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Heading for the Future:

Convergence of medical products

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History

- **19 July 2007:** consultation of European Commission on “The Future of Pharmaceuticals for Human Use in Europe”
- **10 October 2007:** Dutch reaction one of the key issues: “Convergence of technologies”
- **25 January 2008:** letter of European Commission on the outcome of the Public Consultation

MEB supports the Community action in the field of pharmaceuticals for human use, because it

- safeguards public health
- stimulates innovation
- stimulates competitiveness


MEB thanks the EC for the opportunity to comment on the Consultation paper

This was a wonderful initiative and a success:
104 contributors

Consultations

In 2007/8, the EC (3 different DGs) has sofar conducted 6 consultations and an inquiry:

- Variations
- Medical devices
- Counterfeit
- Advanced therapy
- Pharmacovigilance
- Information to patients
- Competition


$$\frac{c \quad B \quad G}{M \quad E \quad B}$$

Who is keeping direction, or has an overview?

Are the consultations together a goal-oriented action?

Pharmaceuticals

In October 2008 the EC will deliver a
“Pharmaceutical Package” concerning:

- Pharmacovigilance
- Counterfeit
- Information to patient
- Variations

The field is broader than just pharmaceuticals.

MEB strongly suggests to also consider the products that are to a smaller or greater extent “adjacent” to pharmaceuticals:

- medical devices
- human tissues
- advanced therapy products
- cosmetics
- food supplements and functional foods

There is a certain *convergence* in these fields.

Transparency and coherence in regulation across product categories are necessary.

In addition, it should be clear to any user, producer or other stakeholder, under what category a product resorts.

Blurring of ‘traditional’ boundaries

Which products cross the ‘traditional’ border
between drugs and devices?

- Borderline Products
- Combination products

Borderline products

A lot of discussion about:

- Osmotic laxans
- Cooling gel with menthol
- Active charcoal
- Heparin solution for rinsing catheters
- Electronic sigaret
- “Cosmetic” products, e.g. Botox / tooth whiteners

Borderline discussions could be considered as ‘indicator’ of coherence between definitions

Super Smoker:
pharmaceutical?
consumer product?
medical device?
tabacco?



Convergence of technologies

Convergence of technologies blurs the traditional boundaries between pharmaceuticals and the “adjacent” product categories

Cooperation and coordination with other sectors will be mandatory and challenging

Even more challenging will be to aim for coordination and harmonization at a global level

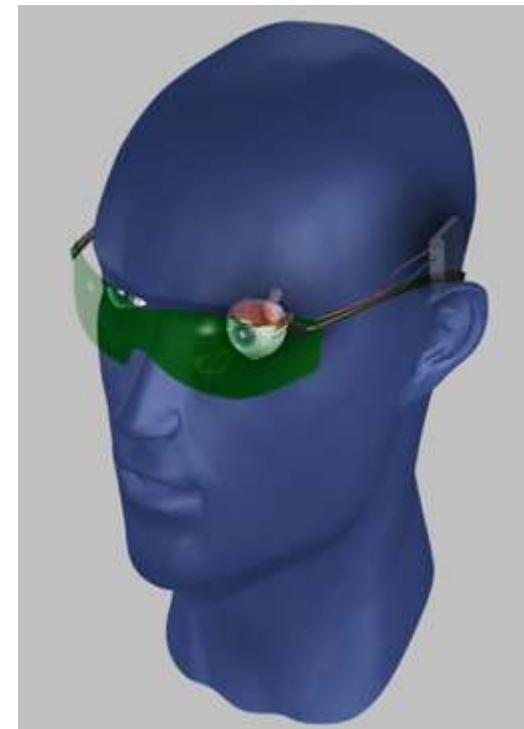
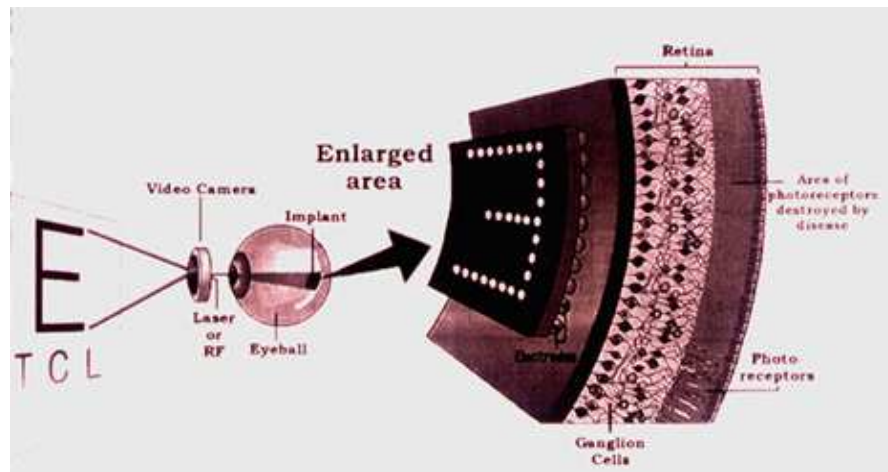
Converging Technologies: Artificial Limbs

Rheoknee^R: joint filled with fluid with nanoparticles,
with a 'memory'

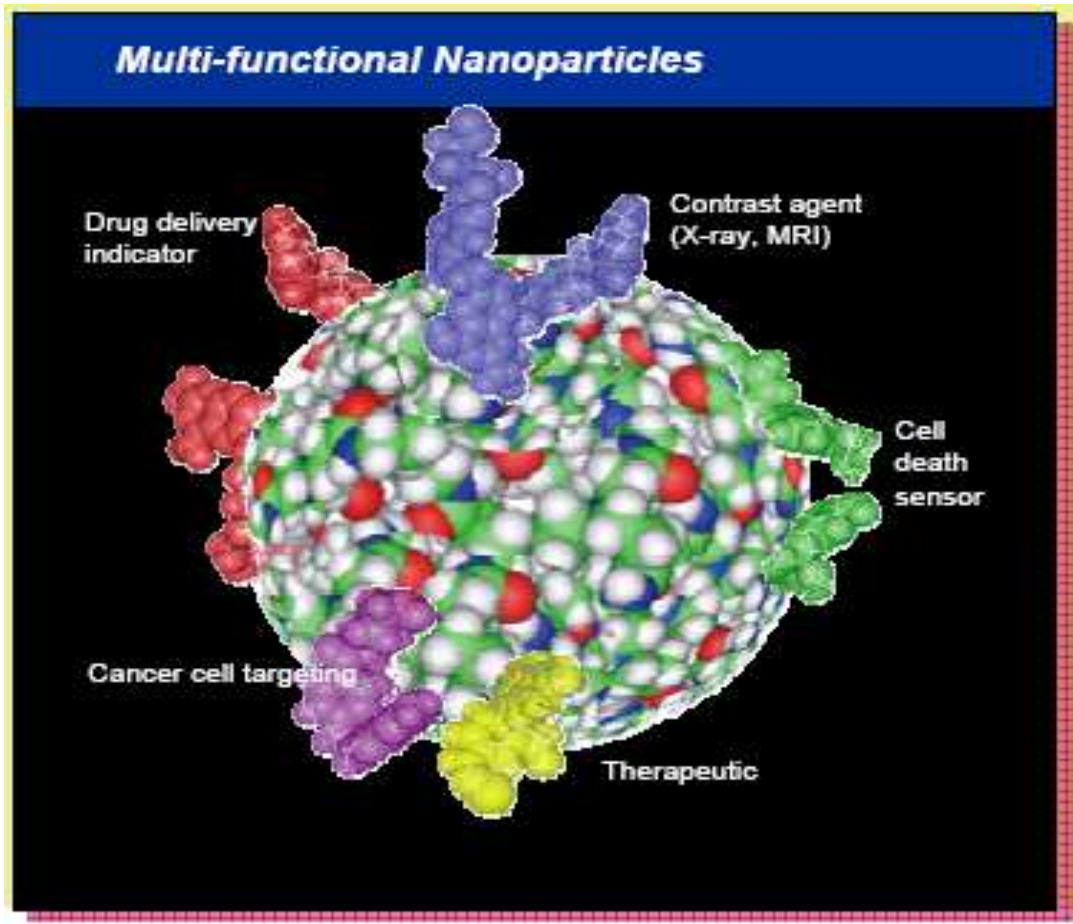


Converging Technologies: Retinal prosthesis

Second Sight^R: array of electrodes, attached to the retina and used in conjunction with an external camera and video processing system.



Converging Technologies: $\frac{c \ B \ G}{M \ E \ B}$ Treatment of cancer

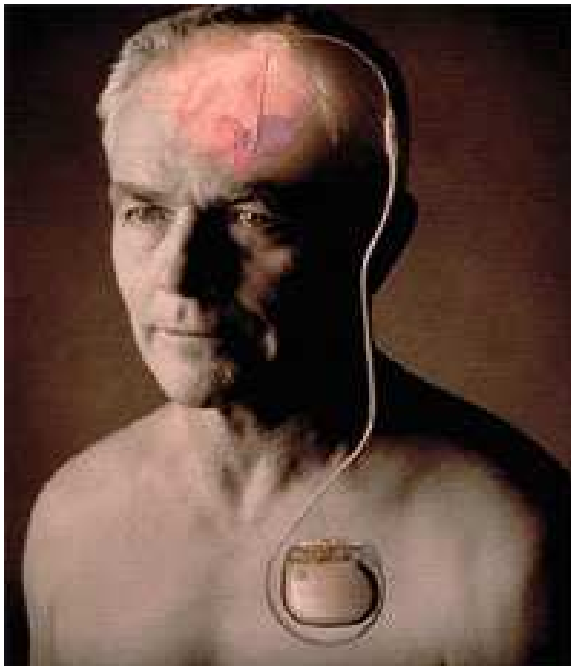


- Targeting
 - Imaging
 - Therapy
 - Monitoring
- in one molecule

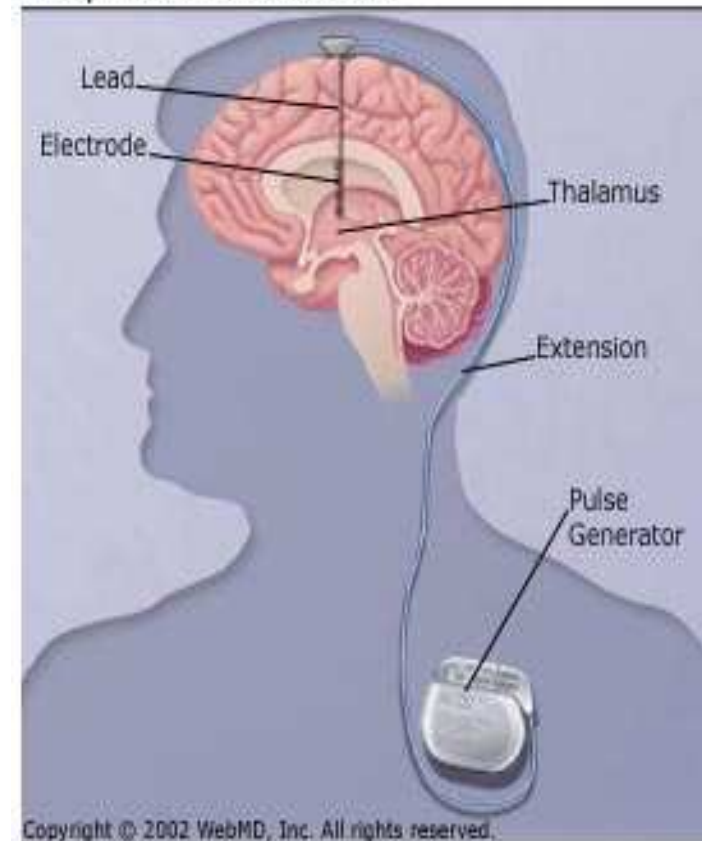
DRUG or DEVICE?
DRUG

Converging Technologies: Deep Brain Stimulation

Parkinson's Disease
Syndrome of Gilles de la Tourette
DRUG or DEVICE? DEVICE



Deep Brain Stimulation



Discussion

The classification of borderlines and combination products of pharmaceuticals and medical devices is:

- complex
- time-consuming
- no clear outcome

In case of a borderline product: the court decides

The Netherlands feel that there is room for improvement towards coherence and consistency.

Discussion

The Netherlands feel that it would be most important that the Commission would take that fact sufficiently into account.

The Netherlands would like to have a discussion with the other European member states on proposals for the next Review of the Medicinal Product Directives / Regulations and of the Medical Device Directives concurrently.

Thanks

My colleagues at the ministry of
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- Sabine Hoekstra
- Marie Louise Bilgin
- Birte van Elk



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