The aim of this workshop is to consider safety when dealing with medicinal products with particular regard to demographic change. Especially where the elderly are concerned, medication errors and adverse drug events frequently occur. Therefore, preventive measures shall be discussed above all, as they may help to avoid medication errors among this group of patients, and also the subsequently resulting expenses in the future. WHO will present the 'Global Patient Safety Challenge - Medication Safety' which it plans to launch in the first half of 2017.
The German Action Plan for Medication Safety

Prof. Dr. med. Wolf-Dieter Ludwig, M.D., Ph.D.
Chairman of the Drug Commission of the German Medical Association (DCGMA) and Head of the Dept. of Hematology, Oncology, Tumor Immunology and Palliative Care, HELIOS Clinic Berlin-Buch
Disclosure of Competing Interests

- No financial conflicts of interest to disclose
- Chairman of the DCGMA
- Head of the Dept. of Hematology, Oncology, Tumor Immunology, and Palliative Care
- Editor of the independent drug bulletin “DER ARZNEIMITTELBRIEF” (ISDB)
- Member of the EMA Management Board
- Member of the scientific advisory board of two health insurance funds in Germany
Action plans for improving medication safety in Germany

- Focus of the action plans to improve medication safety
  - Provide necessary information
  - Support the patient
  - Support physicians and pharmacists
  - Initiation of research

Selected results of the Action Plan

1. Action plan for improving medication safety in Germany
   - Embryotox-database (https://www.embryotox.de/)
   - Patient information leaflet for safe drug therapy
   - ADE-Database (PEI) online
   - DIVI-Norm for syringes
   - 2007

2. Congress for Patient Safety during Drug Therapy
   - 2008–2009

3. Congress for Patient Safety during Drug Therapy
   - 2005

4. Action plan for improving medication safety in Germany
   - "eHealth"-law from 21.12.2005:
     § 31a SGB V medication list: claim from 01.10.2016
   - Specification for a medication plan (Version 2.2)
   - 2013–2015

5. Congress for Patient Safety during Drug Therapy
   - 2016–2019

- Memorandum on Drug Therapy Safety Management Research
- Definitions related to pharmacovigilance and drug safety
- Mediation guide (MTX, NOAC)
- Specification BMP Version 2.0
- Test phase medication plan
- Project Medication Error at the DCGMA (2015–2017)
- ADE-database (BfArM) online
- 2010–2012

Selected results of the Action Plan

2. International Day of Patient Safety 2016: Medication Safety
   - 2016–2019

4. Congress for Patient Safety during Drug Therapy
   - 2013–2015

- ADE-database (BfArM) online
- 2013–2015

3. Action plan for improving medication safety in Germany
   - UAW-Database (BfArM) online
   - 2010–2012

2. Action plan for improving medication safety in Germany
   - PRISCUS-list
   - Bulletin Drug Safety
   - 2008–2009

1. Action plan for improving medication safety in Germany
   - 2005

- Patient information leaflet for safe drug therapy
- ADE-Database (PEI) online
- DIVI-Norm for syringes
- 2007

2. Congress for Patient Safety during Drug Therapy
   - 2008–2009

3. Congress for Patient Safety during Drug Therapy
   - 2005
Selected results of the Action Plan
Embryotox database

- Database on drugs during pregnancy and lactation of the
- Pharmacovigilance Center in Berlin

www.embryotox.de
Selected results of the Action Plan

1. Action plan for improving medication safety in Germany
   Embryotox-database (https://www.embryotox.de/)
   Patient information leaflet for safe drug therapy
   ADE-Database (PEI) online
   DIVI-Norm for syringes

2. Congress for Patient Safety during Drug Therapy
   PRISCUS-list
   Bulletin Drug Safety
   Memorandum on Drug Therapy Safety Management Research
   Definitions related to pharmacovigilance and drug safety
   Medication guide (MTX, NOAC)

3. Action plan for improving medication safety in Germany
   Specification BMP Version 2.0
   "eHealth"-law from 21.12.2005:
   § 31a SGB V medication list: claim from 01.10.2016
   Specification for a medication plan (Version 2.2)

4. Action plan for improving medication safety in Germany
   UAW-Database (BfArM) online
   Test phase medication plan
   Project Medication Error at the DCGMA (2015–2017)
   ADE-database (BfArM) online


2007
1. Congress for Patient Safety during Drug Therapy

2008–2009
2. International Day of Patient Safety 2016: Medication Safety

2009–2012

2010–2015

2013–2018

2016–2019

2016–2019
Selected results of the Action Plan
Patient information leaflet for safe drug therapy

Tips (e.g.) for safe drug therapy

- Please list all medicines you are currently using (medication plan).
- Please show the medication plan at each doctor's visit.
- Please observe all instructions for use of your medicines.
- Please ensure that you have understood all the information correctly.

Selected results of the Action Plan

Bulletin Drug Safety (BfArM and PEI)

- Published by the NCAs (BfArM and PEI)
- Information on current aspects of the risk assessment of drugs
- Communication of possible risks
- Appears four times a year

Reference: http://www.bfarm.de/DE/Arzneimittel/Pharmakovigilanz/Bulletin/_node.html
Selected results of the Action Plan
DIVI-Norm for syringes

- Working group from the Action plan and DIVI (German Interdisciplinary Association for Intensive Care and Emergency Medicine)
- Uniform design of syringe labels in anesthesia, emergency and intensive care

Reference: http://www.divi.de
Selected results of the Action Plan

1. Action plan for improving medication safety in Germany
   - Embryotox-database (https://www.embryotox.de/)
   - Patient information leaflet for safe drug therapy
   - ADE-Database (PEI) online
   - DIVI-Norm for syringes

2. Action plan for improving medication safety in Germany
   - PRISCUS-list
   - Bulletin Drug Safety
   - Memorandum on Drug Therapy Safety Management Research
   - Definitions related to pharmacovigilance and drug safety
   - Medication guide (MTX, NOAC)

3. Action plan for improving medication safety in Germany
   - UAW-Database (BfArM) online
   - Test phase medication plan
   - Project Medication Error at the DCGMA (2015–2017)

4. Action plan for improving medication safety in Germany
   - ADE-database (BfArM) online

5. Congress for Patient Safety during Drug Therapy

Additionally:
- Specification for a medication plan (Version 2.2)
High-alert medications

- Drugs that bear an increased risk of causing significant patient harm when used in error.

- Although mistakes may or may not be more common with these drugs, the consequences of an error are clearly more devastating to patients.
Selected results of the Action Plan
Recommendations for high-risk drugs

- Drugs with high risk potential in case of incorrect application (ISMP-list)
- Publishing recommendations for different target groups (physicians, pharmacists, nurses, patients)
  - Methotrexate (MTX)
  - Vincristine
  - New anticoagulants

Reference: https://www.ismp.org
1. Congress for Patient Safety during Drug Therapy

2. Action plan for improving medication safety in Germany
   - PRISCUS-list Bulletin Drug Safety
   - Embryotox-database (https://www.embryotox.de/)
   - Patient information leaflet for safe drug therapy
   - ADE-Database (PEI) online
   - DIVI-Norm for syringes

3. Congress for Patient Safety during Drug Therapy

4. Action plan for improving medication safety in Germany
   - UAW-Database (BfArM) online
   - Test phase medication plan
   - Project Medication Error at the DCGMA (2015–2017)
   - ADE-database (BfArM) online


Selected results of the Action Plan
ADE-database PEI and BfArM

http://nebenwirkung.bfarm.de

http://pei.de/db-uaw
# Selected results of the Action Plan

**Medication plan**

### Medikationsplan

<table>
<thead>
<tr>
<th>Wirkstoff</th>
<th>Handelsname</th>
<th>Stärke</th>
<th>Form</th>
<th>Mo Mi Ab 2N</th>
<th>Hinweise</th>
<th>Grund</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kombi-Präp.</td>
<td>INEGY 10mg/20mg N</td>
<td>500 mg</td>
<td>Tabl.</td>
<td>0 0 1</td>
<td>Stöck</td>
<td>nach der Mahlzeit</td>
</tr>
<tr>
<td>Mometason-17-2-...</td>
<td>Nasonex 50 µg/25 µg</td>
<td>50 µg</td>
<td>Spray</td>
<td>1 1 1</td>
<td>Hübe</td>
<td>kompletter Sprühstöll</td>
</tr>
<tr>
<td>Theophyllin</td>
<td>Trommophil retard 600</td>
<td>600 mg</td>
<td>Tabl.</td>
<td>1/2 0,5 1/2</td>
<td>Stöck</td>
<td>vor dem Essen mit viel W</td>
</tr>
<tr>
<td>Calcium Carbonat</td>
<td>Calcium Sandoz D 1900 mg</td>
<td>0,11 mg</td>
<td>Tabl.</td>
<td>1/4 0,26 1/4</td>
<td>Stöck</td>
<td>in 1 Glas Wasser lösen</td>
</tr>
<tr>
<td>Ibuprofen-Lysin</td>
<td>Ibu-Lysin AbZ Migraine 648 mg</td>
<td>0,61 mg</td>
<td>Tabl.</td>
<td>1 0 1 1</td>
<td>Stöck</td>
<td>bitte an die Zeiten halten</td>
</tr>
<tr>
<td>Hauptsaft (Polidocanol-600-Zinkoxidabcesetmixture 5%)</td>
<td>Polidocanol-600-Zinkoxidabcesetmixture 5%</td>
<td>2x täglich auf Handflächen (mo. &amp; ab. nach Handewasch</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Selbstmedikation

<table>
<thead>
<tr>
<th>Wirkstoff</th>
<th>Handelsname</th>
<th>Stärke</th>
<th>Form</th>
<th>Einheit</th>
<th>Grund</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetaminol</td>
<td>Ormolon A Orabase</td>
<td>50 mg</td>
<td>Salbe</td>
<td>1 1 1 1</td>
<td>Hühne in Brasilen erworben</td>
</tr>
<tr>
<td>Diphenhydramin-HCl</td>
<td>50 µg/25 µg</td>
<td>50 µg</td>
<td>Tbl.</td>
<td>0 0 0 0</td>
<td>Stöck</td>
</tr>
<tr>
<td>Magnesium</td>
<td>Magnesium A.A.A.</td>
<td>500 mg</td>
<td>Granul.</td>
<td>Immer möglich Beutel</td>
<td>gleich nach den Aufwach</td>
</tr>
<tr>
<td>Ein-neuer/Winne</td>
<td>10 mg Pulver</td>
<td>1/ Woche</td>
<td>EL</td>
<td>nur nach Rücksprache</td>
<td></td>
</tr>
</tbody>
</table>

### Wichtige Angaben

Bitte melden Sie Ihren Blutdruck täglich!
Nächster Impftermin: 24.02.2014
Beider Rissen in der Hornhaut bitte Desinfektion auftragen.

Firma 24medplan - rund um Uhr die erreichbar

Reference: [http://www.kbv.de/media/sp/Medikationsplan_Beispiel.pdf](http://www.kbv.de/media/sp/Medikationsplan_Beispiel.pdf)
Selected results of the Action Plan

1. Action plan for improving medication safety in Germany
   - Embryotox-database (https://www.embryotox.de/)
   - Patient information leaflet for safe drug therapy
   - ADE-Database (PEI) online
   - DIVI-Norm for syringes

2. Congress for Patient Safety during Drug Therapy
   - PRISCUS-list
   - Bulletin Drug Safety

3. Congress for Patient Safety during Drug Therapy
   - Memorandum on Drug Therapy Safety Management Research
   - Definitions related to pharmacovigilance and drug safety
   - Medication guide (MTX, NOAC)

4. Action plan for improving medication safety in Germany
   - "eHealth"-law from 21.12.2005:
     § 31a SGB V medication list: claim from 01.10.2016
   - Specification for a medication plan (Version 2.2)

5. Congress for Patient Safety during Drug Therapy
   - UAW-Database (BfArM) online
   - Test phase medication plan
   - Project Medication Error at the DCGMA (2015–2017)

2005
1. Congress for Patient Safety during Drug Therapy

2007
2. Congress for Patient Safety during Drug Therapy

2008 – 2009
- Patient information leaflet for safe drug therapy

2008
- ADE-Database (PEI) online
- DIVI-Norm for syringes

2010 – 2012
- Specification BMP Version 2.0

2010
- Memorandum on Drug Therapy Safety Management Research
- Definitions related to pharmacovigilance and drug safety
- Medication guide (MTX, NOAC)

2013 – 2015
- UAW-Database (BfArM) online
- Test phase medication plan
- Project Medication Error at the DCGMA (2015–2017)

2013
- ADE-database (BfArM) online

2016 – 2019

2016
- ADE-database (BfArM) online

2017 – 2019
4. Action plan (2016-2019) for improving medication safety in Germany

- 42 measures (14 workshops)
- Focus of the action plan
  1. Raising awareness among patients, physicians, pharmacists, nurses and the public for avoidable risks of drug therapy
  2. Improvement of information on drugs, labeling of drugs
  3. Documentation of drug therapy and measurement of medication safety
  4. Strategies to improve the safety of the medication safety process
  5. Research in the field of medication safety
  6. Organization of the implementation and continuation of the action plan

Unwanted drug effects occur particularly in people who use several drugs simultaneously for long time. It is estimated that there are seven preventable side effects per 100 outpatients with drug therapy every year. About five percent of all hospital admissions are attributable to adverse drug effects, a quarter could be avoided. This means that approximately 250,000 hospital admissions are attributable to preventable medication errors every year.
Thank you for your attention.

http://www.akdae.de
Project of recording and assessing medication errors within the German spontaneous reporting system

**Funding:** Federal Ministry of Health (Germany)

**Organization:** Drug Commission of the German Medical Association

**Project duration:** 2015 - 2017

**Aims:** Feasibility of an analysis of medication errors (ME) within the existing structures of the spontaneous reporting system

Deduction of risk factors and intervention strategies

**Methods:** ME reported spontaneously by physicians

ME that have caused or may cause harm to the patient

Possibility of anonymous reporting

**Results:** Are expected by the end of 2017