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2 EMA/CVMP/121133/2025
3 Committee for Veterinary Medicinal Products (CVMP)

4 **Concept paper on the development for guidance on**
5 **demonstration of biosimilarity of biological veterinary**
6 **medicinal products**
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Agreed by the CVMP Temporary Drafting Group on Biosimilar Veterinary Medicinal Products	10 April 2026
Adopted by the CVMP for release for consultation	16 April 2026
Start of public consultation	24 April 2026
End of consultation (deadline for comments)	31 July 2026

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Comments should be provided using this [template](#). The completed comments form should be sent to vet-guidelines@ema.europa.eu.

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Keywords	<i>Biosimilar veterinary medicinal product, hybrid approach, comparability</i>
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12 **1. Introduction**

13 This concept paper addresses the need for a guideline on data requirements for applications for
14 marketing authorisations based on Article 19 of Regulation (EU) 2019/6 ("hybrid veterinary medicinal
15 products") for similar biological veterinary medicinal products, henceforth referred to as "biosimilars".
16 The need to clarify the data requirements for hybrid applications for marketing authorisation
17 concerning biosimilars was identified by requests for scientific advice from companies seeking guidance
18 in this area. Therefore, guidance on the comparability approach in line with section IV.2.3 of Annex II
19 to Regulation (EU) 2019/6 is needed.

20 **2. Problem statement**

21 There is currently no guidance available for veterinary biosimilars concerning how comparability with a
22 biological reference veterinary medicinal product can be demonstrated in order to support a hybrid
23 application which would rely in part on safety and efficacy data for an already authorised biological
24 reference veterinary medicinal product, and in part on new data. In contrast, for non-biological VMPs,
25 guidance is available (Guideline on the conduct of bioequivalence studies for veterinary medicinal



26 products - Revision 4 (EMA/CVMP/016/2000-Rev.4)) and it is assumed that a new candidate VMP
27 containing the same active substance will have similar distribution, metabolism, elimination, and
28 pharmacological effects provided bioequivalence with the reference VMP is demonstrated in accordance
29 with the guideline mentioned above.

30 Biological active substances, however, are generally more complex and more difficult to characterise
31 than non-biological active substances. Moreover, potential differences in the raw materials or in the
32 manufacturing processes between the reference biological VMP and the biosimilar candidate may have
33 an impact on the safety or efficacy profile of the latter. In Section IV.1. Applications for generic
34 veterinary medicinal products (second paragraph of point IV.1.1.) of Annex II to Regulation (EU)
35 2019/6, it is stated that, "for biological (including immunological) veterinary medicinal products, the
36 standard generic approach is in principle not considered appropriate and a hybrid approach shall be
37 followed (see Part IV.2)". In line with section IV.2.3 of Annex II to Regulation (EU) 2019/6, "in case of
38 biological (including immunological) VMPs, a comprehensive comparability review, addressing the
39 quality, safety and efficacy, shall be provided." The extent of new data required to support safety and
40 efficacy will depend on the nature of the active substance and how similar it can be considered to the
41 biological reference VMP.

42 Annex II indicates that the hybrid approach can apply to both immunological and non-immunological
43 biological VMPs. The guideline will take both into account as long as biosimilarity can be demonstrated
44 by side-by-side characterisation.

45 As the data requirements addressed in Annex II are of general nature only, this guideline aims at
46 elaborating more detailed data requirements.

47 **3. Discussion (on the problem statement)**

48 The guidance to be developed intends to focus on the following items:

- 49 • Out of scope: products, which by their nature are more difficult to characterise, such as
50 biological substances arising from extraction from biological sources
- 51 • Choice of reference product (the rationale for the selection of a suitable reference product
52 which would be considered appropriate should be justified).
- 53 • Principles of establishing biosimilarity (e.g. stepwise approach).
- 54 • Quality considerations:
 - 55 ○ Product-specific: analytical techniques, characterisation, physicochemical properties,
56 biological activity, immunochemical properties, purity, impurities, specifications,
57 stability
 - 58 ○ Manufacturing process
 - 59 ○ Demonstration of comparability during development.
- 60 • Nonclinical and clinical considerations; comparative non-clinical studies (PD, toxicology),
61 comparative clinical studies (PK/PD, efficacy, safety, immunogenicity), i.e. the data
62 requirements for Part 3 and Part 4 of the dossier for veterinary biosimilars.
- 63 • Explanation of the principle of the "tailored clinical approach", i.e. authorisation based on
64 demonstrated comparability at the quality level with a limited clinical data package.

65 **4. Recommendation**

66 The Committee for Veterinary Medicinal Products (CVMP) recommends the temporary Drafting group
67 for Biosimilars to develop a guideline on biosimilars. The issues identified above will be taken into
68 consideration and options for possible solutions may be included if these are known.

69 **5. Proposed timetable**

70 Q2 2026 Draft concept paper to be released for public consultation
71 Q3 2026 End of public consultation
72 Q3 2027 Draft guideline to be released for public consultation

73 **6. Resource requirements for preparation**

74 The development of the new guideline will involve the temporary drafting group for biosimilars, the
75 BMWP, the NTWP, EWP, SWP-V, IWP and the CVMP.

76 The drafting group will meet virtually as required (e.g. 4-6 virtual meetings). Discussion/endorsement
77 is foreseen at 5-7 drafting group meetings and 4 CVMP plenary meetings.

78 **7. Impact assessment (anticipated)**

79 The guidance will clarify data requirements for regulators, industry and assessors with respect to
80 biosimilars in order to encourage consistent and predictable decisions.

81 Overall, it is anticipated that the guideline will have a positive impact on the development of veterinary
82 biosimilars and is expected to facilitate their submission and authorisation.

83 **8. Interested parties**

84 Veterinary pharmaceutical industry, EU regulatory authorities involved in assessment of marketing
85 authorisation applications.

86 **9. References to literature, guidelines, etc.**

87 ICH Q5E Biotechnological/biological products subject to changes in their manufacturing process:
88 comparability of biotechnological/biological products. CPMP/ICH/5721/03

89 Similar biological medicinal products (overarching guideline). CHMP/437/04 Rev. 1

90 Similar biological medicinal products containing biotechnology-derived proteins as active substance:
91 non-clinical and clinical issues. EMEA/CHMP/BMWP/42832/2005 Rev. 1

92 Comparability of biotechnology-derived medicinal products after a change in the manufacturing process
93 - non-clinical and clinical issues. EMEA/CHMP/ BMWP/101695/2006

94 Immunogenicity assessment of biotechnology-derived therapeutic proteins.
95 EMEA/CHMP/BMWP/14327/2006

96 Immunogenicity assessment of monoclonal antibodies intended for in-vivo clinical use.
97 EMA/CHMP/BMWP/86289/2010

- 98 Guideline on good pharmacovigilance practices (GVP), Product- or Population-Specific Considerations
99 II: Biological medicinal products. EMA/168402/2014
- 100 Reflection paper on a tailored clinical approach in biosimilar development
101 (EMA/CHMP/BMWP/60916/2025)
- 102 Guidelines on evaluation of biosimilars (Replacement of Annex 2 of WHO Technical Report Series, No.
103 977)
- 104 VICH GL40 Test procedures and acceptance criteria for new biotechnological/biological veterinary
105 medicinal products (EMA/CVMP/VICH/811/04-corrig.)
- 106 VICH GL1 Validation of analytical procedures: Definition and Terminology
- 107 VICH GL2 Validation of analytical procedures: Methodology