Opportunities in pediatrics and geriatrics

October 2, 2012

Boston (USA)

Sven Stegemann
History (2006)

ICH E 11 „Clinical investigation of medicinal products in the paediatric population“

Preterm newborn infants  Term newborn infants  Infants and Toddlers  Children  Adolescents

0 → 1 m → 2 y → 6 y → 12 y → 16 y → 18 y

Preterm newborn infants  Term newborn infants  Infants and Toddlers  Pre-school children  School children  Adolescents

CHMP reflection paper „Formulations of choice for the paediatric population“

Paediatric Investigation Plan (PIP)

New chemical entities:
Supplementary Protection Certificate (SPC)

„Old“ drug substances:
Paediatric Use Marketing Authorisation (PUMA)
History (2011)

- Cumulative number of drug launches: > 600 drug between 1992 – 2012

![Graph showing the cumulative number of drugs launched from 1992 to 2008.](image)

- N° of chronic disease ↑
- N° of prescribed medicines & Polypharmacy ↑

“Age trend” across sections

Birth cohorts:
- 1887–1900
- 1901–1910
- 1911–1922

Number of chronic diseases

Life decade

Berliner Alterstudie Akademie Verlag 2010
History (2011)

<table>
<thead>
<tr>
<th></th>
<th>2010</th>
<th>2050</th>
<th>% increase</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Developed Countries</strong></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Total population</td>
<td>1,365,899</td>
<td>1,402,753</td>
<td></td>
</tr>
<tr>
<td>People ≥ 65 years</td>
<td>204,140</td>
<td>343,396</td>
<td></td>
</tr>
<tr>
<td>90 + years</td>
<td>8,166</td>
<td>37,774</td>
<td>463 %</td>
</tr>
<tr>
<td>80 – 89 years</td>
<td>46,952</td>
<td>85,849</td>
<td>183 %</td>
</tr>
<tr>
<td>65 – 79 years</td>
<td>149,022</td>
<td>219,773</td>
<td>147 %</td>
</tr>
<tr>
<td><strong>Developing countries</strong></td>
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<tr>
<td>Total population</td>
<td>5,539,491</td>
<td>7,785,103</td>
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<tr>
<td>People ≥ 65 years</td>
<td>323,716</td>
<td>1,122,963</td>
<td></td>
</tr>
<tr>
<td>90 + years</td>
<td>12,949</td>
<td>123,526</td>
<td>954 %</td>
</tr>
<tr>
<td>80 – 89 years</td>
<td>74,455</td>
<td>280,741</td>
<td>377 %</td>
</tr>
<tr>
<td>65 – 79 years</td>
<td>236,312</td>
<td>718,696</td>
<td>304 %</td>
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Table: Total population and people ≥ 65 years between 2010 & 2050 and their percentage in different age groups beyond 65 years (www.earthtrends.wri.org)

- Today 10% of the population is ≥ 65 years, they use 30-50% of all prescribed medicines. In 2050 20% will be ≥ 65 years and use 60 – 90% of all Rx products
- The European Medicines Agency has launched their Geriatric Medicines Roadmap 2015 in February 2011
History (20xx)

The actual and future situation is a recent development

- The significantly increasing number of the older patients in our clinical practice
- The increasingly higher age of our patients in primary and secondary care
- The early onset and number of chronic diseases (due to lifestyle)
- The extend of drug therapy and polypharmacy
- The level of “demand” and “involvement” of older adults
- The diversity and complexity of healthcare services to older adults
## Stages of drug product supply

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<tr>
<th>Controlled</th>
<th>Strictly Controlled</th>
<th>No control</th>
</tr>
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<tr>
<td><strong>Industry</strong></td>
<td><strong>Distribution</strong></td>
<td><strong>Patient</strong></td>
</tr>
<tr>
<td><strong>Physician</strong></td>
<td><strong>Pharmacy</strong></td>
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### Knowledge

- **Drug Product**
- **Clinical**
- **Healthcare support**

### Stages

1. **Diagnosis**
   - Prescri
   - Prescription
   - Physician
   - Distribution
   - Industry
2. **Diagnosis**
   - Prescri
3. **Diagnosis**
   - Prescri

### Therapeutic outcome

- Discovery
- Development & Clinical
- Manufacturing & QA
- Supply Chain
- Wholesaler
- Patient
- Therapy schedule
- Administration
- Adherence

?
Stages in drug therapy

Stage I: From health issue to drug
1. Experience a health symptom
2. Decides to visit a physician
3. Visit one or more physician's
4. Examination by the physician
5. Information by the physician on disease
6. Receipt of a prescription
7. Decision to execute the prescription
8. Goes to the pharmacy
9. Receipt of (other) information about the medication
10. Exchange the prescription with one or more drug products

Stage II: From drug to adherence
1. Return home with the drug product(s)
2. Receipt of further information through internet and relatives
3. Understand the therapy and proceedings
4. Development of a therapeutic management schedule
5. Establish a therapeutic implementation plan
6. Follow the therapeutic schedule on time
7. **Access and take out the medication of primary packaging**
8. Pick up the medication and administer
9. Judge the therapeutic effect & ADRs of the medication
10. Decide to continue medication or re-schedule
11. Decide to visit the physician again
The challenge

- Homogeneity - heterogeneity
- Disease - morbidity
- Single drug - polypharmacy
- Age relation - differential
- Developmental - declining
- Acute - chronic
- ...
From Pediatrics to Geriatrics

Geriatry

Health status

Efficacy

Quality of life

Healthcare efficiency

Gerontology

Independence

Effectiveness
AAPS Workshop on Patient-centric Drug Delivery, Product Design and Development: Meeting the Requirements in Future Healthcare

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October 13-14, 2012
McCormick Place Chicago
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Discovery
Development & Clinical Manufacturing & QA
Supply Chain
Wholesaler

1. Diagnosis
2. Prescription
3. Diagnosis

Therapeutic outcome

Disciplinary responsibility and knowledge