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**meda**

# MEDA

## Dealing with old drugs – the industry perspective

Old drugs for Bad Bugs – OD4BB



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25 years of experience  
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# We need to discuss about..

- The landscape
- Possibilities for candidates
- The way to success and other challenges



# The landscape – important challenges

- Review of old antibiotics
  - Open access of data on file (IP – intellectual property) without violating commercial issues, patents.
- Challenges for the industry and stake holders
  - Sharing new knowledge generated in the medical community
  - Regulatory requirements
  - Production issues
- Participation of the industry
  - Secure participation of relevant parties
  - Commercial rewards to be defined e.g pricing

# The industry – in a changing landscape

| Specialty Pharma   | Big Pharma               | Generics                          | Biotech  | Production                |
|--------------------|--------------------------|-----------------------------------|----------|---------------------------|
| Search and develop | Research and Development | Lowest price for off patent Drugs | Research | Competive Price & Quality |

Aquisitions, Partnerships, Pricing, Environment, open access to data

## MEDA's antibiotics

amoxicillin (Imacillin), amoxi+clavulanic acid (Spektramox), ampicillin (Doktacillin) cefalexin (Keflex), cloxacillin (Ekvacillin) doktacillin (Doktacillin), erythromycin (Ery-Max), **flucloxacillin (Heracillin)**, flucytosin (Ancotil), **isoniazide (Tibinide)**, **metenamin (Hiprex)**, metronidazol (Zidoval) Penicillin G (Bencylpenicillin), **Penicillin V (Kåvepenin)**, **nitrofurantoin (Furadantin)**, ribavirin (Virazole), trimetoprim (Trimetoprim) tetracycline (Tetracyklin), tobramycin (Nebcina)

# The landscape – structured open processes

Document  
OD4BB

Existing Drugs

Share of Data<sup>1</sup>

Reward for  
the parties

- Chair of projects
- Stake holders
- Resources
- Financing
- Open round for participation

- New countries
- Dose/Dosing

- Intellectual property – IP platform for
- New data
- Data on File

- Short term: reimbursement Pricing
- Long term: prolong Patent

1. Thomas Hedner. Dissertation 2012. Change in the Pharmaceutical Industry Aspects on Innovation, Entrepreneurship, Openness, and Decision Making

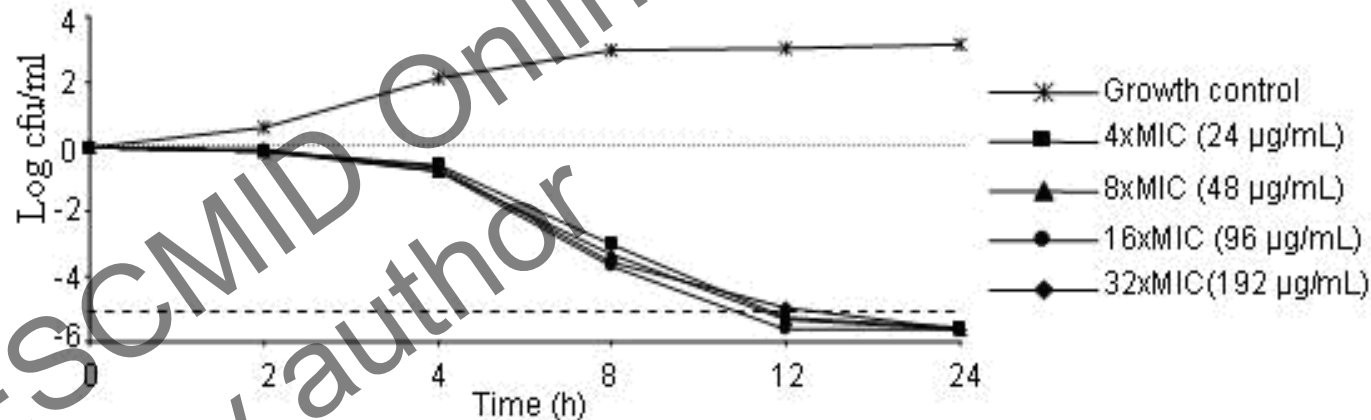
# Comments on Candidates

| Candidate               | Comments   |
|-------------------------|--|
| Temocillin              |  |
| Fosfomycin              |  |
| Fosfomycin + Trometanol | <ul style="list-style-type: none"><li>• Defined Medical need</li><li>• Regulatory status/Docs needed</li><li>• MIC breakpoints / Mutants</li></ul> |
| Mecillinam              | <ul style="list-style-type: none"><li>• Doses/Dosing regimen</li></ul>   |
| Chloramphenicol         | <ul style="list-style-type: none"><li>• Needed documentation:<br/>Phase 2,3,4? PK/PD? in vitro?</li></ul>  |
| Colistin                |  |
| Nitrofurantoin          | As above and..   |

# Comments on Candidates

| Product              | Comments   |
|----------------------|--|
| Nitrofurantoin (NIT) | <ul style="list-style-type: none"> <li>•ESBL documented in PD study<sup>1</sup>,</li> <li>•Respiratory safety shown<sup>2</sup></li> <li>•Define formulation to be further documented</li> <li>• Define strain specific activity.</li> </ul> |

Bactericidal effect of NIT on *E. coli* ESBL strain. T>MIC confirmed in kinetic model<sup>1</sup>



## References

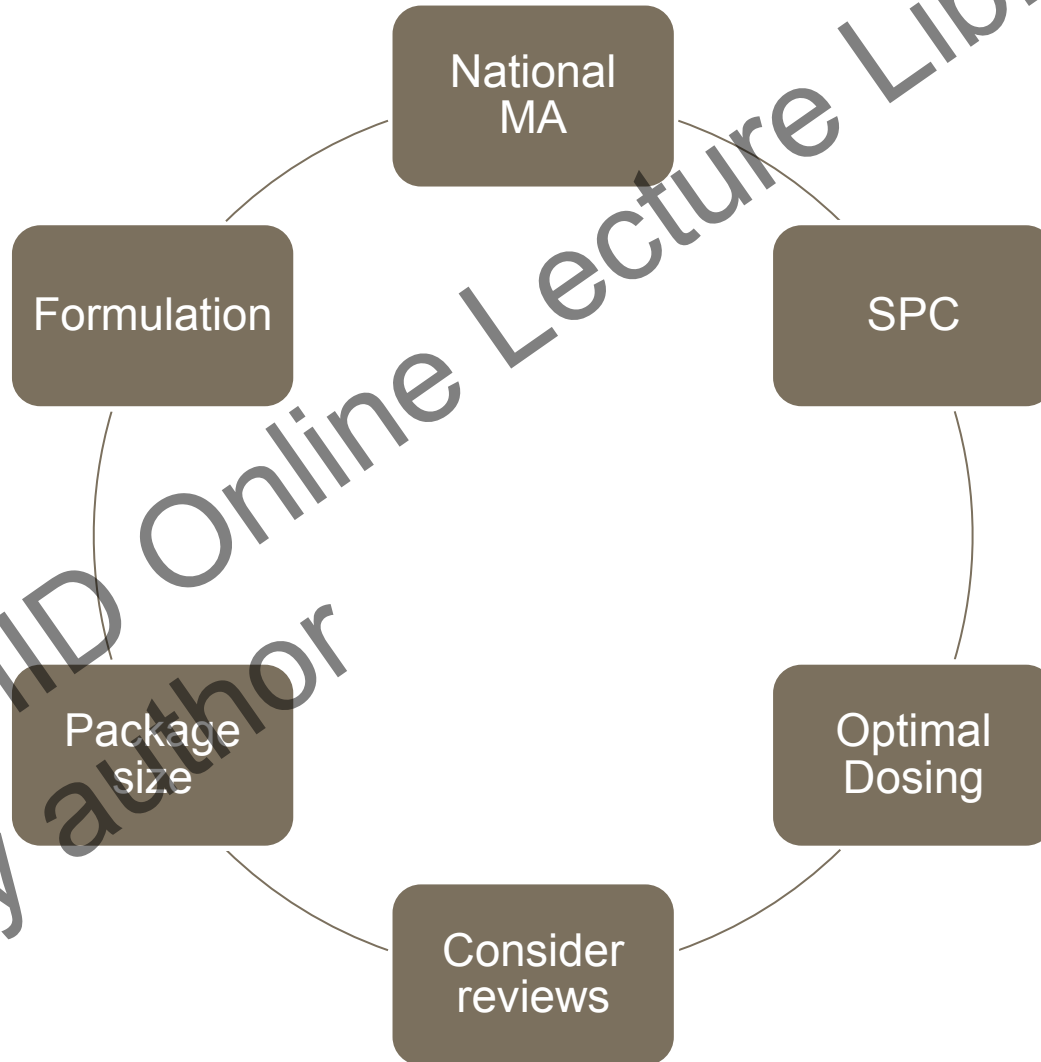
1. Komp Lindgren P, O. Klockars, P. Lagerbäck, O. Cars  
Pharmacodynamic studies of nitrofurantoin against common uropathogens. ICAAC 2010.
2. von Fircks H, Naeslund K, Hammarlund-Udenaes M.  
Nitrofurantoin – an overview with focus on respiratory safety aspects 1977-2010. SSAC 2010.



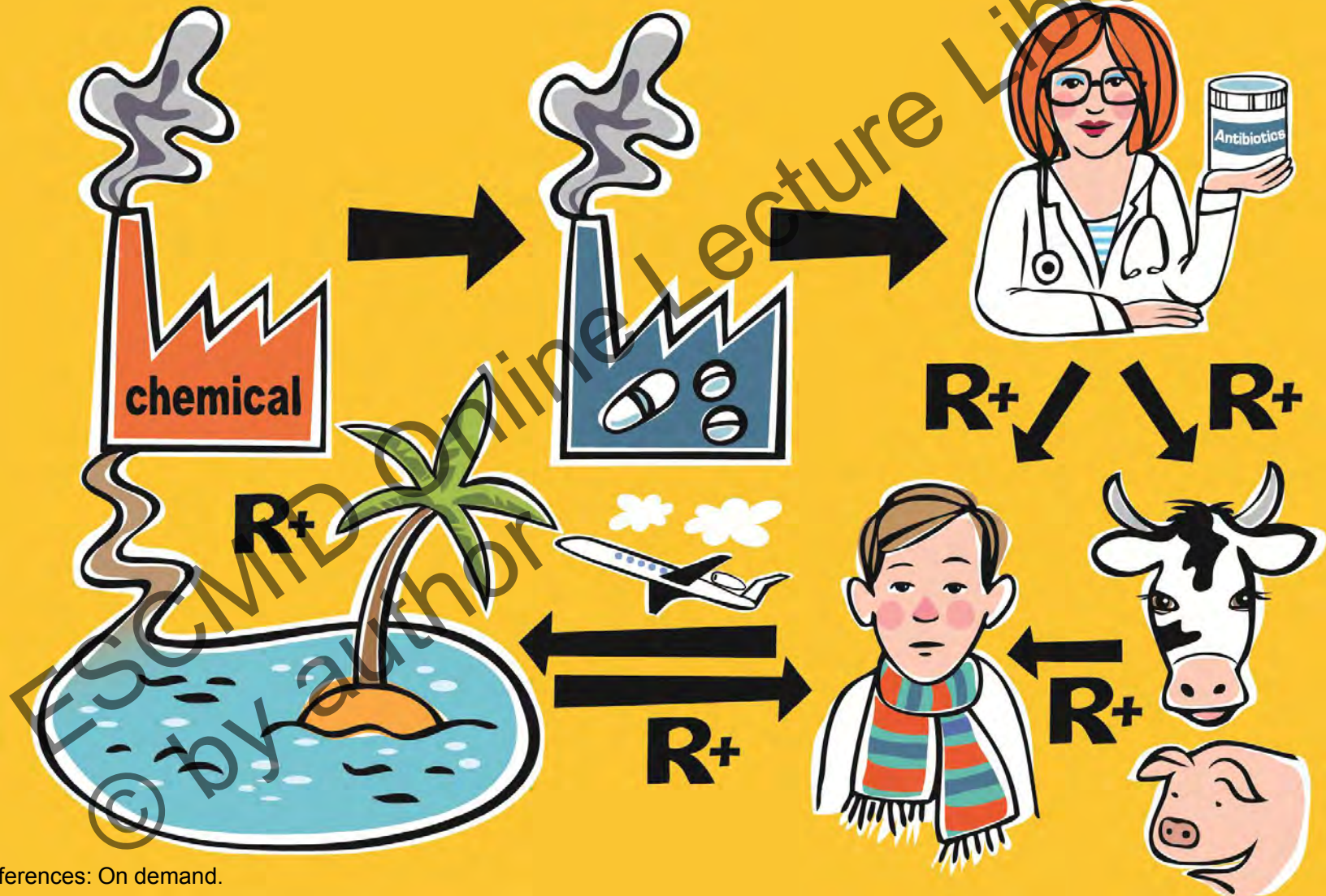
# The way to success – the industry perspective

- Define stakeholders
  - Important: open application process for all relevant industry stakeholders
- Define programs for candidate(s) and resources needed
  - Define required data
  - Challenge timelines continuously and define exits.
- Obtain all available data incl Data on file
- Secure financing and pricing – reward for the industry

# Challenges & opportunities



# .. and other challenges for all of us



References: On demand.

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**Thank you for your time!**

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