

Risk Management Guidance (2):



Risk Minimization Action Plans – “RiskMAP” (cont.)

Category	Description	Examples
Targeted Education and Outreach	<p>Recommended when:</p> <ol style="list-style-type: none">1. Product risks cannot be minimized with risk minimization measures alone2. As a component of “RiskMAPs” using reminder or performance-linked access systems	<ul style="list-style-type: none">• Healthcare provider letters• Training programs for healthcare providers/patients & CE• Prominent professional or public notifications• Patient labeling or package inserts• Focused or limited promotional techniques such as product sampling or DTC advertising
Reminder Systems	<p>Recommended when targeted education and outreach are insufficient</p>	<ul style="list-style-type: none">• Patient agreement forms• Certification program for providers• Limited amount of uses• Specialized Packaging
Performance-Linked Access Systems	<p>Recommended when:</p> <ol style="list-style-type: none">1. Product have significant or otherwise unique benefits in a particular patient group or condition but unusual risks exist2. Above categories insufficient	<ul style="list-style-type: none">• Only by certified Healthcare providers• Product dispensing only by specially certified pharmacies• Product utilization only to patients with evidence or other documentation of safe use conditions