Recent Developments in German Health Policy:

Non-Rx products delisted?

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BAH
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Change of Paradigms

On 22 July 2003:

A political coalition in Germany decided on a change of paradigms

Basic principle in the past: → **all medicines are prescribable (with exemptions)**

Basic principle in the future: → **non-Rx-medicines are not prescribable (with exemptions)**

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Change of Paradigms

This is a desaster for many herbal medicinal products (HMP)

because

99% are non-Rx

German Medicines Manufacturers' Association

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Basic Points of the Consensus Negotiations on the Health Care Sector Reformation, 22 July 2003

4.3 New regulations for reimbursement of non-Rx medicines

In principle, non-Rx medicines are to be taken into the patients' self-responsibliity, above all because patients predominantly acquire these medicinal products without a receipt today. Exemptions are made for children up to 12 years and adolescents with development disorders.

Furthermore, the mentioned medicinal products remain reimbursable in certain indications. For this purpose, the *Bundesausschuss* (an expert panel of physicians and health insurances) prepares a catalogue of exemptions for approx. 10 - 12 indications (e.g. acetyl salicylic acid after seizure, mistletoe preparations for cancer). In this context, therapeutic diversity is to be taken account of.

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Draft law (11 August 2003)

"Non-Rx medicines are excluded from SHI-accredited physician services. This does not apply to:

1. insured children up to 12 years
2. insured adolescents up to 17 years with development disorders

The SHI-accredited physician can exceptionally prescribe medicines, which are exluded from the service according to sentence 1, by stating reasons, if these medicines are included in an indication-related list of active substances which is to be set up by the *Gemeinsamer Bundesausschuss* by 31 March 2004 in the directives according to §92 para. 1 sentence 1 no. 6. Before this list comes into force, the decision is up to the physician. The mentioned list is to include those medicinal products which represent the therapeutic standard in the treatment of severe diseases. In this context, therapeutic diversity is to be taken account of."

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Exemptions for the Prescription of Non-Rx-Medicines

(as stated in the reasons of the draft law)

- The prescription has to be substantiated in the individual cases
- Indications are stipulated in the *Arzneimittel-Richtlinien* (Directives for the prescription of medicinal products)
- List including standard active substances for the treatment of severe diseases (e.g. for oncology, rehabilitation measures after cardiac infarct, treatment of the climacteric)

  Medicinal products from the "*Besondere Therapierichtungen*" (phytotherapy, homoeopathy, anthroposophy) are to be taken into account
- List to be prepared by 31 March 2004
  Up to that date, the physician decides.

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Someone's estimation for further prescription of HMP

Front line	**Hypericum (depression)** **Sabal, â-Sitosterin (BPH)** **Ginkgo (Dementia)** **?**
2nd line	**Viscum album (cancer)** **Cimicifuga (climacteric complaints)** **?**

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Requirements

In order to maintain prescriptions, the following claims must be fulfilled:

- **disease has to be severe**
- **active substance has to be indispensable and standard in its indication**

This has to be supported by data.

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Requirements for Research

prescribed medicines	→	**high**
non-prescribable medicines	→	**medium**
food supplements	→	**low**

The possibility of reimbursement in clear indications was the motor for research in HMP.
But all kinds of products profited from the research done for prescribed medicines.

How can HMP be kept prescribable?

- **lobbying**
- **resolution of the GPhy / GA**
- **applications to be put on the "list", supported by data**