



## Table of correspondence – good manufacturing practice for active substances used as starting materials in veterinary medicinal products

Commission Implementing Regulation (EU) 2025/2154 of 17 October 2025 laying down good manufacturing practice for active substances used as starting materials in veterinary medicinal products in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council	Previous legislation/guidelines
Article 1 Subject matter and scope	<ul style="list-style-type: none"> <li>• EudraLex Volume 4, Part II : 1.1, 1.2</li> <li>• EudraLex Volume 4, Part II : 17.10</li> <li>• EudraLex Volume 4, Annex 6, point 3</li> <li>• EudraLex Volume 4, Annex 7: principle</li> </ul>
Article 2 Definitions	<ul style="list-style-type: none"> <li>• EudraLex Volume 4, Part I, Chapter 1: 1.12</li> <li>• EudraLex Volume 4, Part II: Glossary</li> <li>• EudraLex Volume 4, Part II: 18.12</li> <li>• EudraLex Volume 4, Annex 1: Glossary</li> <li>• EudraLex Volume 4, Glossary</li> </ul>
Article 3 Starting point for the manufacture of active substances	<ul style="list-style-type: none"> <li>• EudraLex Volume 4, Part II: Table 1</li> </ul>
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Article 13 General requirements for premises	<ul style="list-style-type: none"> <li>• EudraLex Volume 4, Part II: 4.1, 4.2, 4.5, 4.6</li> </ul>
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Article 34 Production operations	• EudraLex Volume 4, Part II: 8.1
Article 35 Time limits	• EudraLex Volume 4, Part II: 8.2
Article 36 In-process controls and in-process sampling	• EudraLex Volume 4, Part II: 8.3
Article 37 Blending batches of intermediates or active substances	• EudraLex Volume 4, Part II: 8.4
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Article 39 General requirements concerning packaging and labelling	• EudraLex Volume 4, Part II: 9.1
Article 40 Containers	• EudraLex Volume 4, Part II: 9.2
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Article 43 Storage conditions and warehousing procedures	• EudraLex Volume 4, Part II: 7.4, 10.1
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Article 65 Procedures for complaints and recalls for manufacturers	<ul style="list-style-type: none"> <li>• EudraLex Volume 4, Part II: 15</li> </ul>
Article 66 Requirements for outsourced activities	<ul style="list-style-type: none"> <li>• EudraLex Volume 4, Part II: 16</li> </ul>
Article 67 Traceability of active substances and intermediates	<ul style="list-style-type: none"> <li>• EudraLex Volume 4, Part II: 17.2</li> </ul>
Article 68 Quality management	<ul style="list-style-type: none"> <li>• EudraLex Volume 4, Part II: 17.3</li> </ul>
Article 69 Stability studies	<ul style="list-style-type: none"> <li>• EudraLex Volume 4, Part II: 17.5</li> </ul>
Article 70 Transfer of information	<ul style="list-style-type: none"> <li>• EudraLex Volume 4, Part II: 17.6</li> </ul>
Article 72 general requirements for active substances manufactured by cell culture or fermentation	<ul style="list-style-type: none"> <li>• EudraLex Volume 4, Part II: 18.1</li> </ul>
Article 72 Cell bank maintenance and record keeping	<ul style="list-style-type: none"> <li>• EudraLex Volume 4, Part II: 18.2</li> </ul>
Article 73 Cell culture or fermentation	<ul style="list-style-type: none"> <li>• EudraLex Volume 4, Part II: 18.3</li> </ul>
Article 74 Harvesting, isolation and purification	<ul style="list-style-type: none"> <li>• EudraLex Volume 4, Part II: 18.4</li> </ul>
Article 75 Viral removal and inactivation steps	<ul style="list-style-type: none"> <li>• EudraLex Volume 4, Part II: 18.5</li> </ul>
Article 76 Active substance gases	<ul style="list-style-type: none"> <li>• EudraLex Volume 4, Annex 6, point 3</li> </ul>
Article 77 Entry into force and application	new
ANNEX Starting point of manufacture of active substances	<ul style="list-style-type: none"> <li>• Volume 4 Part II: Table 1</li> </ul>