

			Availability of Alternatives		
			No Alternatives Available	Alternative Products Available: Similar Therapy	Exact Product Available but in Other Presentations
Therapeutic Use & Consequences if Alternate 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. Assess the likelihood of shortage: at each level consider the likelihood of drug shortages and the risk controls to prevent it

3. Define the risk priority level

		Likelihood of Shortage		
		High	Medium	Low
Therapeutic Use & Consequences if Alternate 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. Risk Output: Develop and Implement preventive risk control strategies

Risk Priority	Suggested controls/preventive actions
Level 1	Preventive actions and/or response plan required
Level 2	Preventive actions and/or response plan recommended; option to accept residual risk
Level 3	Generally accepted risk level

Figure 6.1.1-1 The Four Steps in the Risk-Based Approach to Drug Shortage Prevention