

# 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"><li>1. Product risks cannot be minimized with risk minimization measures alone</li><li>2. As a component of “RiskMAPs” using reminder or performance-linked access systems</li></ol>	<ul style="list-style-type: none"><li>• Healthcare provider letters</li><li>• Training programs for healthcare providers/patients &amp; CE</li><li>• Prominent professional or public notifications</li><li>• Patient labeling or package inserts</li><li>• Focused or limited promotional techniques such as product sampling or DTC advertising</li></ul>
Reminder Systems	<p>Recommended when targeted education and outreach are insufficient</p>	<ul style="list-style-type: none"><li>• Patient agreement forms</li><li>• Certification program for providers</li><li>• Limited amount of uses</li></ul> <p>Specialized Packaging</p>
Performance-Linked Access Systems	<p>Recommended when:</p> <ol style="list-style-type: none"><li>1. Product have significant or otherwise unique benefits in a particular patient group or condition but unusual risks exist</li><li>2. Above categories insufficient</li></ol>	<ul style="list-style-type: none"><li>• Only by certified Healthcare providers</li><li>• Product dispensing only by specially certified pharmacies</li><li>• Product utilization only to patients with evidence or other documentation of safe use conditions</li></ul>