

European Parliament Interest Group on CAM

Brussels, 16 November 2010

**Availability of Homeopathic and
Anthroposophic Medicinal Products in the EU
and in the 27 Member States.**

Content

- Important official EU positions on the regulatory framework
- Citizens choice: YES to integration of CAM
- Recent data from Switzerland & The Netherlands
- Regulatory facts from 27 MS in brief so far
- Facts and Action needed: Summary document

Milestones along the way

1992

Directive 92/73/EEC

1997

EP Resolution on status CAM
European Commission report

1998

European Parliament Resolution

1999

Foundation of ECHAMP

2001

Consolidation Human Code:
Dir 92/73 integrated in 2001/83

2003

Review of Directive 2001/83

2004

Mandate HMA to HMPWG

2007

Election first Chair HMPWG

2009

CAMBrella project accepted

European Commission

Homeopathic Medicinal Products

Commission Report to the European Parliament and Council on the Application of Directives 92/73 and 92/74

Brussels, 14.07.1997

COM(97) 362 final

‘It has been shown that starting from regulatory texts whose objectives were clearly expressed in 1992 – to achieve the harmonisation of regulations for homeopathic medicinal products and **enable their free circulation** – a certain but **not satisfying degree of harmonisation** has been achieved in 1997’

European Commission

Homeopathic Medicinal Products

Commission Report to the European Parliament and Council on the Application of Directives 92/73 and 92/74

Brussels, 14.07.1997

COM(97) 362 final

- Over the past 30-40 years homeopathy has benefited from growing demand both from doctors and from the public in the majority of European Countries. Three out of four EU citizens know about homeopathy **of these 29% use it for their Healthcare**

- **European Parliament Report Nov 1998**
on the Commission report on the application of Directives 92/73/EEC and 92/74/EEC on homeopathic medicinal products
- Rapporteur: *Mr Raphaël Chanterie*
- ‘...**the existing Directives need to be amended** ..(to) ensure the **free movement** of homeopathic medicinal products, and ..(to) **take account of the peculiar nature of homeopathic medicinal products**’

European Commission

- **COMMISSION Communication 2008** on the experience acquired as a result of the application of the provisions of Directive 2001/83/EC, as amended by Directive 2004/24/EC, on specific provisions applicable to traditional herbal medicinal products:
- Medical traditions such as those mentioned above are based on a **holistic approach**, and the set of requirements for the simplified registration procedure under **Directive 2004/24/EC is not appropriate** for a global regulation of such medical practices. The regulation of such traditions would demand a **different approach** from that introduced by Directive 2004/24/EC. Therefore, the Commission does not envisage extending the scope of the simplified registration procedure to cover traditional medical systems as such. **Nevertheless, independently of this report, the suitability of a separate legal framework for products of certain traditions should be assessed.**

European Court of Justice

JUDGMENT OF THE COURT
20 September 2007

41. In reality, the fact that Directive 2001/83 lays down a complete system of authorisation procedures for medicinal products **in no way means that the Community legislature cannot amend or adapt those procedures or, if necessary, introduce new ones so as better to attain the objectives of removing barriers to intracommunity trade and the protection of public health.**

- On those grounds, the Court (First Chamber) hereby rules:
- Anthroposophic medicinal products may be marketed only on condition that they have been authorised under one of the procedures referred to in Article 6 of Directive 2001/83 of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.

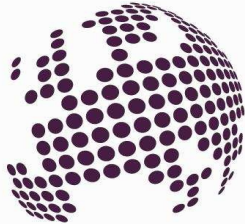
Citizens' Choice ?

- Medicinal products contribute considerably to the health of EU citizens.
- But they can also have adverse effects: it is estimated that 5% of all hospital admissions are due to an adverse drug reaction (ADR), and that ADR is the fifth most common cause of death.
- **It is estimated that 197,000 deaths per year in the EU are caused by ADRs** and that the total cost to society of ADRs in the EU is €79 billion.



MEMO/European Commission
Brussels, 10 December 2008

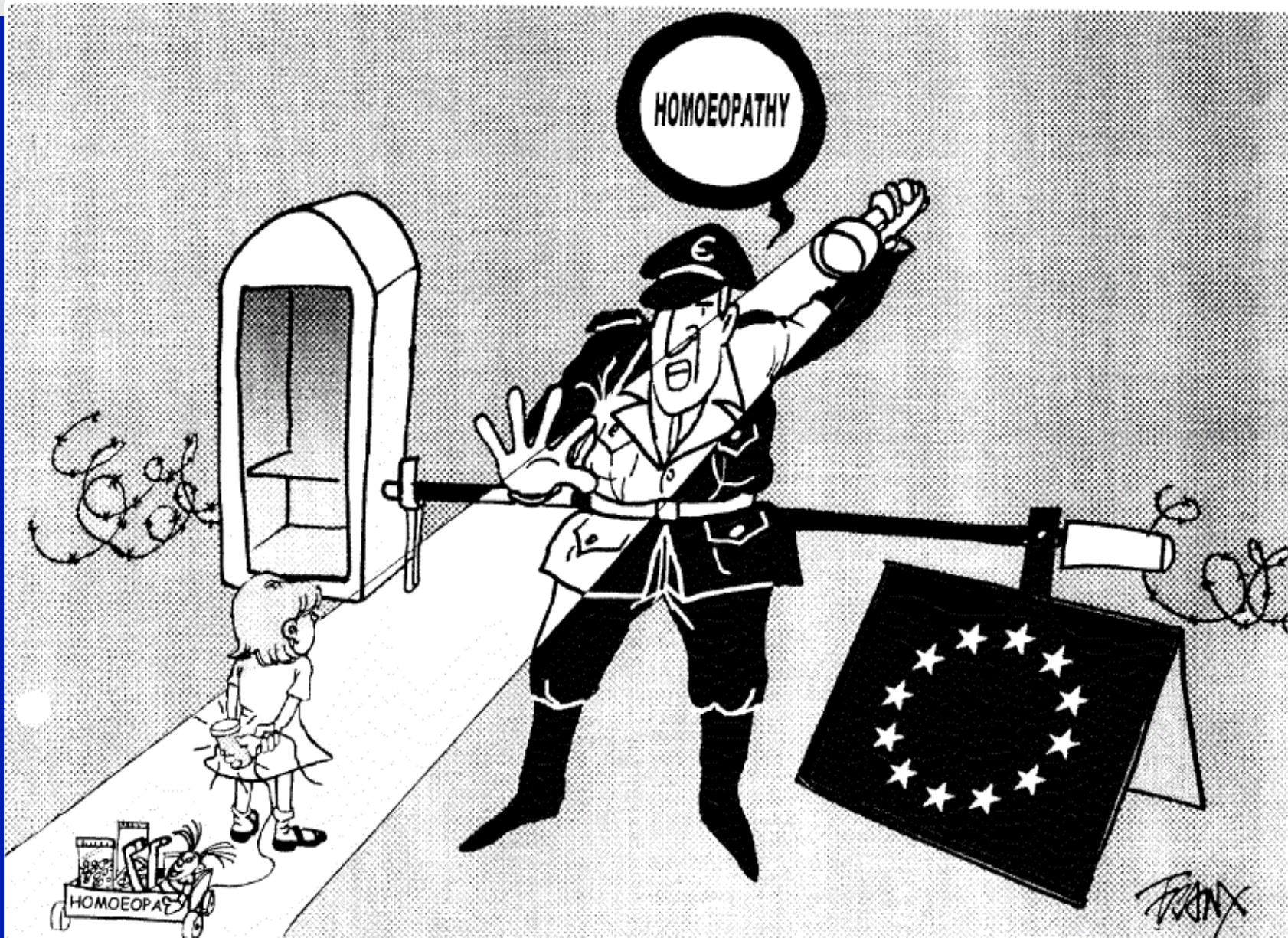
Clear Citizens' demand for Integration



European Citizens' Consultations

- Overview of the recommendations for the Economic and Social Future of Europe developed at the national 'European Citizens Consultations' that has taken place in all EU Member States in March 2009
- Health, **recommendation 6** out of 7:
- **"The EU should encourage links between alternative and mainstream medicine.** It should regulate research, transfer of good practices, and education in alternative medicine. Treatments in alternative medicines should also be fully reimbursed by health insurance providers."

Not the choice of the Citizen



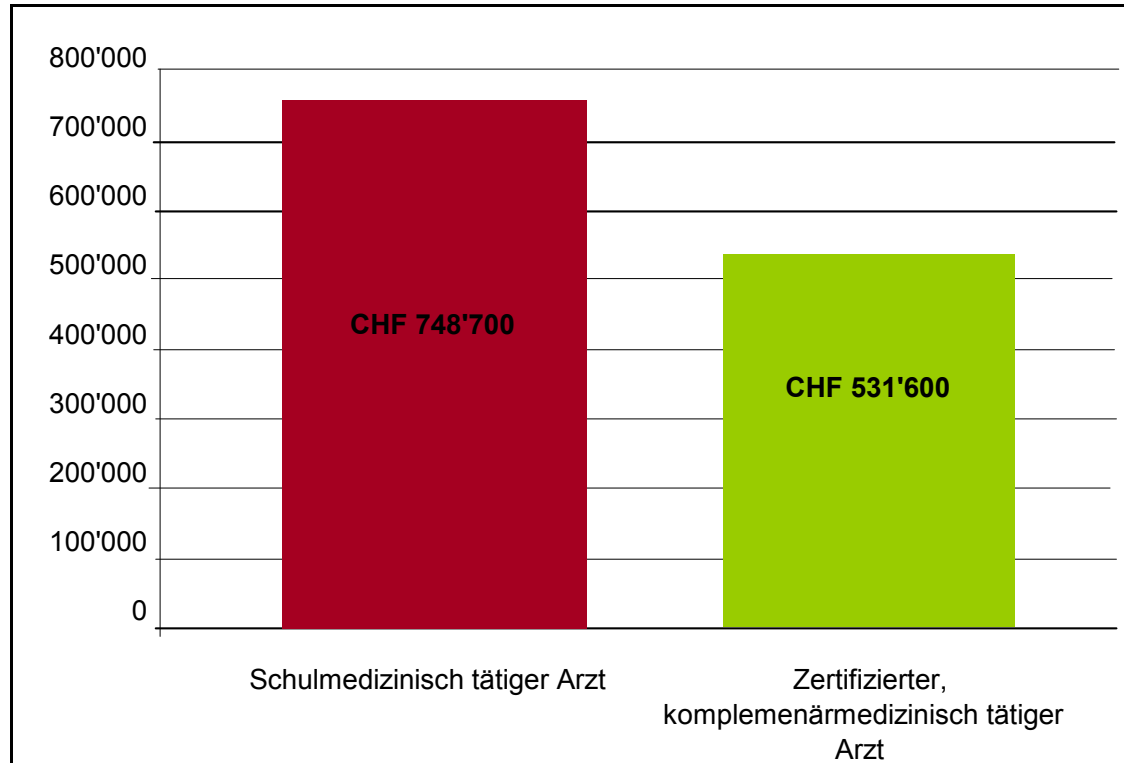
Not the choice of the citizen



If you want to receive this cartoon by e-mail, please contact us: press@echamp.be

Recent figures from Switzerland

Tabelle 1: Gesamtkosten pro Arzt

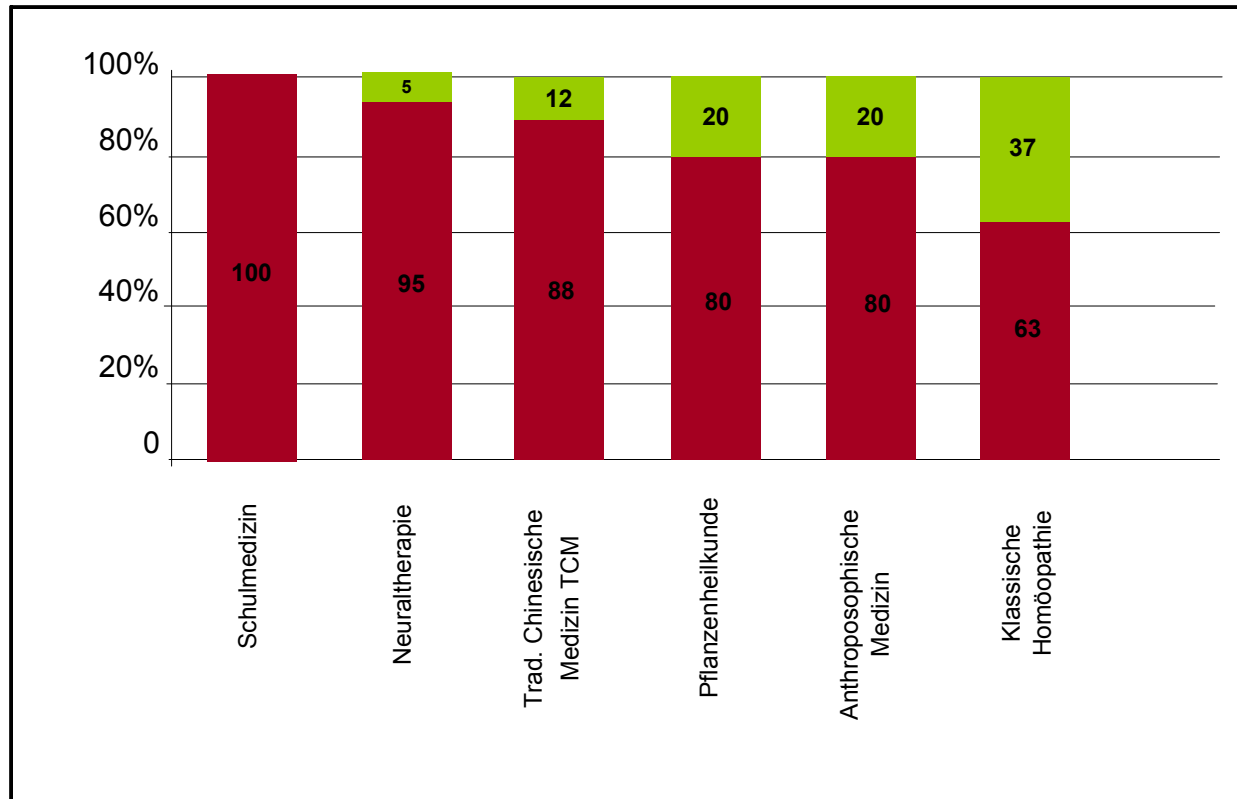


Jährliche Kosten (in CHF) zu Lasten der obligatorischen Krankenpflegeversicherung von zertifizierten komplementärmedizinisch tätigen Ärzten (CAM-Ärzten) sowie von rein schulmedizinisch tätigen Ärzten (COM-Ärzten), 2002/2003, ohne Kostenselbstbehalte der Patienten./ Modellbasierte Daten (Modellbasierter Mittelwert, errechnet mittels nicht parametrischer Regression (Least Square Mean))

Quelle Tabelle 1: Ist ärztliche Komplementärmedizin wirtschaftlich? Hans-Peter Studer, André Busato in: Schweizerische Ärztezeitung vom 5. Mai 2010

Recent figures from Switzerland

Tabelle 3: Durchschnittskosten pro Patient pro Fachrichtung / Einsparungspotential (2008)

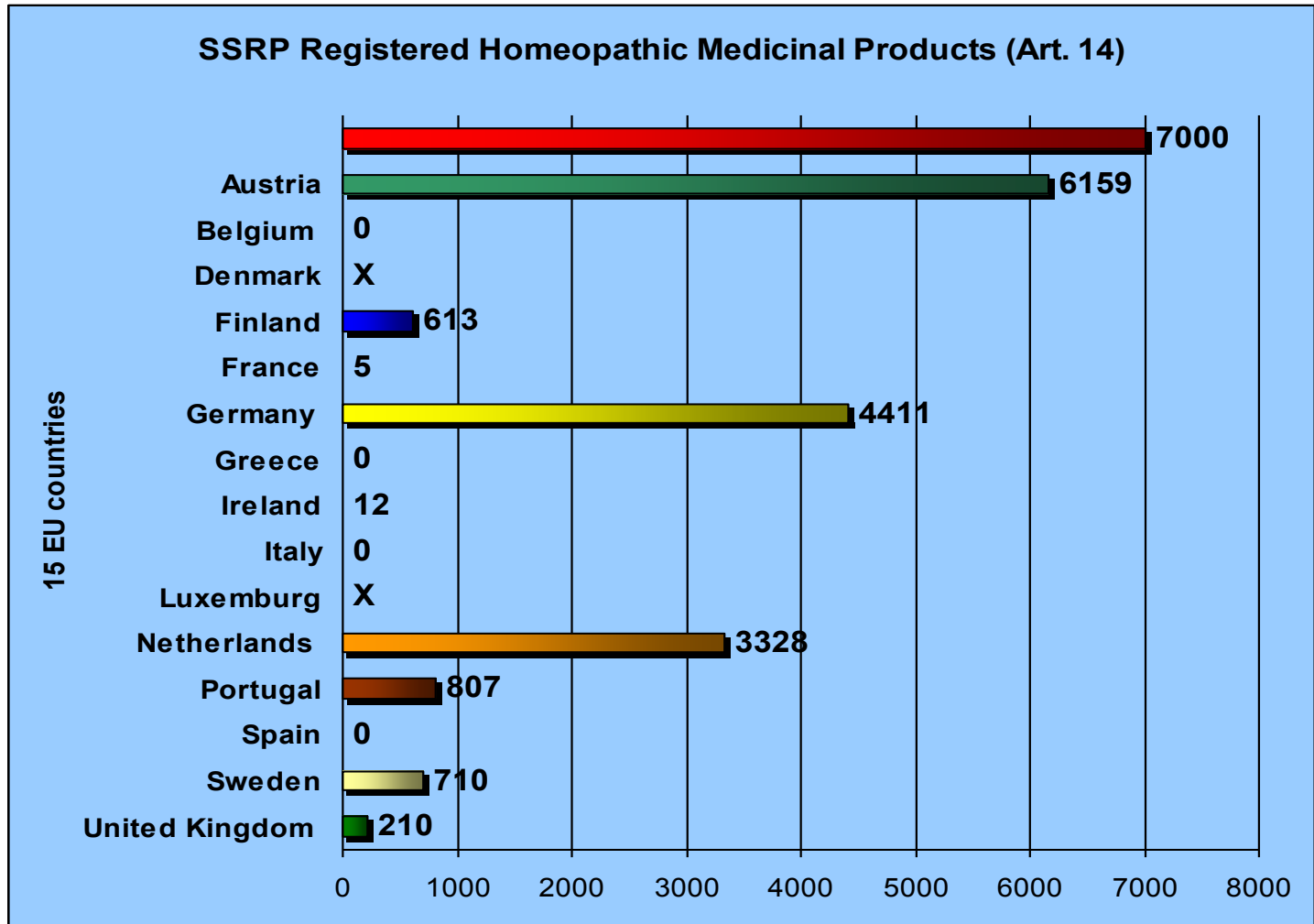


Quelle Tabelle 3: santésuisse Datenpool 2008

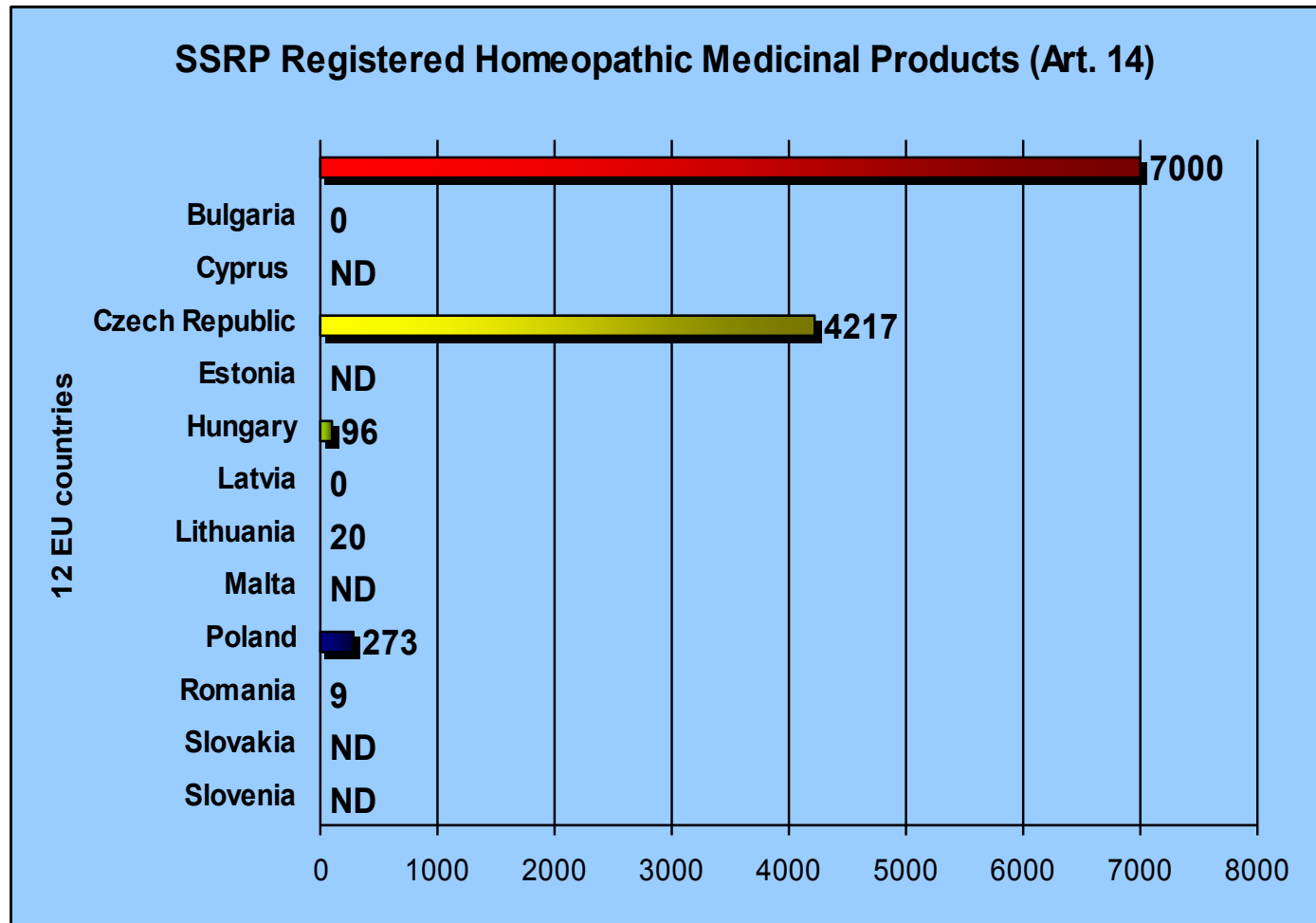
Recent figures from The Netherlands

- **Patients Whose GP Knows Complementary Medicine Have Lower Costs and Live Longer**
- Peter Kooreman & Erik Baars – Univ. Tilburg/Leiden - May 2010
- Using a data set from a health insurer – 150000 patient dossiers during 4 years - , this paper documents that patients whose GP has additional training in anthroposophic medicine, homeopathy, or acupuncture have substantially **lower health care costs and lower mortality rates.**

Availability - Regulatory Facts in 15 MS



Availability - Regulatory Facts in 12 MS



Conclusion and urgent request



Summary: 'AVAILABILITY OF REGISTERED & AUTHORISED HOMEOPATHIC and ANTHROPOSOPHIC MEDICINAL PRODUCTS FOR USERS, PATIENTS AND PRACTITIONERS IN THE EU'

- 1.Relevant EU figures**
- 2.Examples of failing Regulatory Environment**
- 3.Where are legal changes needed**

Thank you

- Thank you for your attention
- Questions and discussion
- Info: www.echamp.eu

Nand De Herdt - Industrial Pharmacist - President - ECHAMP