

Figure 6.1-1 Risk-Based Approach to Drug Shortage Prevention

1. Define impact to patient			Availability of Alternatives		
			No Alternatives Available	Alternative Products Available: Similar Therapy	Exact Product Available but in Other Presentations
Therapeutic Use & Consequences if Product not Available	Medically Necessary Product, Life supporting or Life sustaining	Fatal or severe irreversible harm if the patient is not treated with the product	Risk Level A	Risk Level A	Risk Level B
	Acute short term or chronic long term	Severe harm but reversible if patient is not treated with the product	Risk Level A	Risk Level B	Risk Level C
	Other indications	Inconvenience if patient is not treated with the product	Risk Level B	Risk Level C	Risk Level C

2. At each risk level consider the likelihood of a drug shortage and ways to avoid this

3. Define priority		Likelihood of Shortage		
		High	Moderate	Low
Therapeutic Use & Consequences if Product not Available	Risk Level A	Risk Priority Level 1	Risk Priority Level 1	Risk Priority Level 2
	Risk Level B	Risk Priority Level 1	Risk Priority Level 2	Risk Priority Level 3
	Risk Level C	Risk Priority Level 2	Risk Priority Level 3	Risk Priority Level 3

4. Triage output: Drug Shortage Prevention and Response Plan

Risk Priority	Suggested Controls
Level 1	<ul style="list-style-type: none"> Appropriate inventory and safety stock management Multi site sourcing with higher manufacturing capacity reserves Supplier management controls (see sec. 5.4 of TR54) Supply chain/transportation line security, business continuity and communication plan Extended Value Stream Mapping (VSM)
Level 2	<ul style="list-style-type: none"> Consider multi site sourcing Value Stream Mapping (VSM) Proactive inventory management Process capability and robustness exercised (with Quality Metrics)
Level 3	<ul style="list-style-type: none"> Generally accepted risk level