



Council of the
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COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	29 January 2021
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union

No. Cion doc.:	C(2021) 435 final ANNEX
Subject:	ANNEX to the COMMISSION DELEGATED REGULATION supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council with regard to requirements for the collection of data on the volume of sales and on the use of antimicrobial medicinal products in animals

Delegations will find attached document C(2021) 435 final ANNEX.

Encl.: C(2021) 435 final ANNEX



Brussels, 29.1.2021
C(2021) 435 final

ANNEX

ANNEX

to the

COMMISSION DELEGATED REGULATION

**supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council
with regard to requirements for the collection of data on the volume of sales and on the
use of antimicrobial medicinal products in animals**

ANNEX

1. VETERINARY ANTIMICROBIAL MEDICINAL PRODUCTS FOR WHICH DATA ON THE VOLUME OF SALES SHALL BE COLLECTED AND REPORTED TO THE AGENCY AS REFERRED TO IN ARTICLE 1

- (1) Antidiarrheals, intestinal anti-inflammatory and anti-infective agents:
 - (a) QA07AA; QA07AB;
 - (b) QA07AX03;
 - (c) QA07AX04.
- (2) Gynaecological antiinfectives and antiseptics:
 - (a) QG01AA;
 - (b) QG01AE;
 - (c) QG01BA;
 - (d) QG01BE.
- (3) Antiinfectives and antiseptics for intrauterine use:
 - (a) QG51AA;
 - (b) QG51AG.
- (4) Antibacterials for systemic use: QJ01.
- (5) Antibacterials for intramammary use: QJ51.
- (6) Antiprotozoals (with antibacterial effect): QP51AG.
- (7) Antimycobacterials for intramammary use: QJ54.

2. VETERINARY ANTIMICROBIAL MEDICINAL PRODUCTS FOR WHICH DATA ON THE VOLUME OF SALES MAY BE COLLECTED AND REPORTED TO THE AGENCY AS REFERRED TO IN ARTICLE 2

- (1) Antiprotozoals (other than QP51AG): QP51.
- (2) Antifungals for topical use: QD01A.
- (3) Antifungals for systemic use: QD01B.
- (4) Antimycotics for systemic use: QJ02.
- (5) Antimycobacterials: QJ04.
- (6) Antivirals for systemic use: QJ05.
- (7) Antibiotics and chemotherapeutics for dermatological use: QD06.
- (8) Other nasal preparations:

- (a) QR01AX06;
 - (b) QR01AX08.
- (9) Ophthalmological antiinfectives:
- (a) QS01AA;
 - (b) QS01AB;
 - (c) QS01AD;
 - (d) QS01AE;
 - (e) QS01CA;
 - (f) QS01CC.
- (10) Otological antiinfectives:
- (a) QS02AA;
 - (b) QS02CA;
 - (c) QS03AA;
 - (d) QS03CA.

3. ANTIMICROBIAL MEDICINAL PRODUCTS FOR WHICH DATA ON USE IN ANIMALS SHALL BE COLLECTED AND REPORTED TO THE AGENCY AS REFERRED TO IN ARTICLE 3

- (1) Antidiarrheals, intestinal anti-inflammatory and anti-infective agents:
- (a) QA07AA, A07AA;
 - (b) QA07AB, A07AB;
 - (c) QA07AX03, A07AX03;
 - (d) QA07AX04, A07AX04.
- (2) Gynaecological antiinfectives and antiseptics:
- (a) QG01AA, G01AA;
 - (b) QG01AE, G01AE;
 - (c) QG01BA, G01BA;
 - (d) QG01BE, G01BE.
- (3) Antiinfectives and antiseptics for intrauterine use: QG51AA.
- (4) Antibacterials for systemic use: QJ01, J01.
- (5) Antibacterials for intramammary use: QJ51.
- (6) Antiprotozoals (with antibacterial effect): QP51AG.

4. ANTIMICROBIAL MEDICINAL PRODUCTS FOR WHICH DATA ON USE IN ANIMALS MAY BE COLLECTED AND REPORTED TO THE AGENCY AS REFERRED TO IN ARTICLE 4

- (1) Antibiotics and chemotherapeutics for dermatological use: QD06, D06.
- (2) Other nasal preparations:
 - (a) QR01AX06, R01AX06;
 - (b) QR01AX08, R01AX08.
- (3) Antimycobacterials for intramammary use: QJ54.
- (4) Ophthalmological antiinfectives:
 - (a) QS01AA, S01AA;
 - (b) QS01AB, S01AB;
 - (c) QS01AD, S01AD;
 - (d) QS01AE, S01AE;
 - (e) QS01CA, S01CA;
 - (f) QS01CC, S01CC.
- (5) Otological antiinfectives:
 - (a) QS02AA, S02AA;
 - (b) QS02CA, S02CA;
 - (c) QS03AA, S03AA;
 - (d) QS03CA, S03CA.
- (6) Antiprotozoals (other than QP51AG): QP51, P01.
- (7) Antifungals for topical use: QD01A, D01A.
- (8) Antifungals for systemic use: QD01B, D01B.
- (9) Antimycotics for systemic use: QJ02, J02.
- (10) Antimycobacterials: QJ04, J04.
- (11) Antivirals for systemic use: QJ05, J05.