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Collection of antimicrobial sales data in Ireland – progress update

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Approach

- Introduction and context
- Progress update
- Issues which have arisen

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Introduction and context

- No established system for collection of sales data up to now
- Some companies have provided data previously to the UK authorities
- 43 marketing authorisation holders involved
- Over 70 wholesalers involved in distribution
- Wholesalers are licensed by the Dept of Agriculture and not the IMB

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Progress update

- IMB discussed merits of wholesaler approach with Dept of Agriculture in early summer – IMB has no authority to ensure compliance
- IMB identified 43 companies involved in August 2010
- IMB mapped company product data from its own files into EMA template
- IMB sent the template to MAHs in early September with a deadline for response of 24 September
- 15 responses to date

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Issues 1

- We have not been able to address the amount of information requested in these tables in the allotted time given by the IMB.
- This exercise is quite detailed and clarification is also needed from the IMB as regards the use of 'conversion factors', 'ingr content....etc. In particular, for products with more that one active, this level of detail requires considerable time and calculation.
- As you may be aware, on a yearly basis the industry provides total sales figures to the UK, VMD which includes the following product information: Active (mg/unit) pack size (pack), sales volumes (Packs), Volume of products sold, grams of active and Kgs of active. There is no difficulty in providing this level of information to the IMB.

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Issues 2

- According to the EMA ESVAC guideline only veterinary medicinal products within certain ATC vet code categories are undergoing the survey - please refer to the copied text from the guideline below. None of our products are within these categories.
- Antimicrobial agents for intestinal use QA07AA; QA07AB
- Antimicrobial agents for intrauterine use

  QG01AA; QG01AE; QG51AX
  QG51BA; QG51BC; QG51BE
- Antimicrobial agents for systemic use QJ01
- Antimicrobial agents for intramammary use QJ51
- Antimicrobial agents used as antiparasitic agents QP51AG

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Issues 3

- According to the EMA ESVAC guideline salts should only be specified in the "salt" column if the strength of the substance is stated in International Units (IU). Is this the correct interpretation or should we state as indicated by IMB for instance Diethanolamine fusidate and Framycetin sulphate with the salts "Diethanolamine salt" and "Sulphate salt" in the "salt" column and state only the "real" active substances Fusidic acid and Framycetin in the "Ingredient" column.

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Issues 4

- Should the calculations be based on the "real" active ingredients or on the salts ? - in the submitted survey we have made the calculations with reference to the salts.

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Issues 5

- Some of our products are combined with Active ingredients which does not possess antibiotic activity. We have only made all calculations for the antibiotic substances and left the rows blank for the substances which are not antibiotic. Is this correct ?

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