

# Table of Contents

<b>1</b>	<b>Introduction .....</b>	<b>7</b>
1.1	Background.....	7
1.2	Overview.....	8
1.3	Scope.....	8
1.4	Purpose.....	9
1.5	Benefits.....	9
1.6	Key Concepts.....	9
<b>2</b>	<b>Regulatory Framework and Considerations .....</b>	<b>13</b>
2.1	Summary and Interpretation of Current Regulations Related to NIMPs .....	13
2.2	Interpretation of the Regulations.....	14
2.3	Is the Medicinal Product an IMP or a NIMP? .....	17
2.4	NIMPs without Market Authorizations and Off-label Use .....	19
<b>3</b>	<b>Technical Aspects of NIMPs in Clinical Trials .....</b>	<b>21</b>
3.1	Sourcing Strategy .....	21
3.2	Considerations When Compiling a Sourcing Strategy .....	24
3.3	Packaging and Labeling.....	28
3.4	Storage and Distribution .....	29
3.5	Management of Drug Traceability, Accountability, Returns, and Destruction.....	29
3.6	Management of Complaints and Recalls Associated with NIMPs.....	31
3.7	Management of Adverse Events Associated with NIMPs .....	32
3.8	Comparison of the Impact Sourcing Strategy on NIMP Management .....	32
<b>4</b>	<b>Commercial Aspects for Consideration .....</b>	<b>35</b>
4.1	Reimbursement.....	35
<b>5</b>	<b>Appendix 1 – Knowledge Sharing Table.....</b>	<b>37</b>
<b>6</b>	<b>Appendix 2 – References .....</b>	<b>45</b>
<b>7</b>	<b>Appendix 3 – Glossary .....</b>	<b>49</b>
7.1	Acronyms and Abbreviations .....	50
7.2	Definitions .....	50