2SPD-015: RISK-ADAPTED MANAGEMENT OF DRUG SHORTAGES TO ENSURE PROPER CARE FOR PATIENTS IN MEDICAL NEED

B. Bel Ladron de Guevara1, K. Bornhauser2, T. Lange1, S. Duda1, A. Liekweg3.
1Uniklinik Köln, Hospital Pharmacy, Cologne, Germany.

Background and Aims

**BACKGROUND**
Increase of Drug Shortages (DS) within the last years, also affecting essential drugs. Overview and transparency cannot be guaranteed anymore.

**BACKGROUND**
No reliable German central database. Lack of information from the industry.

**AIM**
Method development: Own monitoring of market situation. Definition of work and communication flow within the pharmacy and to the clinic.

**AIM**
Rapid reaction and management. Improvement of interprofessional cooperation and communication in case of a (critical) DS. Identification of the best alternative for the patients. Adaptation of Drug-Supply Chain (DSC).

Material and methods
Development of a colour-coded algorithm depending on drug availability in an Excel Sheet for our 1600 bed maximal care facility upon each information from the industry, whether automatically informed or after active call. The sheet is updated manually by a pharmacist.

<table>
<thead>
<tr>
<th>Yellow</th>
<th>Orange</th>
<th>Red</th>
<th>Blue</th>
</tr>
</thead>
</table>
| • Alternative available on the market
  • Consider brief information to the affected units |
| • Change of supplier needed
  • Usual supplier has an alternative, e.g. different package size |
| • Alternative available, but with relevant changes, e.g. import
  • Very limited supply
  • Internal compounding at the pharmacy
  • No alternative
  • Consider interprofessional consultation
  • Information hand-out to the affected units |
| • DS was recorded but we were not affected in any form e.g. due to sufficient stock |

Check if any changes have to be made to:
• master-data
• ward-order-system
• kanban-system

Cut-out from the Excel Sheet:

<table>
<thead>
<tr>
<th>Internal Ref.-No.</th>
<th>Name</th>
<th>Internal Nr.</th>
<th>Ordered on</th>
<th>Supplier</th>
<th>Estimated shortage until</th>
<th>Alternative (supplier)</th>
<th>Reason/Comments</th>
<th>Hand-Out to unit/clinic</th>
<th>Received on</th>
</tr>
</thead>
<tbody>
<tr>
<td>2018.55</td>
<td>Theophylline Ampoules</td>
<td>100345</td>
<td>11/01/2018</td>
<td>Levy Pharma</td>
<td>Unknown</td>
<td>None. Import from Austria</td>
<td>Stockpiling: Consultation with public officer (pharmacist) needed</td>
<td>Yes, Info-sheet</td>
<td>09/07/2018 (German product)</td>
</tr>
<tr>
<td>2018.57</td>
<td>Erythromycin Sirup</td>
<td>107079</td>
<td>03/01/2018</td>
<td>Hexal</td>
<td>Unknown</td>
<td>Infectopharm</td>
<td>None</td>
<td>Yes, e-mail</td>
<td>Still open</td>
</tr>
<tr>
<td>2018.225</td>
<td>Flupentixol Drops</td>
<td>103097</td>
<td>Not ordered yet</td>
<td>Bayer</td>
<td>Unknown</td>
<td>Tablets</td>
<td>Informative e-mail from Bayer</td>
<td>No</td>
<td>26/07/2018</td>
</tr>
</tbody>
</table>

Algorithm of DS-Management of an essential drug (classified as red):

**STEP 1**
Pharmaceutical analysis
• Range of coverage
• Check for alternatives
• Check for possible use restrictions (dependent on indication)

**STEP 2**
Interprofessional consultation with physicians and nurses for the medical management

**STEP 3**
Informative hand-out to the affected units/clinics

**STEP 4**
Implementation of the measures in the everyday clinical practice
• Changes in the DSC
• Restrictions in the dispensing process e.g. dependent on indication
• Self-compounding in the pharmacy
• Import

**STEP 5**
Send information to the affected units as soon as the drug is available again

Results

Drug Shortages 1st January 2018-30th June 2018

Conclusions
• Standard procedures and interdisciplinary communication paths are necessary.
• Different decisions have to be made for each DS individually.
• Restrictions of therapeutic alternatives need to be determined.
• Close collaboration among pharmacists, nurses, physicians and even logistics is inevitable and may as well have to be reinforced in the future due to the continuous increase of DS.
• The development of this algorithm has provided our clinic with an overview which enables every co-worker of the pharmacy to find the information needed fast.
• The colour-coded list allows every co-worker to immediately understand the importance and risk of the listed DS.
• One interprofessional consultation lasts 1 hour on average. The management of DS of essential drugs takes up approximately one full time equivalent of a pharmacist. In addition resources of medical staff have to be taken into account.
• A greater impact is expected in the next years due to the current political situation (Brexit), which will most likely increase the time and energy spent on those issues on all sides. This might also lead to the need to recruit more pharmaceutical staff.
• The publishing and communication of each drug shortage in a centralized national database should become mandatory in Germany.
• It would be helpful to get more support on the search and supply for alternatives by the authorities, e.g. from the Ministry of Health or attached departments, in case of a DS of an essential drug. This would at least diminish the time invested in each German hospital.
• The local drug production should be supported. Despite higher initial costs, the investment may well be worth it in the long run.

blanca.bel@uk-koeln.de