

Portfolio strategies of
cytotoxic drugs – current
topics of regulatory economy

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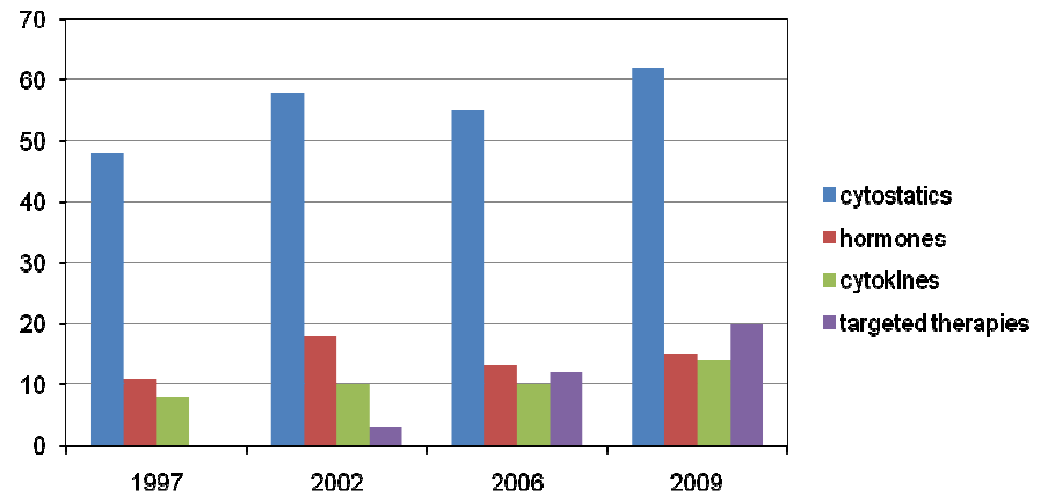
13th DGRA Annual Congress 2011

Market situation and trend for oncological drugs

— **Special market with a high growth potential**

— **Market growth for**

- „Classic“ cytotoxic drugs
- Targeted therapies

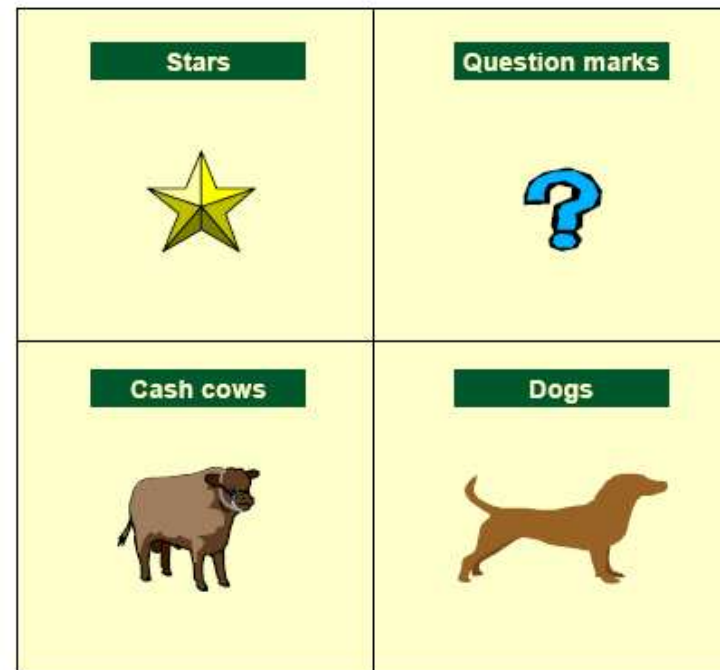


Portfolio strategies for cytotoxic drugs

— Analysis of the actual situation

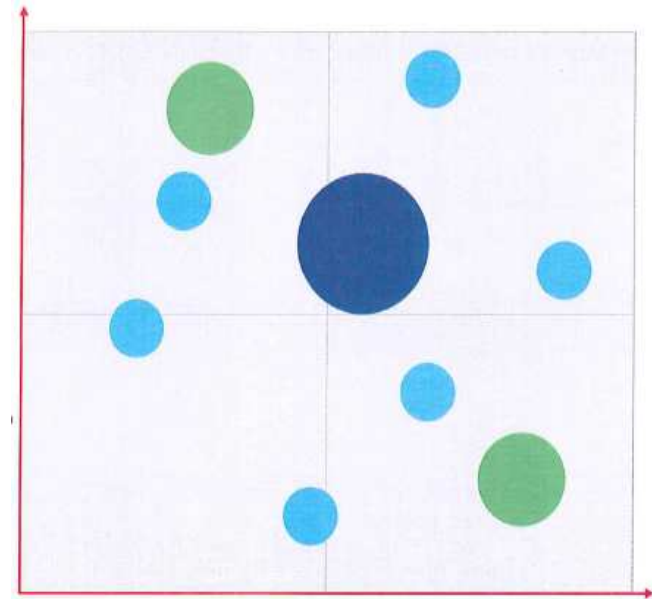
- BCG-Matrix

— Management of the portfolio



Analysis of the actual situation

- **Self-evaluation of the manufacturer**
- **Competitor analysis**





Management of the portfolio

- **Cost minimisation / optimisation**
- **Product differentiation**
- **Market focus / market expansion**



Development and authorisation of new products

— **Centralised Procedure** (Reg. (EC) 726/2004)

- **Mandatory for anti-cancer products**

— **Special procedures within the Centralised Procedure**

- **Accelerated assessment procedure**
- **Conditional approval**
- **Approval under exceptional circumstances**
- **Authorisation as orphan drug**
- **Compassionate use**



Management of profitable existing products

- **Renewals**
- **Variations**
- **Off-label use**



Management of non-profitable existing products

— **Out-licensing**

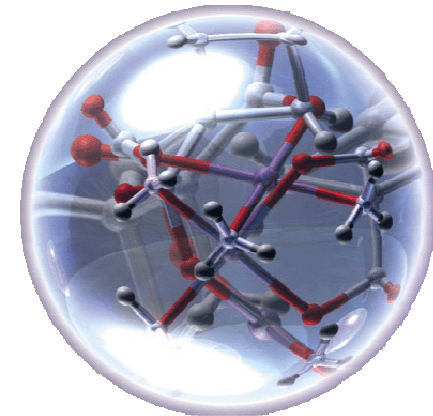
- **Loss of market share**
- **Portfolio changed**

— **Implication of the „Sunset Clause“**

- **Future product differentiation**

Decision Analysis: Authorisation of a new cytotoxic drug

- **New drug: capsule with Pt-containing API**
- **Efficacy against**
 - **Main cancer types: lung cancer, breast cancer**
 - **Rare cancer types: renal cell carcinoma, cervical carcinoma**
- **Possible marketing authorisation applications**
 - **For main cancer types: Accelerated Approval**
 - **For rare cancer types: Conditional Approval**
Orphan Drug Designation





Decision Analysis: Authorisation of a new cytotoxic drug

— **Strategies:**

- „Push marketing-strategy“: first MA for main indication
- „Pull marketing-strategy“: first MA for rare indication

— **Best balanced choice:**

- First MA for rare indication „renal cell carcinoma“
- Then MAs for main indications „lung cancer“ and „breast cancer“



Herzlichen Dank

**Herrn Dr. J. Hofer
(Exdra GmbH)**

**Herrn H. A. Jopp
(Jopp & Wilkens)**

**Heraeus GmbH
Hanau**