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(OR. en)

**5163/26
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COVER NOTE

From: Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director

date of receipt: 6 January 2026

To: Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union

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Subject: ANNEX to the COMMISSION REGULATION (EU) .../... of XXX amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council as regards synthetic polymer microparticles

Delegations will find attached document [...] (2025) XXX draft - D 110142/03 ANNEX.

Encl.: [...] (2025) XXX draft - D 110142/03 ANNEX



EUROPEAN
COMMISSION

Brussels, **XXX**
D110142/03
[...](2025) **XXX** draft

ANNEX

ANNEX
to the
COMMISSION REGULATION (EU) .../...

**amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament
and of the Council as regards synthetic polymer microparticles**

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ANNEX

In Annex XVII to Regulation (EC) No 1907/2006, entry 78 is amended as follows:

(1) paragraph 4 is amended as follows:

(a) point (b) is replaced by the following:

	‘‘medicinal products’ as defined by Directive 2001/83/EC ⁺ or ‘veterinary medicinal products’ as defined by Regulation (EU) 2019/6 ⁺⁺ ;
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⁺ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67, ELI: <http://data.europa.eu/eli/dir/2001/83/oj>).

⁺⁺ Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43, ELI: <http://data.europa.eu/eli/reg/2019/6/oj>).¹

(b) the following point (g) is added:

	‘synthetic polymer microparticles, on their own or in mixtures, for use in product and process orientated research and development, in quantities of one tonne per year or less;’
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(2) in paragraph 5, point (c) is replaced by the following:

	‘synthetic polymer microparticles which are permanently incorporated into a solid matrix during an intended end use of a duration of one year or longer.’
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