Drug shortages seen from the hospital side – How to improve the situation?

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The situation in May 2016

1. Methodology
   - Count of the shortages: permanent, temporary, no delay
   - Count of the limitation of supply: quota

2. Results
   - Out of 51 shortages:
     - 26 under patent specialties
     - 25 generics
     - 50% no delay of supply

3. Main difficulties
   - Antibiotics (cefotaxime, cefamandole, cloxacillin, fosfomycin, erythromycin ...)
   - Vaccines ++
   - Contrast media
   - Ig IV

Comparison with May 2013
Worsening of the situation = increase of 60% (31 shortages)
Other reasons for drug shortages (GPO side)

- Big GPOs
- Supply chain management failure
- Pricing management: too low prices offered to the different GPOs whatever their size → suppliers leave the national market
- No harmonisation of the tendering calendar
- Duration of the tender
- Too late responses for the deal (ex: December for a start of delivering in January)
Two different situations of shortages

- Under patent pharmaceuticals
- Generics

→ Consequences are slightly different
→ Bad care for the patient in each situation

A new law on the modernisation of the French health system (Jan. 2016)

- Safety for care: Reaction to drug shortages
- Major therapeutic interest medications:
  - A break in the treatment puts the patient in danger
  - Brings an important loss of chance regarding the situation of his illness
- Information of the National Drug Agency (ANSM)
- Shortage management plan for these specific medications driven by the suppliers
Generic pharmaceuticals

- Example: oncology agents
- Consequences for the supply chain: quota distribution
- Consequences for the patient: disruptive treatment, risk management ++
- Technical consequences:
  - changes in the concentrations
  - disruptive changes in the manufacturing card
- Economic consequences:
  - changes in the different IT systems (name of the drug, strength ...), financial compensation follow-up, cost difference for the contract holder, financial consequences, delay penalties
  - staff consuming
  - additional costs ++

These consequences are all the more important in regard of the developing GPOs

Propositions

1. Information of the GPO coordinator, the pharmacists, the prescribers +++
2. Anticipation of the shortage
3. Embed the supply safety in the bid analysis criteria (tenders):
   - description of the appropriate means to reduce the shortage risks,
   - consider the shortage risks in the tender evaluation (supplier survey)
4. Pro-activity of the contract holder giving a perspective of the re-delivery
5. The defaulting contracter deals with another supplier who can swiftly compensate the pharmacies (or the GPO) for the failure of the holder
6. Creation of a national database (Ansm) with an easy access and consultation for the professionals – Should include comprehensive information for the hospital providers (GPOs)
Supplier survey: global or limited to some therapeutic classes

<table>
<thead>
<tr>
<th>Geographic location</th>
<th>Worldwide</th>
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<tbody>
<tr>
<td></td>
<td>Europe</td>
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<tr>
<td></td>
<td>2 or 3 European countries including France</td>
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<tr>
<td>Delivery channel</td>
<td>Retail and hospital</td>
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<td>Hospital exclusive</td>
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<td>API sourcing</td>
<td>Single-site</td>
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<td>Multi-site</td>
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<td>Production means</td>
<td>Inner</td>
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<td></td>
<td>Outsource</td>
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<td>Management means to prevent shortages</td>
<td>Monitoring</td>
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<td></td>
<td>Quality control</td>
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<tr>
<td>Medium rates of shortages on the last three years</td>
<td>✓</td>
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<td>Investments on the delivery and/or production site achieved on the last three years</td>
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<td>Supply chain connection</td>
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<tr>
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<td>✓ Other</td>
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<td>Stock coverage (months)/deal</td>
<td>✓ Yes - How many months? Cost?</td>
</tr>
<tr>
<td></td>
<td>✓ No</td>
</tr>
</tbody>
</table>

Question: How to evaluate this survey in an objective way?

Conclusion

- Very difficult to appreciate the shortage risk
- Higher requirement levels
- Are we ready to pay slightly more considering a 6 month stock commitment from the supplier?
- In order to limit the risk, why not deal with 2 suppliers: 80/20 volumes