Establish Product Priority

Assess Risk to Supply

Develop Mitigation Options and Agility

Strategy

Implement & Execute Response Plans

ICH Q9

Risk Assessment
  • Risk Identification
  • Risk Analysis
  • Risk Evaluation

Risk Control
  • Risk Reduction
  • Risk Acceptance

Risk Communication

Risk Review

Risk Management Tools

MONITOR and REFRESH

COMMUNICATE with HEALTH AUTHORITIES
Product Priority?

Discretionary Plans Needed?

Assess Risk to Continuous Supply
- Product-Specific Risks
- Business / Operational Risks

Mitigation Approach?
- Redundancy or Stockpiling
- Agility
- Combination

Implement Business Continuity Plans

Health Authority Communications as needed throughout process

Business Continuity Task Force: Monitor and Refresh
<table>
<thead>
<tr>
<th>Indication</th>
<th>Population</th>
<th>Type Of Product</th>
<th>Alternative Care</th>
<th>Dosage Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Life Supporting or Life Sustaining</td>
<td>Serves a large population</td>
<td>Seasonal</td>
<td>First in class</td>
<td>IV used in a hospital or clinical setting</td>
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<tr>
<td>Used in surgery or intensive care</td>
<td>Provides a small population with significant therapeutic value (e.g., orphan drug, CAR T)</td>
<td>Rx or OTC</td>
<td>Alternate brand therapies</td>
<td>Dose for pediatrics (e.g., oral suspension)</td>
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<tr>
<td>Used for a debilitating disease or condition</td>
<td>Part of a national stockpile</td>
<td>Used for emergency events or a public health emergency</td>
<td>Alternative older therapies (e.g., chemotherapy instead of biologics)</td>
<td>Convenience presentation</td>
</tr>
<tr>
<td>Product with more than one indication</td>
<td></td>
<td></td>
<td>Generic options</td>
<td></td>
</tr>
</tbody>
</table>
Establish Product Priority

Therapeutically Important?

Supply subject to Regulatory Requirements?

Is There Business Significance?
- High revenue position?
- Large market share?
- Interconnectedness to other products?

Most products fall somewhere in between

High Priority
Rigorous Business Continuity Planning

Low Priority
Discretionary Business Continuity Planning
Adjust target based on product priority and identified risks

Traditional, pre-selected, well-defined
Predictable, with expected outcomes
More expensive

Multiple Options predefined, dynamic
Flexible, potential for the unexpected
More cost effective
Change in Risk to supply:
1. Loss Of Supplier
2. Inspection results
3. Post -approval CMC changes
4. Changes in demand

Change in Product Priority:
1. Therapeutic value changes
2. Generic competition change
3. Change in market share
4. Product no longer marketed