EASD European Association for the Study of Diabetes

Medical devices in diabetes care

The mission of

the European Association for the Study of Diabetes

is to promote excellence in diabetes care

through research and education.

Dr. med. Viktor Jörgens, Executive Director EASD/EFSD
European Association for the Study of Diabetes www.easd.org

What is the European Association for the Study of Diabetes?

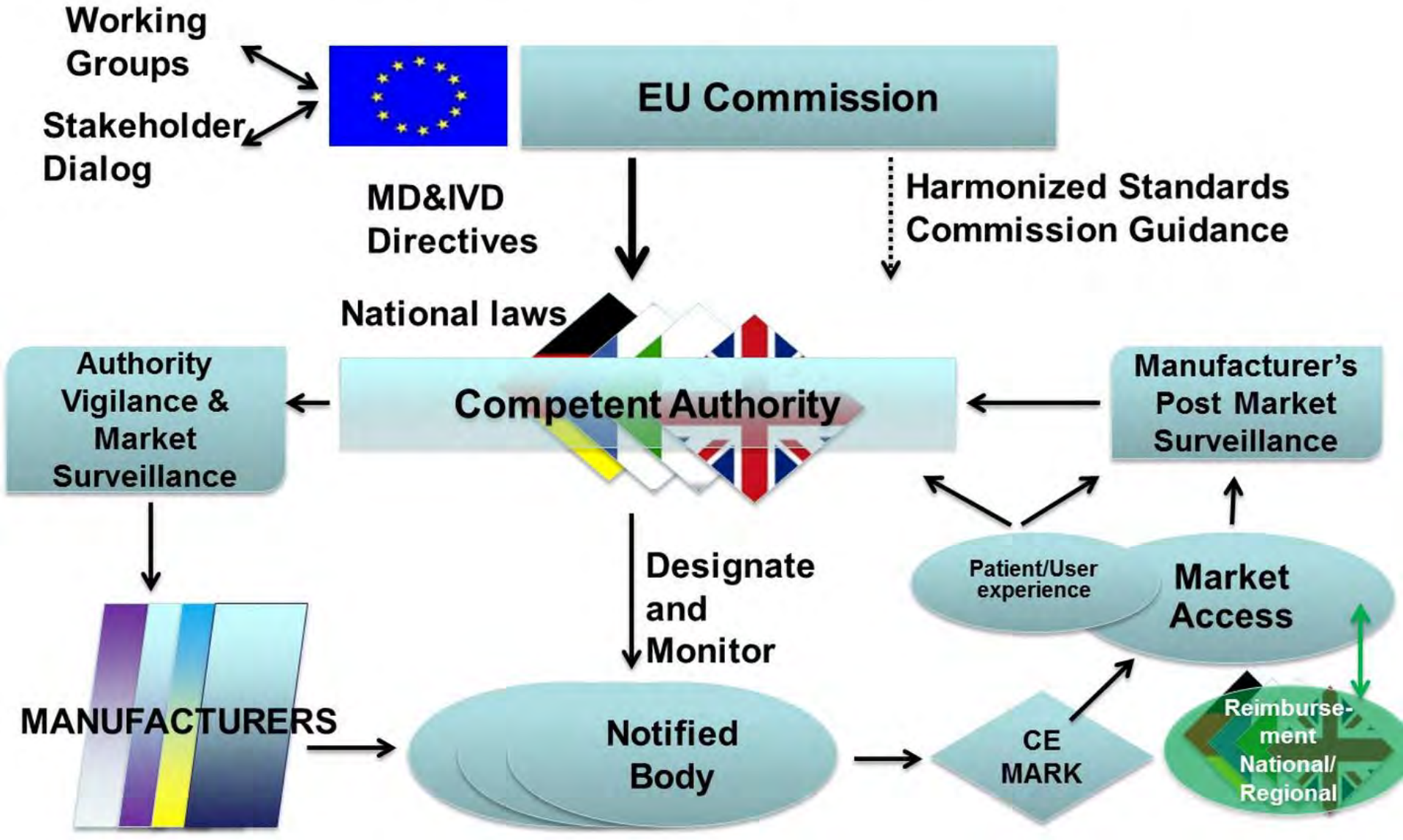
- Founded in 1965
- Based in Düsseldorf, Germany
- Academic non-profit organisation
- The Official Journal of the Association is *Diabetologia*
- Conducts numerous Postgraduate Education Courses
- Our Foundation, EFSD, has donated €90 million
- Annual Meeting with 18,000 delegates from 120 countries

Medical devices in diabetes care

Regretfully, in the past, EASD was not sufficiently active in the area of medical devices.

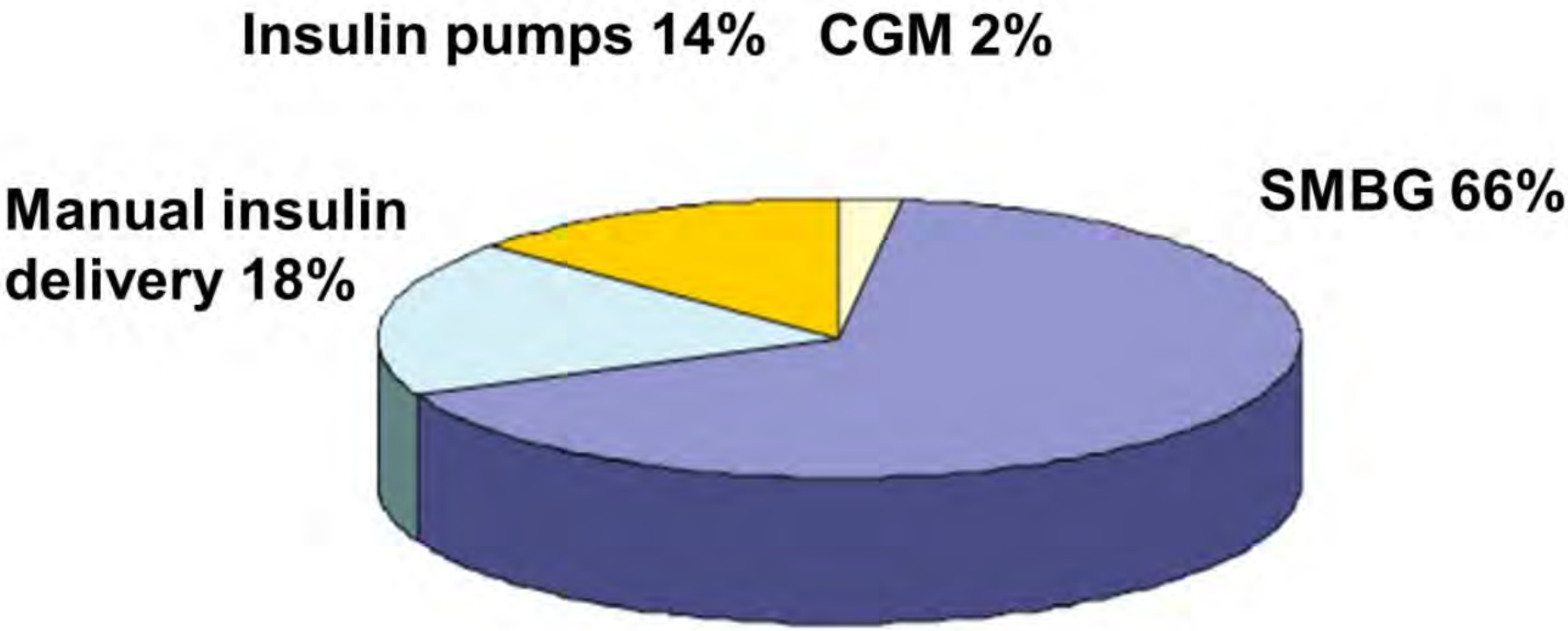
We hope that in the future closer collaboration between academic medical societies, regulatory bodies and industry will improve care and protect the health of millons of people with diabetes.

Current regulatory system for Medical Devices in Europe (Eucomed)



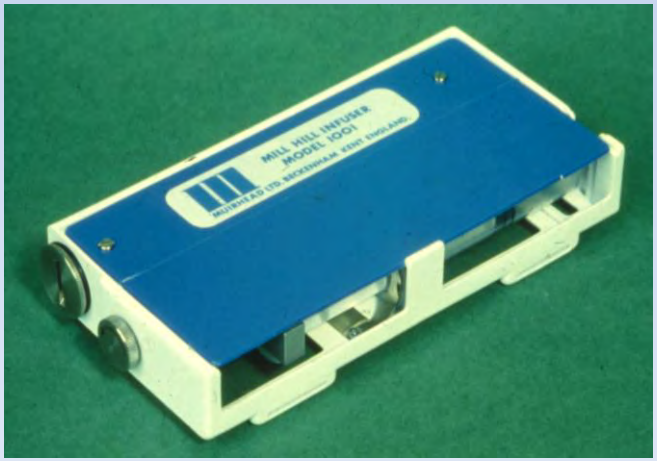
What are we talking about?

Market share of diabetes devices



GBI Research / Espicom Business Intelligence: Diabetes landscape, Market, Technology and Intellectual Property May 2012

Insulin pumps of the 1970s & 1980s



- Simple technology
- No software control
- No or few alarms
- No wireless connectivity
- Used experimentally or for limited routine clinical care
- Little or no pre-market testing or regulation of pumps

Insulin Pump Therapy 2013

- Complex, sophisticated technology
- Many alarms for malfunction
- Onboard software, bolus calculators etc.
- Wireless connectivity with BG meters, computers etc.
- In widespread use

Diabetologia

Pumps failures still occur

Isabelle Guilhem et al., Diabetologia 2009; 52: 2662-4

- 2001-2007, survey of 640 new pumps from 4 manufacturers
- Any defect: 36% of pumps
- Complete pump failure: 16% of pumps
- Mechanical defects requiring replacement: 6.5% of pumps

No large, independent, systematic survey of technical, non-metabolic complications of CSII since 1980s

- Are modern pumps safer and more reliable than in the1980s?
- Are there less complications?
- Lack of research data to claim for reimbursement

Presented by Prof. J. Pickup, EASD 2013 in Barcelona

EASD European Association for the Study of Diabetes

Device research is underrepresented in the EASD scientific meeting

- **1360** abstracts accepted for presentation in the 2013 EASD Meeting attended by 18,000 diabetologists
- Only **42** abstracts accepted on medical devices
- **Only 3% of the scientific presentations**
- **Actions are urgently needed to increase research into this area**

49 EASD BARCELONA 2013

Diabetologia

Position of the EASD

Diabetologia (2012) 55:2295–2297
DOI 10.1007/s00125-012-2580-7

LETTER

Regulation of medical devices used in diabetology in Europe: Time for reform?

A. J. M. Boulton · S. Del Prato

EASD Press Release
March 14, 2013
Avoiding a medical device disaster in diabetes

The European Association of Diabetes (EASD) today announces its intention to lobby for an urgent overhaul of medical device regulation in Europe to make it fit for purpose. "We want to avoid disasters similar to those that occurred with PIP breast implants and metal-on-metal hip replacements," says Professor Andrew Boulton, President of EASD, Professor of Medicine at the Universities of Manchester (UK) and Miami (FL, USA), and Consultant Physician at Manchester Royal Infirmary, UK.

Dr. Deborah Cohen

from the Department of Investigative Journalism at the British Medical Journal giving her lecture in the EASD Annual Meeting in Barcelona on medical devices.

Research on Medical Devices needs more publicity in academia!

The new annual EASD Diabetes Technology Conference will provide a top-level forum for research into devices in diabetes care and will unite all stakeholders to discuss worldwide regulatory issues.

EASD / ADA Statement on Insulin Pumps

A committee of experts was nominated by EASD and the American Diabetes Association to compose a joint statement on the evaluation of insulin pumps to be released in 2014.

Continuous glucose monitoring CGM

- Most data on efficacy and safety comes from, a small few, clinical investigators

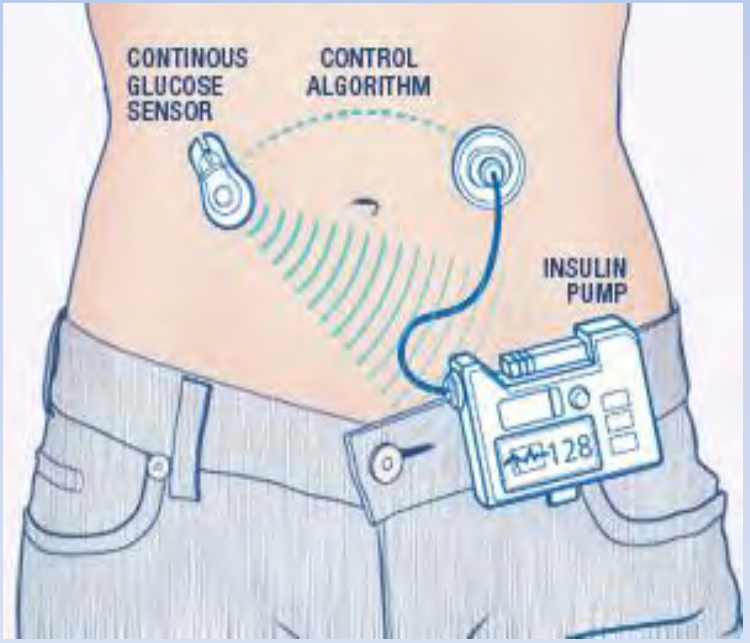
- Insufficient systematic monitoring of adverse events

The future: the Artificial Beta Cell

- Modern diabetes technologies are becoming ever more sophisticated – hopefully providing a closed loop system in the future.

- Assessment and regulation of quality will become increasingly more complex, demanding and expensive

- It cannot be left to manufacturers, 'Notified Bodies' or *ad hoc* academic reports.



European academic medical societies should collaborate with strengthened regulatory bodies and industry concerning medical devices.

The aim is to provide patients with safe and effective modern technology for better care.