plant-based medicine alongside chemically defined modern Western medicine, and have conducted intensive scientific research on it in the recent years
- # **USA legally set the course for a herb-free, purely chemically defined so-called Modern Western Medicine in 1912 and has never deviated from it. (only food supplements)**
- # **Triggered by the pharmac. industry, the U.S. generally rejects herbal-based medicine.**

In Europe and also Asia, herbal based pharmaceuticals require marketing authorization or at least a regulatory registration

For this purpose, extensive scientific and experience-based basic data must be presented and will be intensively examined by the authorities, analogous to the chemically defined Modern Western Medicine.

a) Europe

α) traditional Herbal Medicinal Products (tHMP's) with a Regulatory Registration

Simplified registration is only possible, if the product has been in use in the country of origin for at least 30 years without any incident or problem.

Furthermore, it is required that the product has been in use in the European Union for at least 15 years without any problems in parallel.

β) approved Phyto-Therapeutics with an European Marketing Authorization

Only with complete approval process analog to Modern Western Medicine.

Production under EU-GMP including the necessary complete batch-specific analysis and permanent monitoring by the authorities.

Legal requirements for Asian Traditional Herbal Medicine

b) Asia

α) traditional experience-based Herbal Mixtures

as tea decoctions made from so called decoction pieces or
as modernized dosage forms as combinations of specific granules

β) approved Phyto-Therapeutics

for modern combinations (non-traditional) complete approvals from
the authorities like for modern therapeutics are required

Production under national GMP including the necessary complete batch-specific analysis and permanent monitoring by the authorities.

In the US natural-based “food supplements” are under FDA supervision in the market field of natural products.

In Europe “food supplements” are implemented, in parallel to “Functional Foods”

In Asia also “food supplements” are flooding the natural product markets

Nature-based products are not “food supplements” in every case

My main scope of work in my laboratory in Germany is to provide **high pure natural substances** with full regulatory documentation as officially recognized **reference substances** by all authorities worldwide and used by Pharmaceutical Industry.

My team and I typically purify the one desired pure substance from the natural matrix with one to two million components of one herb in our daily work.

What is the relevant difference between chemically defined pure substances, also of natural origin, and real natural herbal extracts?

Pharmaco-Kinetics and Bio-Availability is completely different

The reason for this is the human liver and its detoxification function

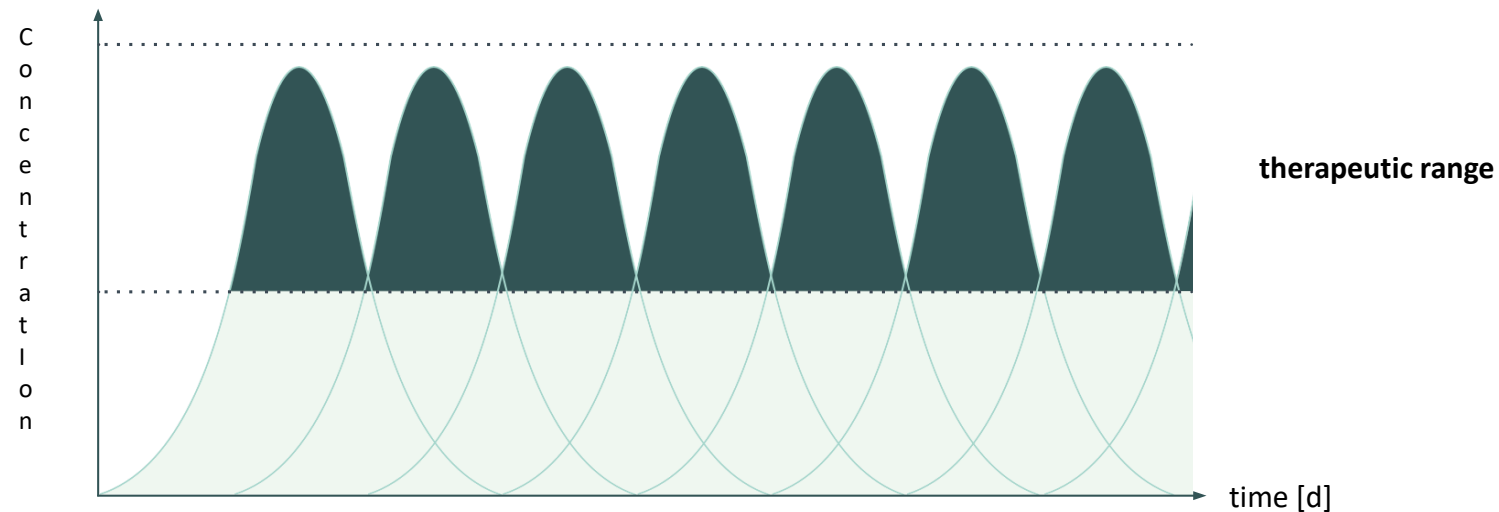
Active substances are usually foreign substances for the human body

Pharmacologically we have to observe the absorption, the mode of action, but also the degradation and excretion of foreign substances like active principles.

The liver recognizes these chemical components as foreign bodies, their detoxification process also begins very quickly (**first pass effect**).

Such a chemical component is only effective in the body, if its **plasma concentration** is always within the therapeutic range.

Thus, it is necessary to permanently maintain an effective concentration against **degradation** or excretion by repeated doses and high amounts.

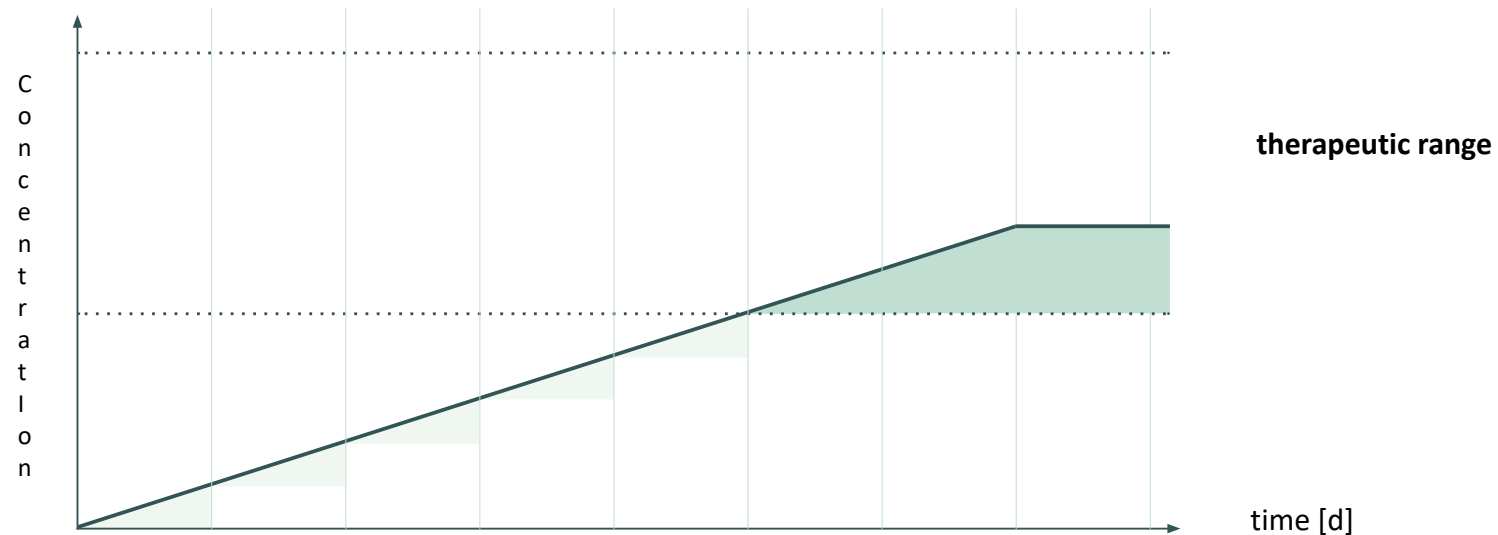


Graph 1: Plasma concentration of a repeated dose of a chemical active principle

Pharmacology of natural herbal substances in a natural matrix like extracts

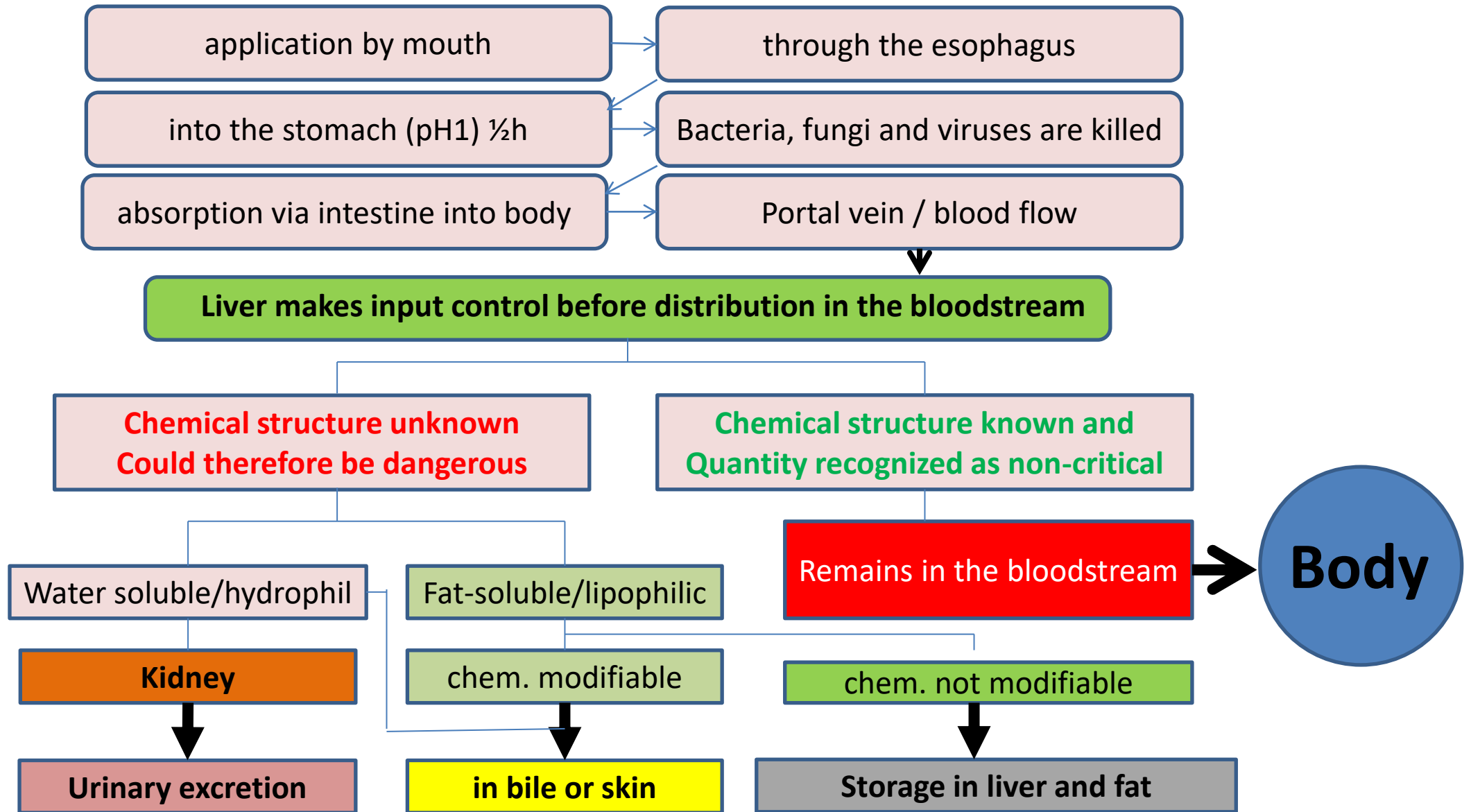
The liver recognizes most natural substances in lower doses and in their natural matrix as non-critical and reduces the degradation processes to a minimum. This makes it possible to build up an effective dose in the body over a period of time and minimizes the risk of side effects.

By supplying lower doses of natural substances in an extract, the effect is delayed until the therapeutic range is reached by multiple doses. Due to the massively reduced degradation, the efficacy is maintained by lower daily doses. This is considered to be gentle on the body.



Graph 2: Plasma concentration of a repeated dose of a natural active ingredient

The liver - gatekeeper of the human body



What makes plant components so valuable?

independent of biodegradation

the so-called “matrix effects”

In addition to the pharmacological aspect, the positive influences on the **physical parameters in dosage forms** are also very beneficial.

better solubility

better stability

better emulsifiability

better shelf life

positive influence on the microbiome and better resorption

synergistic effects are often multiplicative not only additive

no significant side effects even with prolonged use

better acceptance by authorities for industrially manufactured products

instead of experimental individual therapies by medical doctors

without toxicological validation!!!

Vedicinals 9 a new opportunity for intervention

A synergistic composition of high potent natural based compounds in a natural matrix for high efficient bio availability and therapeutic approaches.

Details presented from Joachim Gerlach

But also the support of the natural function of kidneys and liver are additionally great challenges

But what happens to "toxins" that cannot be eliminated very easily?

This toxins remain in and destroys or enlarges the liver

Later this compounds are deposited in the fat tissue for long time storage and with low metabolism

How can we support the flushing of our kidneys for better elimination

And what happens within the brain?

The new food supplement **HEPA by NATURWERK**

- **unique new development** based on a synergistic composition of medicinal plants
- **effective composition** developed from only a few **efficient natural plant special extracts**

pure effective mechanisms

Yarrow (*Achillea millefolium* L.)

bitter substances promoting bile secretion and anti-hepatotoxic effects

Artichoke (*Cyara Cardunculis* L.)

normalization of disturbed hepatobiliary function and influencing the lipid metabolism of human body

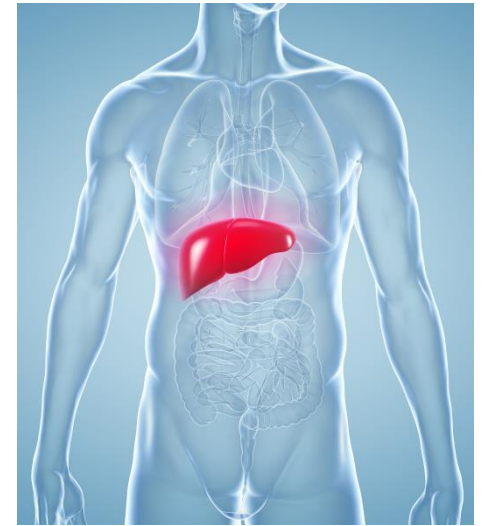
Tea leaves (*Camellia sinensis* L.)

Positive antioxidant and anti-carcinogenic effects

Milk thistle (*Silybum marianum* L.)

alteration of hepatocytes so that liver toxins can not penetrate into the cell interior.

stimulates the regenerative capacity of the liver and stimulates the formation of new hepatocytes



Renaturates the liver



The new food supplement **NEPHRO by NATURWERK**

- **unique new development** based on a synergistic composition of medicinal plants
- **effective composition** developed from only a few **efficient natural plant special extracts**

pure effective mechanisms

Dandelion (Taraxacum officinalis W.)

increased diuresis ("kidney flushing")

also in kidney gravel and among other rheumatic problems etc.

Nettle (Urtica dioica L.)

increase of maximum urine flow

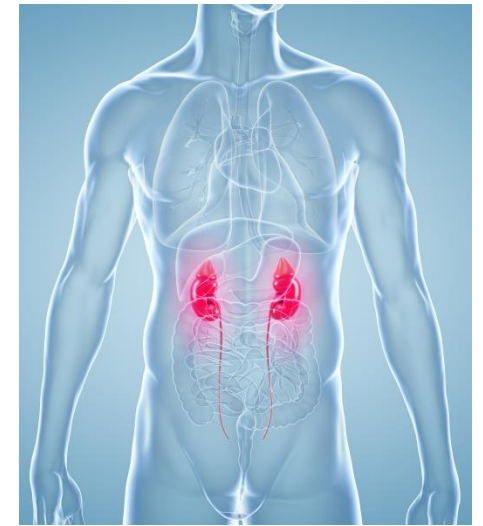
combined with anti-inflammatory effects

Horsetail (Equisetum arvense L.)

improved flushing of the draining urinary tract in cases of inflammation, kidney gravel and other kidney problems

Goldenrod (Solidago virgaurea L.)

Anti-inflammatory, diuretic, stoniferous urological effects to improve renal flushing.



flushes the kidneys



Strengthening of body's own regeneration "The capsule for happiness"



How can this be realized?

All physiological reactions of the human body are influenced by neuronal processes

We want to achieve positive effects in the body

So why do we not strengthen the mental performance naturally?

A novel synergistic natural component mixture according to Hans Rausch
5-Hydroxytryptophan the natural precursor of serotonin, our Hormone for well-being combined with GABA to strengthen the nerves, additional natural caffeine and taurine together with further synergistic natural components like St. John's wort, as well as an essential amino acid, vitamins and selenium **migrate through the blood brain barrier**

