

Belgian Veterinary Surveillance of Antibacterial Consumption

National consumption report

2019

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## **SUMMARY**

This annual BelVet-SAC report is now published for the 11<sup>th</sup> time and describes the antimicrobial use (AMU) in animals in Belgium in 2019 and the evolution since 2011. For the second year this report combines sales data (collected at the level of the wholesalers-distributors and the compound feed producers) and usage data (collected at farm level). This allows to dig deeper into AMU at species and farm level in Belgium.

With a **consumption of 87,4 mg antimicrobial/kg biomass** a decrease of **-7,6%**, in comparison to 2018, is achieved in 2019. This marks the fifth year in a row where an important decrease of antimicrobial usage in animals is observed resulting in a **cumulative reduction of -40,3% since 2011.** The reduction in 2019 is spread over a **reduction in pharmaceuticals (-7,8%)** and **antibacterial premixes (-5,1%).** 

When looking at the **evolution in the number of treatment days (BD**<sub>100</sub>), as calculated from the Sanitel-Med use data, **reductions of -5,8% for pigs and poultry and -21,3% for veal calves** are observed. The fact that as well the sales data as the use data are showing comparable trends is reassuring with regard to the data validity and the representation of reality.

In 2019, on a median pig farm fatteners were treated with antimicrobials for around 3% of their lifetime, sucklers for around 2% and pigs for breeding for around 0,4%. These are for all categories, except for the breeders reductions in comparison to 2018. **These are encouraging results for the pig sector**. Yet, challenges remain as the use in the weaners remains high with a median BD<sub>100</sub> of 17,9 (a reduction of 10% in comparison to 2018). In the **veal calf sector the median BD<sub>100</sub> was reduced with -21%** in comparison to 2018. This is likely the result of the enhanced actions in the sector summarized in their "10 point program". However, even after this important reduction the AMU in the veal remains the highest value of all sectors and therefore needs to be further addressed. Also in the **broiler production a moderate improvement** (-4%) is observed. Yet this is partially superseded by the **continued high use of fluoroquinolones** in this sector. Therefore the broiler sector is urged to take measures in the coming years.

In dairy cattle it is disturbing to see that since 2015 there is a steady increase in the use of antimicrobial dry cow applicators. Also the number of applicators used for the treatment of mastitis cases has steadily increased over the last 3 years. In dogs and cats the volume of antimicrobial use has again increased in 2019 with +13,0% in comparison to 2018. **Compared to 2014 the total increase of antimicrobial substances used in dogs and cats is + 24,3%**. These results clearly demonstrate that both the dairy sector and the sector of companion animals urgently need to take actions to start to bend the curve.

When comparing the results with the AMCRA 2020 reduction targets, the **goal of reducing the overall AMU in animals with 50% by 2020 has not been achieved yet**, however the objective becomes in range with still 9,7% to reduce in the final year compared to the use in 2011 (this corresponds to an additional reduction of 16,2% in 2020 compared to 2019). It is anticipated that the herd level data-collection and benchmarking through the Sanitel-Med and AB register systems, in combination with multiple other initiatives such as herd health plans, continuous education, increased biosecurity,.... will provide invaluable support to achieve this goal. Moreover, AMCRA has in the meantime also already communicated further reduction goals up to 65% by 2024 compared to the reference year 2011, indicating that even after 2020 the efforts will need to be continued. With regard to **antibacterial premixes** it is promising to see that again in 2019, even after largely achieving the goal of reducing the use with 50% by 2017, a further reduction is achieved, now already **resulting in a cumulative reduction of -71,1% in comparison to 2011**. In regard to the different AMCRA colour classes, the use of "yellow" (-7%) and "orange" (-8%) classes substantially reduced in 2019. Yet the use of the **critically important "red" products** increased for the second year in a row (+8%) after a very spectacular drop in 2016 and 2017. Fortunately, this increase does not yet put at risk the reduction target of -75% by 2020 (which was already achieved in 2017) as there **still is a reduction of -77,3% in comparison to 2011**. However it is certainly an evolution that requires close surveillance.

## Conclusion

This report shows several promising results with a continued reduction of the total use and the achievement of two out of the three quantitative goals (use of premixes and use of critically important antimicrobials). These evolutions strengthen us in the believe that also the third and overarching objective of a 50% reduction in use by 2020 remains feasible, yet substantial efforts will be required from all stakeholders to obtain this goal. The pig and veal sectors are encouraged to sustain their efforts, while the broiler, dairy and companion animal sectors are urged to increase their efforts.

## **SAMENVATTING**

Dit 11<sup>de</sup> BelVet-SAC rapport beschrijft de resultaten van het antibioticumgebruik bij dieren in België in 2019 en de evolutie sinds 2011. Voor het tweede jaar op rij combineert het rapport zowel verkoopdata (verzameld ter hoogte van de groothandelaars – verdelers en mengvoederfabrikanten) als gebruiksdata (verzameld op het niveau van de veehouderij). Deze combinatie laat toe om het gebruik meer in detail te bestuderen per diercategorie.

Met een consumptie van 87,4 mg antibiotica/kg biomassa werd in 2019 een reductie van -7,6% gerealiseerd in vergelijking met 2018. Hiermee wordt voor het vijfde jaar op rij een belangrijke reductie gerealiseerd wat resulteert in een cumulatieve reductie van -40,3% sinds 2011. De reductie is verdeeld over een reductie in de 'pharmaceuticals' (-7,8%) en in de antibacteriële premixen (-5,1%).

Bekijken we de **evolutie in het aantal behandeldagen (BD**100), berekend uit de Sanitel-Med gebruiksdata, dan zien we **reducties van -5,8% voor varkens en pluimvee en -21,3% voor vleeskalveren**. Het feit dat zowel de verkoopdata als de gebruiksdata een vergelijkbare evolutie weergeven geeft vertrouwen in de validiteit van de data en de weergave van de reële evoluties.

In een mediaan varkensbedrijf in België werden in 2019 de vleesvarkens ongeveer 3% van hun levensdagen behandeld met antibiotica, voor de zuigende biggen was dat 2% en voor de zeugen en beren 0,4%. Dit zijn, in vergelijking met 2019, reducties in alle categorieën behalve bij de zeugen en beren. **Dit zijn bemoedigende resultaten voor de varkenssector.** Echter blijven er nog uitdagingen aangezien het gebruik bij de gespeende biggen, met een BD<sub>100</sub> van 17,9 (een reductie van -10% t.o.v. 2018), nog steeds erg hoog blijft. In de sector van de **vleeskalveren is de mediane BD<sub>100</sub> gedaald met -21%** in vergelijking met 2018. Dit is waarschijnlijk een gevolg van de acties ondernomen in deze sector die werden samengevat in hun "10 punten plan" met als doel het antibioticumgebruik te verminderen. Zelfs na deze belangrijke reductie blijft het gebruik in de vleeskalveren echter het hoogste van alle sectoren en dringt verdere actie zich dus op. In **de braadkippen sector wordt een bescheiden reductie van -4%** opgemeten. Dit goed resultaat wordt evenwel **deels teniet gedaan door het aanhoudende hoge gebruik van fluoroquinolones**. Daarom wordt de braadkippensector opgeroepen om dringend bijkomende maatregelen te nemen.

In de melkveehouderij is het verontrustend om vast te stellen dat dat er sinds 2015 een continue stijging van het gebruik van droogzetpreparaten wordt waargenomen. Ook het gebruik van intramammaire producten voor de behandeling van uierontsteking neemt de laatste 3 jaar toe. Bij honden en katten is het volume van gebruikte antibiotica in 2019 met 13% toegenomen. In vergelijking met 2014 is de stijging zelfs +24,3%. Deze resultaten tonen duidelijk aan dat zowel de melkvee sector als de sector van de gezelschapsdieren dringend actie moeten ondernemen om de curve van het gebruik af te buigen.

Als we deze resultaten uitzetten tegenover de AMCRA 2020 reductiedoelstellingen dan zien we dat het doel van 50% reductie van het totaal gebruik tegen 2020 nog niet gerealiseerd is. Echter het objectief komt steeds dichter bij en met een verdere reductie van 9,7% in het laatste jaar ten opzichte van het gebruik in 2011 is het objectief binnen bereik (Dit stemt overeen met een bijkomende reductie van 16,2% in 2020 ten opzichte van 2019). Er wordt vanuit gegaan dat de datacollectie van het AB gebruik op bedrijfsniveau in combinatie met een veelvoud aan andere initiatieven, zoals het bedrijfsgezondheidsplan, blijvende opleiding, toenemende bioveiligheid, ... zal bijdragen om het doel te bereiken. Daarenboven heeft AMCRA recent ook een reductie van -65% ten opzichte van het referentiejaar 2011 als doelstelling voor 2024 vooropgesteld, waardoor er een blijvende inspanning zal nodig zijn ook na 2020. Voor wat betreft de antimicrobiële premixen is het hoopgevend om te zien dat, zelf na het ruimschoots behalen van de reductiedoelstelling van -50% in 2017, er nog steeds verdere reducties worden gerealiseerd wat resulteert in een cumulatieve reductie van -71,1% in vergelijking met 2011. Wat betreft het gebruik van de verschillende soorten antibiotica hebben we in 2019 een duidelijke reductie gezien van het gebruik van "gele" (-7%) en "oranje" (-8%) antibiotica terwijl het gebruik van de kritisch belangrijke "rode" antibiotica voor het tweede jaar op rij terug is gestegen (+8%) na de spectaculaire daling in 2016 en 2017. Gelukkig heeft deze stijging nog niet tot gevolg dat de reductie doelstelling van -75% t.o.v. 2011 (die in 2017 werd gerealiseerd) niet wordt gehaald aangezien er nog steeds een totale reductie van -77,3% wordt opgetekend. Desalniettemin is dit een zorgwekkende evolutie die van nabij dient opgevolgd te worden.

#### Conclusie

Dit rapport toont verschillende hoopgevende resultaten met een aanhoudende daling van het totaal antibioticumgebruik en het behouden van twee van de drie kwantitatieve doelstellingen (gebruik van antimicrobiële premixen en kritisch belangrijke

antibiotica). Deze evoluties sterken ons in het geloof dat ook de derde, overkoepelende, doelstelling van -50% reductie tegen 2020 haalbaar blijft. Echter hiervoor zullen belangrijke inspanningen noodzakelijk zijn van alle betrokkenen. De varkens- en de vleeskalversector worden aangemoedigd om verder te gaan op het ingeslagen pad terwijl de braadkippen, melkvee en gezelschapsdierensectoren wordt opgeroepen om bijkomende inspanningen te leveren om de nodige reducties te realiseren.

## RESUME

Ce 11<sup>e</sup> rapport BelVet-SAC décrit les résultats de la consommation d'antibiotiques chez les animaux en Belgique en 2019 et son évolution depuis 2011. Pour la deuxième fois, le rapport combine les données des ventes (collectées au niveau des grossistes - distributeurs et fabricants d'aliments composés pour animaux) et les données de consommation (collectées au niveau de l'élevage). Cette combinaison permet d'étudier plus en détail la consommation par catégorie d'animal et au niveau des élevages.

Avec une consommation moyenne de 87,4 mg d'antibiotiques/kg de biomasse, une réduction de 7,6 % a été réalisée en 2019 par rapport à 2018. Cela représente une diminution significative pour la cinquième année consécutive, aboutissant à une réduction cumulée de 40,3 % depuis 2011. La diminution se répartit en une réduction de 7,8 % pour les produits pharmaceutiques et de 5,1 % pour les prémélanges antibactériens.

Si l'on observe **l'évolution du nombre de jours de traitement (BD**<sub>100</sub>) calculée sur la base des données de consommation collectées via SANITEL-MED, nous constatons des **réductions de 5,8 % pour les porcs et la volaille et de 21,3 % pour les veaux de boucherie**. Le fait que les données relatives à la vente et celles qui concernent la consommation suivent une évolution comparable permet de confirmer la validité des données et la représentation des évolutions réelles.

Dans une exploitation porcine médiane en Belgique, en 2019, les porcs de boucherie ont été traités avec des antibiotiques pendant environ 3 % de leur durée de vie, 2 % pour les porcelets allaitants et 0,4 % pour les truies et verrats. Par rapport à 2019, il s'agit de réductions dans toutes les catégories, excepté celles des truies et des verrats. **Ces résultats sont encourageants pour le secteur porcin.** Cependant, des défis subsistent en ce qui concerne l'utilisation chez les porcelets sevrés, avec un BD <sub>100</sub> de 17,9 (une réduction de 10 % par rapport à 2018) qui reste encore très élevé. Dans le secteur des **veaux de boucherie, le BD** <sub>100</sub> **médian a diminué de 21** % par rapport à 2018. Ce chiffre est probablement le résultat des actions entreprises dans ce secteur, qui ont été résumées dans le « plan en 10 points » dans le but de réduire l'utilisation d'antibiotiques. Cependant, même après cette réduction importante, l'utilisation chez les poulets de chair, une modeste réduction de 4 % est enregistrée. Cependant, ce bon résultat est **partiellement compensé par la forte utilisation continue des fluoroquinolones**. Par conséquent, le secteur du poulet de chair est appelé à prendre d'urgence des mesures supplémentaires pour les années à venir.

En élevage laitier, il est inquiétant de constater, depuis 2015, une augmentation continue de l'utilisation des antibiotiques intramammaires pour vache en tarissement . L'utilisation de produits intramammaires pour le traitement de la mammite a également augmenté au cours des 3 dernières années. Chez les chiens et les chats, le volume d'antibiotiques utilisés a augmenté de 13 % en 2019. Par rapport à 2014, la progression est même de 24,3 %. Ces résultats démontrent clairement que tant le secteur laitier que celui des animaux de compagnie ont besoin d'une action urgente pour aplanir la courbe d'utilisation au sein de leur secteur.

Si nous comparons ces résultats avec les objectifs de réduction AMCRA 2020, nous constatons que **l'objectif d'une réduction de 50 % de l'utilisation totale d'ici 2020 n'a pas encore été atteint**. Cependant, l'objectif se rapproche et avec une nouvelle réduction de 9,7 % l'année dernière par rapport à la consommation de 2011, il est à portée de main (cela correspond à une réduction supplémentaire de 16,2 % en 2020 par rapport à 2019). On suppose que la collecte de données sur l'utilisation d'AB au niveau de l'entreprise, combinée à une multitude d'autres initiatives, contribuera à atteindre l'objectif. En outre, l'AMCRA a également récemment fixé les objectifs de réduction pour 2024 à -65 % par rapport à l'année de référence 2011, de sorte qu'un effort soutenu sera également nécessaire après 2020. En ce qui concerne les prémélanges antimicrobiens, il est encourageant de voir que, même après avoir dépassé les objectifs de réduction de 50 % en 2017, de nouvelles réductions sont encore en cours, ce qui se traduit par une **réduction cumulée de 71,1 %** par rapport à 2011. En ce qui concerne l'utilisation des différents types d'antibiotiques, nous avons observé une nette réduction de l'utilisation d'antibiotiques « jaunes » et « orange » en 2019, tandis que l'utilisation des **antibiotiques « rouges » d'une importance cruciale a augmenté** pour la deuxième année consécutive (+ 8 %) après la baisse spectaculaire de 2016 et 2017. Heureusement, cette augmentation n'a pas encore entraîné l'impossibilité d'atteindre l'objectif de réduction de 75 % par rapport à l'année 2011 (qui avait été réalisé en 2017) étant donné **qu'il y a toujours une réduction totale de 77,3 %.** Il s'agit néanmoins d'une évolution préoccupante qui doit être suivie de près.

## Conclusion

Ce rapport montre des résultats prometteurs avec une baisse persistante de l'utilisation totale d'antibiotiques et la confirmation que deux des trois objectifs quantitatifs (utilisation de prémélanges antimicrobiens et d'antibiotiques d'importance critique) sont atteints. Ces évolutions renforcent notre conviction que le troisième objectif primordial restera également réalisable. Cependant, cela nécessitera des efforts importants de la part de toutes les parties concernées. Le secteur des porcs et des veaux de boucherie est encouragé à poursuivre sur la voie empruntée, tandis que les secteurs des poulets de chair, des vaches laitières et des animaux de compagnie sont appelés à faire des efforts supplémentaires pour réaliser les réductions nécessaires.

## PREFACE

Antibacterial products are valuable tools in the preservation of animal health and animal welfare, and must be used responsibly as they may save lives and prevent animal suffering. However, the use of antibacterial products invariably leads to selection of bacteria that are resistant against the substance used. Resistance can then spread in populations and the environment.

Antibacterial consumption in animals selects for antibacterial resistant bacteria in animals, leading to therapy failure in bacterial infections. Yet it might also jeopardize human health through transfer of resistant bacteria or their resistance genes from animals to humans and vice versa via direct or indirect contact.

Today, antibacterial consumption and its link to antibacterial resistance in humans and animals is a worldwide point of concern. The World Health Organization has indicated the follow up of antibacterial resistance as one of the top priorities for the coming years. In 2013, the world economic forum has indicated the emergence of antibacterial resistance a global threat with the ability of destabilizing health systems, profound cost implications for economic systems and for the stability of social systems. In 2015 the World Health Assembly unanimously adopted the Global Action Plan<sup>1</sup> (GAP) on Antimicrobial Resistance developed by the World Health Organization (WHO) with the contribution of the Food and Agricultural Organization (FAO) and the World Organization for Animal Health (OIE), calling all Member States of the World Health Organization to put in place national action plans against AMR by mid-2017.

Given the importance in securing public as well as animal health and since it is by far the leading driver for antibacterial resistance, it is crucial to measure the level of antibacterial consumption and antibacterial resistance in animals. This is moreover also required at the European level where consumption data of antibacterial products in veterinary medicine are collected by EMA (European Medicines Agency) in the framework of the ESVAC (European Surveillance of Veterinary Antibacterial Consumption) project. Therefore the data collected and presented in this report also fit into the European commitments of Belgium. This tenth BelVet-SAC report gives an overview of the consumption of antibacterial products in veterinary medicine in Belgium in 2018 and describes evolutions in use since 2011.

<sup>&</sup>lt;sup>1</sup> http://apps.who.int/gb/ebwha/pdf\_files/WHA68/A68\_ACONF1Rev1-en.pdf?ua=1

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## **THE AUTHORS**

The 2018 data collection and analysis was performed by the Veterinary Epidemiology Unit of the faculty of Veterinary Medicine from the Ghent University (sales data) and the Data Analysis Unit of the centre of expertise on Antimicrobial Consumption and Resistance in Animals (AMCRA) (consumption data) under the authority of the Federal Agency for Medicines and Health products.

The data collection and analysis of the sales data has been performed by:

Drs. Reshat Jashari, Prof. dr. Jeroen Dewulf, Veterinary Epidemiology Unit Faculty of Veterinary Medicine Ghent University Belgium

The data analysis of the use data has been performed by:

- Dr. Wannes Vanderhaeghen,
- Dr. Jorien De Loor,
- Dr. Ghislain Barré
  - AMCRA vzw Belgium

The report has been written by:

Prof. dr. Jeroen Dewulf,

Veterinary Epidemiology Unit Faculty of Veterinary Medicine Ghent University Belgium

Dr. Wannes Vanderhaeghen Dr. Bénédicte Callens Dr. Fabiana Dal Pozzo *AMCRA vzw Belgium* 

Dr. Bart Hoet, Apr. Dries Minne, DG PRE Federal Agency for Medicines and Health products Belgium

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Contact: infovet@fagg-afmps.be

## **MATERIALS AND METHODS**

## **ANTIMICROBIAL SALES DATA**

## **Data collection**

#### a) Antibacterials for veterinary use

#### i. Antibacterial pharmaceuticals

Sales data of all products in all pharmaceutical formulations registered on the Belgian market that contain antibacterials were aggregated. These data were asked from the 22 wholesaler-distributors that are registered and active for supplying veterinarians and pharmacies in Belgium with veterinary medicines during the observation period. The distributors are obliged by law (article 12sexies, Law on medicines 25<sup>th</sup> March 1964; Articles 221 and 228 Royal Decree 14<sup>th</sup> December 2006 on medicines for human and veterinary use) to keep record of all sales and to deliver these records to the competent authority of the Belgian authority (Federal Agency for Medicines and Health Products, FAMHP) on demand. They were asked by letter dd. January 2020 to upload the required data via a secured web-application (www.belvetsac.ugent.be). The required data consisted of **all veterinary antibacterials sold in the year 2019 to a veterinarian or pharmacist in Belgium**. In Belgium, antibacterial products in their daily practice, or sell them to animal owners (fig. 1). Sales from one wholesaler-distributor to another were excluded from the input data to prevent double counting. A pre-filled list of antibacterial containing veterinary medicinal products authorized and marketed on the Belgian market was provided, together with its market authorization holder and national code, formulation and package form. The wholesaler-distributor only needed to provide the number of packages sold for each product per year.



Figure 1. Distribution of Veterinary Medicinal products in Belgium.

#### ii. Antibacterial premixes

As antibacterial premixes can be purchased by feed mills directly from the producers or wholesalers (not necessarily through wholesaler-distributors) (fig. 2) also data on medicated feed were collected. This was done by contacting all Belgian

compound feed producers that are active and licensed to produce medicated feed<sup>2</sup> (n=43). They received a list of registered and marketed Antibacterial containing premixes. The feed mills were asked by letter dd. January 2020 to upload the required data, on legal basis of article 12sexies Law on medicines 25<sup>th</sup> March 1964; Article 221 and 228 Royal Decree 14<sup>th</sup> December 2006 on medicines for human and veterinary use. This data on medicated feed delivered at Belgian farms in 2019 was also submitted via the secure web-application<sup>3</sup>. Producers of medicated feed were asked to provide **data on the use of Antibacterial containing premixes as well as ZnO containing premixes for the year 2019**. Antibacterial and ZnO premixes can only be incorporated into medicated feed on prescription of a veterinarian.



Figure 2. Distribution of Veterinary premixes in Belgium.

## iii. Antibacterial classes included

Table 1 provides an overview of the groups of Antibacterial agents covered in the BelVet-SAC data-collection system, together with the corresponding ATCvet codes. The ATCvet codes included in each Antibacterial class are listed in appendix A.

In the BelVet-SAC data collection all antibacterials used for veterinary medicine are covered (Table 1). No antibacterials are excluded which is in contrast to the ESVAC reporting system where antibacterials for dermatological use and for use in sensory organs are excluded. This explains why consumption data as presented in this report may slightly differ from what is reported for Belgium in the ESVAC report.

As Zinc Oxide (ZnO) products (premixes) were authorized in Belgium since September 2013, sales data were collected and are presented separately.

<sup>&</sup>lt;sup>2</sup> http://www.favv-afsca.be/bo-documents/Inter R0-1002 3 dierlijke producten erkende bedrijven.PDF

<sup>&</sup>lt;sup>3</sup> <u>www.BELVET-SAC.ugent.be</u>

Table 1. Groups of Antibacterial agents covered in the data collection and corresponding ATCvet codes.

Groups of Antibacterial agents	ATCvet codes
Antibacterial agents for intestinal use	QA07AA; QA07AB
Antibacterial agents for dermatological use	QD06A; QD06BA
Antibacterial agents for intrauterine use	QG51AA; QG51AC; QG51AE; QG51AX QG51BA; QG51BC; QG51BE
Antibacterial agents for systemic use	QJ01
Antibacterial agents for intramammary use	QJ51
Antibacterial agents for use in sensory organs	QS01AA; QS01AB QS02AA QS03AA
Antibacterial agents for use as antiparasitic	QP51AG

#### b) Animal population

Animal population data to calculate the produced biomass were derived from the Eurostat website<sup>4</sup>.

From these animal population data, biomass (in kg) was calculated, according to Grave<sup>5</sup> et al., (2010), as the sum of the amount of meat of beef, pork, poultry and small ruminants produced that year in Belgium plus the number of dairy cattle present in Belgium times 500 kg of metabolic weight per head.

## Data analysis

The total number of packages sold per product for all wholesalers was linked to a for that purpose developed database that contained all additional product information in accordance with the ESVAC recommendations. This additional information consisted of:

- the different active antibacterial substances the product contains per ml for liquids or mg for solids
- the weight per substance
- the number of units in one package
- for active substances expressed in International Units: the conversion factor to mg
- calculated from the above: the total amount of active substance (per active substance) in one package
- the ATC vet code for each (combination of) active substance(s) required for the ESVAC (European Surveillance of Veterinary Antibacterial Consumption) reporting

Through this extra information, the number of packages sold can be converted to the amount of active substance used.

All sales data on antibacterial feed premixes included in the data from wholesaler-distributors were excluded from the above data-source to prevent double counting. Data concerning antibacterial premixes from medicated feed producers were added to the data on pharmaceuticals from wholesaler-distributors to account for total coverage of veterinary antibacterial consumption in Belgium.

<sup>&</sup>lt;sup>4</sup> <u>http://ec.europa.eu/eurostat/data/database</u>

<sup>&</sup>lt;sup>5</sup> Grave K, Torren-Edo J en Mackay D (2010). Comparison of the sales of veterinary antibacterial agents between 10 European countries. *Journal of Antibacterial Chemotherapy*, 65, 2037-2010

As in the previous reports (BELVET-SAC 2007-2018)<sup>6</sup>, yearly consumption figures were put versus biomass as a yearly adjusted denominator according to the methodology described by Grave et al. (2010). The animal species included were based upon the vast majority of the biomass present (estimated to be 93% of the total biomass present in Belgium). It should however be made clear that the calculation of the biomass does not contain other animal species such as horses, rabbits and companion animals (dogs, cats, ...) (estimated to be 7% of the biomass present in Belgium), whereas the collected data on antibacterial use also covers the use in these species. The biomass also includes animals slaughtered in Belgium but raised in other countries and it excludes animals raised in Belgium but slaughtered abroad.

## Data validation

## a) External data validation

To check for correctness and completeness the collected data on premixes were compared to data collected by the compound feed producing industry<sup>7</sup>. The datasets do not provide exactly the same information as the used data collection methodology is slightly different. However, trends and evolutions in the different datasets can be compared. If large discrepancies were observed data validity was further investigated and corrected, if needed.

To check for correctness of the reported pharmaceuticals data trends are compared with the data obtained from the market authorization holders (MAH) collected in the framework of the antibiotic tax as well as with the reported use data in Sanitel-Med.

## b) Internal data validation

For each of the data entries of the wholesaler-distributor or compound feed producers results were compared with the data entries of the previous years by the same companies. If large, unexpected, discrepancies were observed between the data provided in the subsequent years data validity was further investigated and corrected, if needed.

<sup>&</sup>lt;sup>6</sup> <u>http://www.belvetsac.ugent.be/</u>

<sup>&</sup>lt;sup>7</sup> <u>www.bfa.be</u>

## **ANTIMICROBIAL USE DATA**

## Data collection in Sanitel-Med

## a) Notification of antimicrobial use at farm-level

Since 27 February 2017, veterinarians are legally obliged (RD of 02.07.2017 modifying RD of 21.07.2016) to register in the secured online data collection system Sanitel-Med all prescriptions, administrations and deliveries of antimicrobial products (pharmaceuticals as well as premixes, incl. premixes containing ZnO as an antidiarrheal substance) on Belgian farms raising pigs, broilers, laying hens and veal calves. The system, developed and maintained by the FAMHP, is accessible as a web application or through automated data transfer using xml (webservices).

Registration is done by first creating a 'Medicinal Delivery Document' containing the identification of the veterinarian and the farm as well as the type, number and date of the reference document (Treatment and Delivery Document, prescription or 'register out' of the veterinarian). To this Medicinal Delivery Document, one or more 'notifications' are added, each representing a specific prescription, delivery or administration of an antimicrobial product.

The following data need to be included in a notification:

The animal species and category for which the antimicrobial product is intended.

The categories that can be selected are

- Pigs:
  - sows (PIGB);
  - gilts (PIGI);
  - fattening pigs (PIGF);
  - weaned piglets (PIGLW);
  - suckling piglets (PIGLU)
- Poultry:
  - broilers (BROIR);
  - laying hens (LAYIH)
- Veal:
  - Veal calves (VECLF)
- The name and quantity of the antimicrobial product.

The product needs to be selected from a regularly updated medicinal product list containing all antimicrobial product packages commercialized in Belgium, identified through a unique cti-ext key. As for the antimicrobial sales data, all groups of antimicrobial agents listed in Table 1 are included. For pharmaceuticals, the number of packages needs to be registered, with the possibility of using decimals. For premixes, either the number of packages, the kg premix or the kg medicated feed in combination with the parts-per-million premix needs to be registered; using decimals is also possible.

Products used off-label need to be registered from the same list. Products used through cascade (products not registered in Belgium, products for human use or products prepared extemporaneously) need to be registered as 'Self-Defined Product' (SDP), requiring additional data fields to allow calculation of the delivered quantity of active substance (see below).

Veterinarians can register the data at any moment under the premise that all data from a given quarter need to be registered at the latest the 14<sup>th</sup> day of the following quarter. The farmer or responsible of the animals must check the correctness of the data from a given quarter at the latest the final day of the first month of the following quarter. This last day is called the 'Data-Lock-Point', hence, there are four DLP in a year.

So-called 'third parties' (i.c. other Belgian data collection systems) can transfer the required data on behalf of a veterinarian and/or farmer. Nonetheless, the respective veterinarian and/or farmer remain responsible for the completeness, correctness and timeliness of the registrations.

Reprising Figure 1 explaining the origin of the antimicrobial sales data, the data from Sanitel-Med originate at the bottom of the chain and concern data about the use of antimicrobial products at the farm-level (Figure 3). However, from the info provided above, it can be noted that not all Sanitel-Med data are 'use data' in a strict sense; indeed, a prescription or delivery is not 'proof' that the products have also been used in practice, especially not at the time of prescription or delivery. Nonetheless, it is deemed very likely that virtually all products prescribed or delivered are eventually used. It is furthermore assumed that by looking at the data over a period of one or more years, the lag between the moment of prescribing/delivering and using in practice will be averaged and play no relevant role in the calculation of the final result. Therefore, the Sanitel-Med data are referred to as 'use data' – in contrast to the 'sales data' described previously.



## Figure 3. Origin of Sanitel-Med data concerning farm-level use of antimicrobial pharmaceuticals.

A list with all notifications is accessible to AMCRA as a report, based on a query developed and maintained by the FAMHP, that can be pulled by AMCRA through a secured online business object tool provided by the Federal Agency for the Safety of the Food Chain (FAFSC). AMCRA extracts the report at least four times a year, i.e. after each Data-Lock-Point.

## b) Number of animals present at farm level

The number of animals present at each farm is needed to calculate the animal mass 'at risk of treatment' at the farm (cfr. calculation of BD<sub>100</sub>). The number is deduced from identification and registration data present in the SANITEL<sup>8</sup>-database or, specifically for poultry farms for the year 2018, from SANITEL-data combined with data from the yearly 'Biosecurity-survey' organized by the FASFC.

## i. Veal calf farms

The average number of calves present at each farm is calculated per semester, as the average over the six corresponding monthly numbers of animals. From January 2018 till July 2019, the monthly number of animals was calculated as the average occupation number taking into account the number of arrivals, births, departures and deaths per month on the farm as notified in SANITEL. From August 2019 onwards, the monthly number of animals is calculated as the average of the number of calves notified as present in SANITEL each 1<sup>st</sup>, 11<sup>th</sup> and 21<sup>st</sup> day of each month and the 1<sup>st</sup> day of the subsequent month.

## ii. Poultry farms

For 2019, SANITEL-capacity data of a poultry facility were calculated as the sum of the SANITEL-capacity data of the corresponding poultry sanitary units.

For 2018, preference was given to the yearly FAFSC 'Biosecurity-survey' capacity numbers above SANITEL-data. These are either a separate capacity for broilers and laying hens on a facility, a total capacity for broilers and laying hens on a facility. If for a given facility notifications were present in Sanitel-Med for a poultry category missing from the Biosecurity-survey but for which capacity data was available in SANITEL, the SANITEL-capacity was used.

## iii. Pig farms

SANITEL-data include capacity data (updated whenever a change is made to the capacity, for example by building a new or changing an existing stable) as well as count data (the number of animals present needs to be registered in SANITEL by the herd veterinarian at least three times a year). The capacity is the preferred animal number in the calculations. If not available, count data are used. The number of suckling piglets is calculated from the number of sows using the formula  $\# sucklers = \# sows \times \frac{27}{12}$ . The number of gilts is added to the number of sows if these are present at the farm; if not, the gilts are counted as fattening pigs. No separate analysis is done for gilts.

## c) Number of active farms

The number of active farms (i.e. having raised animals, hence, where antibacterial products *could* have been used), is needed to determine the reference population for benchmarking (cfr. further in the text). Being 'active' is encoded as a separate feature in SANITEL.

<sup>&</sup>lt;sup>8</sup> <u>http://www.afsca.be/dierlijkeproductie/dieren/sanitel/</u>

## Data analysis

The analysis of the Sanitel-Med data is split in three parts:

- A first part that focusses on the coverage of the Sanitel-Med use data of the sales data and is based only on the mass used (numerator).
- A second part that focusses on the evolution of the use at the species-level, and is based on the number of treatment days calculated with a species-specific denominator.
- A third part that focusses on the use at the farm-level, and is based on the number of treatment days calculated with a farm-specific denominator.

For the first and second part of the analyses, the data were not subjected to the farm-level quality controls for defining the reference populations for benchmarking (see further in the text). Hence, the analyses include all numerator data (all notifications) submitted to Sanitel-Med, except those that were considered erroneous and have not been confirmed as being correct. The errors concerned include notifications that lead to an extremely high used quantity. For the third part, benchmarking reference populations were calculated after subjecting the data to quality controls as described further below.

## a) Determination of the numerator

#### *i.* Mg active substance used

This is calculated per Sanitel-Med notification, using the formula

active substance used (mg) = quantity antibacterial product  $\times$  strength

The quantity of antimicrobial product is the number of packages times the number of units of antimicrobial product per package. The strength is the number of units of active substance per unit of antimicrobial product and is taken from the products' summary of product characteristics (SPC). If the active substance unit is given in international units, a transformation to mg is done using the conversion factors provided on the webpage of the AMCRA data analysis unit<sup>9</sup>. If the product contains more than one active substance, the calculation is done for each substance and the sum is made.

After calculating the total mg of active substance used per notification, the amounts can be aggregated by farm, by type of active substance, by animal category and by animal species, and recalculated to kg or tonnes used.

## *ii.* Number of DDDA<sub>bel</sub> used

The DDDA<sub>bel</sub> (the Defined Daily Dose Animal for Belgium) is the daily dose (in mg) per kg live bodyweight. This is calculated per notification using the formula

 $\# DDDA_{bel} = mg active substance/DDDA_{bel}$ 

The DDDA<sub>bel</sub>-values for all antibacterial products in the Sanitel-Med medicinal product list and for all self-defined products are defined and maintained by AMCRA in 'Antibacterial-dosing' lists made up per animal species<sup>10</sup>. The lists also contain the LA<sub>bel</sub> (Long-acting factor defined for Belgium) of each product. This LA<sub>bel</sub> factor corrects the longer duration of action of certain products in the calculation of the BD<sub>100</sub> (cfr. Further in the text). For not-long-acting products, the LA<sub>bel</sub> equals 1. The procedures for determining the DDD<sub>bel</sub> and LA<sub>bel</sub> values are also available on the AMCRA website<sup>10</sup>.

<sup>&</sup>lt;sup>9</sup>https://www.amcra.be/swfiles/files/Principes%20voor%20bepalen%20van%20DDD-

bel%20op%20productniveau(2)\_109.pdf

<sup>&</sup>lt;sup>10</sup> <u>https://www.amcra.be/nl/analyse-antibioticagebruik/</u>

#### b) Determination of the denominator

#### *i.* Kg at risk per species

The kg animal at risk per species is calculated from the yearly average number of animals present per animal category, consulted in the statbel database<sup>11</sup>. The fields included from the database and the standard weights to calculate the corresponding kg at risk is shown below:

Piglets of <20 kg	12 kg	Laying hens	2 kg	Bovines < 1 year to be	80 kg
Pigs 20-50 kg + fatteners	50 kg	Broilers	1 kg	slaughtered as calves	
Breedings pigs >50 kg	220 kg				

#### ii. Kg at risk per animal category at farm level

Per animal category on each farm, the animal mass 'at risk of treatment' (in kg) is calculated using the formula

mass animals at risk (kg) = number of animals  $\times$  estimated standard weight at treatment

The following estimated standard weights at treatment were used (source: EMA 2013<sup>12</sup>):

Suckling piglets	4 kg	Broilers	1 kg	Veal calves	80 kg
Weaned piglets	12 kg	Laying hens	2 kg		
Fattening pigs	50 kg				
Sows	220 kg				

#### c) Indicators

#### i. Mg used

To make a comparison between the yearly antimicrobial sales data, which include all animal species, and the antimicrobial use data, in total and for each of the species (pigs, poultry, veal calves) separately, the total amount of active substance used in each species was calculated, from the sum of the mg used in all Sanitel-Med notifications for that species.

#### *ii.* BD<sub>100</sub>

To compare and follow-up the usage of antibacterial products in the different animal categories, the  $BD_{100}$  is used, which represents the % of time an animal is treated with antimicrobials. This indicator is calculated with the general formula:

$$BD_{100} = \left[ \binom{\#DDDA_{bel}}{kg \text{ animals at risk} \times days \text{ at risk}} \times LA_{bel} \right] \times 100$$

<sup>&</sup>lt;sup>11</sup> https://statbel.fgov.be/nl/themas/landbouw-visserij/land-en-tuinbouwbedrijven#figures

<sup>&</sup>lt;sup>12</sup> <u>https://www.ema.europa.eu/en/documents/scientific-guideline/revised-european-surveillance-veterinary-antimicrobial-consumption-esvac-reflection-paper-collecting\_en.pdf</u>

To obtain a result per combination of farm and animal category, the BD<sub>100</sub> is first calculated per Sanitel-Med notification and per month (i.e. with 30,42 days at risk and with the animals at risk determined for that month). Then, the sum of these BD<sub>100</sub> values over all notifications in one month is made, from which an average over the 12 months in the year is calculated, resulting in a final month-average BD<sub>100</sub> per animal category on a farm. The comparison between animal categories is then done based on the frequency distribution over all farm-animal category combinations that belong to the core reference population for benchmarking (cfr. below).

## iii. BD100-species

The  $BD_{100}$ -species is calculated with the  $BD_{100}$  formula but with the sum of the  $\#DDDA_{bel}*LA_{bel}$  per species in the numerator and the kg at risk per species in the denominator.

## Quality control for defining the yearly and core reference populations for benchmarking

The <u>yearly reference population</u> for benchmarking is used to study the distribution of the BD<sub>100</sub> in an animal category, and it is per animal category defined as the group of farms that, for the whole year under consideration

- were 'active' (see point a)
- had no 'errors' in their Sanitel-Med notifications (see point b)
- fulfilled the conditions with respect to 'minimum herd size and empty stables' (see points c and d).

The <u>core reference population</u> for benchmarking follows from the yearly refence populations for benchmarking and is used to study the evolution of the distribution of the  $BD_{100}$  in an animal category over several years, and it is per animal category defined as the group of farms that were part of the yearly reference population in all considered years.

In the reference populations, a further distinction is made between zero-use farms and use-farms (see point e).

## a) Active during the whole year

A farm was eligible for inclusion in the benchmarking reference population when it was encoded active during the whole year. For poultry farms, more specifically at least one sanitary unit needed to have been active during the whole year for the facility to be included. Pig farms encoded as 'active' but not having any registration in Sanitel-Med and either having no recent count date (i.e. count date before 2019) or having a recent count date (i.e. count date in 2019) but with counts for all pig categories equalling zero, were excluded. Veal calf farms encoded as 'active' yet not having any registration in Sanitel-Med and having zero animals in 2019 were excluded.

## b) Notification errors

Two types of errors are distinguished:

- i. Notifications that cannot be processed due to missing data on the number of animals present at the farm.
- ii. Notifications where the delivered quantity is considered erratic.

Farmers are made aware of these errors through 'error reports', providing them the opportunity to take the necessary steps to adjust the data. Farms that have notification errors that have not been adjusted or have not been confirmed as correct were excluded from the benchmarking reference population.

## c) Empty stables

Pig farms with recent count data equalling zero at the start of two consecutive trimesters, poultry farms with facility capacities equalling zero at the start of two consecutive trimesters and veal calf farms with at least one semester without animals were excluded from the benchmarking reference population.

## d) Minimum herd size requirements

A minimum herd size is defined, as shown below:

Weaned piglets	50 animals	Broilers	4900 animals	Veal calves	25 animals
Fattening pigs	100 animals	Laying hens	4900 animals		
Sows	10 animals				

Poultry and pig farms with animal numbers below the minimum for at least one quarter were excluded from the reference population for benchmarking. Veal calf farms with animal numbers below the minimum for at least a semester were excluded from the reference population.

## e) Zero-use and use farms

A zero-use farm is defined at species level for pig farms and at animal category level for poultry and veal calf farms. It is a farm that has no notifications in Sanitel-Med in a given period.

To compare the antimicrobial use in 2019 with that in 2018, the core reference population 2017-2019 was determined, with the reference populations for 2017 and 2018 as described in the 2018 BelVet-SAC report.

## RESULTS

## **ANTIMICROBIAL SALES DATA**

## **Response rate and data validation**

All of the 22 wholesaler-distributors, requested to deliver their sales data on veterinary antibacterial products sold in 2019, responded. All 44 compound feed producers, licensed for the production of medicated feed responded. One feed mill indicate not to have produced any medicated feed (any more) while 43 feed producers delivered the data on antibacterial premixes incorporated in medicated feed to be used in Belgium. Based on the response rate data coverage is assumed to be 100%.

Data providers get more and more accustomed to the system. In the last four years, the internal data validation step did not identify unexpected data entries. Therefore no data corrections were needed.

## Number of antibacterial pharmaceuticals and premixes available on the Belgian market

Table 2 provides an overview of the number of antibacterial pharmaceuticals and antibacterial premixes available on the Belgian market since 2011 according to the commented compendium of the Belgian Centre for Pharmacotherapeutic Information<sup>13</sup>.

	2011	2012	2013	2014	2015	2016	2017	2018	2019
Number of Antibacterial pharmaceuticals on the market	282	308	294	298	339	329	323	325	326
Number of Antibacterial premixes on the market	23	22	23	21	21	19	16	18	13
Total number of Antibacterial products on the market	305	330	317	319	360	348	339	343	339

#### Table 2. Armatorium of antibacterial products on the Belgian market in between 2011 and 2019.

The only new antibacterials registered on the market in the last 9 years are tildipirosin (2011), pradofloxacine (2011), fusidic acid (2014) and thiamfenicol (2015). The observed variation in available products is largely due to the marketing of new formulations or new generic products based on existing active substances. The number of Antibacterial premixes on the market has decreased with 43% in the last 9 years. This decrease intensified in 2019, which is probably linked to the strong decrease in the use of antibacterial premixes in the last 3 years.

<sup>13</sup> www.bcfi-vet.be

## Animal biomass produced in Belgium

The produced biomass was calculated based on the Eurostat data for the years 2013-2018 as described above (Table 3).

#### Table 2. Animal biomass produced in Belgium between 2014 and 2019.

Animal biomass	2014	2015	2016	2017	2018	2019
Meat (ton)						
Pork	1 118 330	1 124 310	1 060 540	1 044 560	1 073 120	1 038 916
Beef	257 670	267 880	278 360	281 540	277 310	263 749
Poultry	433 270	452 940	461 250	463 390	469 590	447 786
Sheep/goat <sup>a</sup>	2 560	2 720	3 020	3 230	3 090	3 010
Total biomass from meat production	1 811 830	1 847 850	1 803 170	1 792 720	1 823 110	1 753 487
Dairy cattle						
Dairy cattle (number)	519 090	528 780	529 780	519 160	529 250	537 960
Dairy cattle metabolic weight (ton)	259 545	264 390	264 890	259 580	264 625	268 980
Total biomass (ton)	2 071 375	2 112 240	2 068 060	2 052 300	2 087 735	2 022 450
Evolution since previous year	+2.09%	+1.97%	-2.09%	-0.76%	+ 1.73%	-3.13%

<sup>a</sup> the biomass of sheep and goat was added to the total biomass for the first time in 2016. In all calculations and tables the new biomass (including sheep and goat) was adapted retrospectively to assure a correct evolution over time.

A **decrease in biomass production of -3,13%** is observed between 2018 and 2019. Compared to the reference year 2011 a decrease of -0,91% is observed in the total biomass production in Belgium mainly due to a decrease in pig production, partially compensated by an increase in cattle and broiler production.

## Total consumption of antibacterial drugs for veterinary use in Belgium

The total consumption of antibacterial products for veterinary use in Belgium is presented in Figure 3 in tons of active substance per year since the start of the data collection (2007). The total amount is subdivided into antibacterial pharmaceuticals and antibacterial compounds contained in antibacterial premixes incorporated into medicated feed intended to be used in Belgium.



Figure 3. Total national consumption of antibacterial compounds for veterinary use in Belgium for the years 2007-2019 (tonnes active substance).

As 2011 has been selected as the reference year for all reduction initiatives (see further), further analysis shows the evolution from this year onwards.



Figure 4. Total national consumption of antibacterial compounds for veterinary use in Belgium for the years 2011-2019 (tonnes active substance).

Between 2018 and 2019, there was a **decrease of -10,5%** in the total consumption of antibacterials in veterinary medicine in Belgium (176 819,6 kg in 2019; 197 511,5 kg in 2018). The use of antibacterial **pharmaceuticals decreased with -10,7%** between 2018 and 2019, and the use of **antibacterial premixes decreased with -8,0%**. This is the fifth year in a row of decreasing use. **Since 2011 (reference year for reduction initiative) a decrease of 40,9% is realized in absolute volumes.** 



Figures 5 and 6 show these data separately for the antibacterial pharmaceuticals and the antibacterial premixes.

**Medicated Premixes** 70,0 60.0 **Fons Active Substance** 50,0 40,0 30,0 57.4 55,4 51,2 52,4 50,7 20,0 36,0 10,0 19,3 17,8 16,4 0,0 2011 2012 2013 2014 2015 2016 2017 2018 2019 Medicated Premixes

Figure 5. National consumption of antibacterial pharmaceuticals for veterinary use in Belgium for the years 2011-2019 (tons active substance).



After an increase in use of antibacterial premixes between 2007 and 2010, the decreasing trend firstly observed in 2011 continued till 2013. In 2014 this decrease came to an end and a small increase was observed. Since 2015 the decrease resumed and accelerated in 2016 and 2017. Since 2017 a further limited reduction is observed in 2018 and 2019.

Since 2011 the data collection system allows to differentiate the animal species of destination for the antibacterial premixes. In 2019, 99,7% of the antibacterial premixes went to pig feed and only 0,3% was used in poultry or rabbit feed.

From September 2013, the use of Zinc oxide (ZnO) in therapeutic doses (corresponding to 2500 ppm of Zn) in piglets for two weeks after weaning was allowed. After an increased use between 2013 (use during only one quarter) and 2015 a first decrease was observed in 2016 and continued since. In comparison to 2018 the use of ZnO reduced with -13,6% as is presented in figure 7



Figure 7. Total national consumption of antibacterial compounds for veterinary use in Belgium plus the use of ZnO for the years 2011-2019 (tons active substance).

## Antibacterial use versus biomass

As described above, the total biomass production in 2019 in Belgium has decreased with -3,1% in comparison to 2018. As a consequence the decreasing trends in use observed in absolute values (kg) is partially tempered by the fact that this reduced volume of antimicrobials is used in a decreased population. For 2018, the mg of active substance used in relation to a kg biomass produced was 94,6 mg/kg whereas in **2019 this is 87,4 mg/kg**. This means **a decrease of -7,6% in comparison to 2018.** Split into the different pharmaceutical forms (premix vs other forms), a decrease of -7,8% is observed in the antibacterial pharmaceuticals and -5,1% in the antibacterial premixes.

**Medicated Premixes & Pharmaceuticals** expressed in mg/kg biomass 160,0 mg Active Substance/ kg Biomass 140,0 28,1 27,2 120,0 25,3 25,3 24,0 100,0 8,5 8,1 80,0 60,0 118,4 109,3 104,1 102,6 99,2 99,9 99,1 86,1 40,0 79,3 20,0 0,0 2011 2012 2013 2014 2015 2016 2017 2018 2019 Farmaceuticals Medicated Premixes

Figure 8 presents these data, again subdivided into antibacterial pharmaceuticals and antibacterial premixes.

#### Figure 8. Total mg of active substance used per kg biomass produced in Belgium for 2011-2019.

The reduction seen in 2019 is the fifth year in a row with a reduction in the amount of antimicrobials used per kg biomass. Since the start of the reduction program, in seven out of the eight years a reduction was obtained. When using 2011 as a reference (see AMCRA 2020 objectives), **a cumulative reduction of -40,3% is achieved**, distributed in a reduction of -33,0% in antibacterial pharmaceuticals and -71,1% in antibacterial premixes (Fig. 9).



Figure 9. Evolution of antimicrobial consumption per kg biomass produced in Belgium with 2011 as reference year.

## Positioning of Belgium in comparison to the EU member states.

Since 2009 the European Medicines Agency (EMA) runs the European Surveillance of Antibacterial Consumption (ESVAC) project that aims at the collection of antibacterial sales data in all EU member states in a comparable manner allowing to evaluate trends and compare usage within and between countries. The data collected in Belgium and presented in the annual BelVet-SAC reports are also collected in the framework of this EU wide ESVAC data collection effort.

In 2019, the ninth ESVAC report, presenting results on antibacterial usage in 31 EU /EEA countries in the year 2017 was released<sup>14</sup>. In this report the **antibacterial consumption in animals in 2017 is presented in relation to the animal production in the country.** 

In figure 10 the results of the 31 countries included in the ninth ESVAC report are presented in mg active substance used and the animal production quantified by means of the Population Correction Unit (PCU) which is comparable to the biomass used in this BelVet-SAC report but also includes species as horses and rabbits and corrects more thoroughly for import and export.



# Figure 10. Sales for food-producing species, including horses, in mg/PCU, of the various veterinary antibacterial classes, by country between 2015-2016 (source: 8<sup>th</sup> ESVAC report on Sales of veterinary Antibacterial agents).

When looking at figure 10, it can be observed that Belgium resides at the eighth position in terms of antibacterial usage expressed in mg/PCU in 2017. Obviously, when comparing countries one has to take into account the composition of the animal population (e.g. relative proportion of ruminants versus monogastric species).

<sup>&</sup>lt;sup>14</sup> <u>https://www.ema.europa.eu/en/documents/report/sales-veterinary-antimicrobial-agents-31-european-</u> <u>countries-2017\_en.pdf</u>

Noteworthy, these data do not yet include the substantial decrease in use in Belgium achieved in 2018 and 2019. It is also remarkable to see that although the mean value of use in Europe has decreased from 109 mg/PCU in 2013 to 91,5 mg/PCU in 2017, the median value has remained more or less stable around 60 mg/PCU (62,3 mg/PCU in 2013 and 61,9 mg/PCU in 2017.

Compared to neighbouring countries (France, Luxemburg, Germany, United Kingdom, The Netherlands (Figure 11)) with a relatively comparable structure of livestock farming, the use in Belgium remains high and very substantial further reductions are required to achieve the same levels.



Figure 11. Overall sales of antimicrobials in mg/PCU between 2014-2017 (source: 5<sup>th</sup>-8<sup>th</sup> ESVAC report on Sales of veterinary Antibacterial agents) for Belgium and neighbouring countries.

## Species specific antibacterial use

As mentioned before, a majority of the antibacterial products available on the Belgian market is registered for multiple species. In figure 12 an overview is given of total sales and proportion of total sales according to the authorized target species.

In 2019, antibacterials that are registered solely for pigs are most used (32,5%) followed by antibacterials registered for both pigs and poultry (24,3%). The third most used antibacterial pharmaceuticals are the ones registered for cattle, pigs and poultry (12,7%). The largest decrease in use over the last 4 years is observed in the first two categories (pigs; pigs & poultry).



Figure 12. Use of antibacterial pharmaceuticals and premixes per authorized species, evolution between 2014 and 2018.

## Intramammary products in dairy cattle

Other types of antibacterial products that can be allocated to mainly one animal species are the intramammary products used for prevention (DC = dry cow therapy) and otherwise for treatment of udder infections (LC = lactating cows).

## a) Total use of intramammary products

In figure 13 an overview is given of the use of intramammary products for treatment of udder infections in the last five years separated into the classes of active substance and related to the biomass of dairy cows present in that year.



Figure 13. Evolution in use of antimicrobials for intramammary treatment between 2015 and 2019.

In figure 14 the evolution in use over the last five years of intramammary products is presented.



Figure 14. Evolution in use of antibacterial products for intramammary treatment expressed per kg biomass of dairy cattle between 2013 and 2019.

From the results of figure 14 it can be seen that the use of IM preparations was substantially reduced between 2013 and 2015 (-30%), however since 2015 it has steadily increased again (+22%).

## b) Number of DC and LC injector per dairy cow.



These results can also be presented as the number of injectors used per cow per year.

#### Figure 15. Evolution in use of number of intramammary preparations used per cow present over the last 7 years.

Also from the number of applicators used per cow per year a substantial reduction in use of intramammary applicators was observed between 2013 and 2015 which is mainly due to a reduction of the use of DC applicators. Since 2015 there is a steady increase in the use of DC applicators which shows that there is no indication of a further implementation of selective dry cow therapy. The number of applicators used for the treatment of mastitis cases has also steadily increased over the last 3 years.

## Antibacterial pharmaceuticals in dogs and cats

In 2018, 2369 kg of active substance was used in dogs and cats. In 2019 this was 2677 kg, corresponding to an increase of +13,0% in comparison to 2018. Compared to 2014 the total increase of antibacterial substances used in dogs and cats is + 24,25%. The evolution since 2014 is shown below. In the last 6 years (with the exception of 2017) a constant increase in use of antimicrobials that are only registered for dogs and cats is observed. It is noteworthy to mention that we do not have an accurate estimate of the evolution in the total dog and cat population (denominator). Therefore the observed evolution cannot be placed in contrast to the possible evolution of the population size.







#### Figure 17. Use of different antibacterial classes in products only registered for dogs and cats.

Penicillin/clavulanic acid (1186,2 kg) is the most used antibacterial compound in dogs and cats, followed by cephalosporines of the 1° and 2° generation (618,7kg) and macrolides (323,3 kg). In the cephalosporines of the 1° and 2° generation a substantial increase is observed in 2018 & 2019 due to an increased use in cefalexine, a narrow spectrum cephalosporine. The increased use in "others" is due to an increase in use of metronidazole, administered in combination with spiramycine.

## Antibacterial use per class of antibacterial compound

## a) Total consumption (antibacterial pharmaceuticals and premixes)



In Figure 18 and table 4 the total consumption of antibacterials per class (ATC level 3 or 4 is presented).

#### Figure 18. Total antibacterial use per class of antibacterials from 2011 to 2019.

In 2019, the most used group of antibacterials remained the penicillins (68,6 tons; 38,9%). The tetracyclines (37,1 tons; 21,0%) are the second most used group followed by the sulphonamides and trimethoprim (33,8 tons; 19,1%). 2019 is the seventh year in row where penicillins are the most used compound. In table 4, the evolution of the used products per antimicrobial class in mg/kg biomass in the last 5 years is presented.

Class AB mg/kg biomass	2013	2014	2015	2016	2017	2018	2019	'13 » '14	'14 » '15	'15 » '16	'16 » '17	'17 » '18	'18 » '19	2019%
Penicillins	39,88	39,91	38,09	42,03	40,96	35,78	34,63	0,1%	-4,6%	10,3%	-2,6%	-12,6%	-3,2%	39,61
Sulphonamides & trimethoprim	36,79	37,39	35,08	31,64	21,56	17,49	16,69	1,6%	-6,2%	-9,8%	-31,8%	-18,9%	-4,5%	19,10
Tetracyclines	30,80	29,92	28,49	24,16	27,66	23,96	18,35	-2,8%	-4,8%	-15,2%	14,4%	-13,3%	-23,4%	20,99
Macrolides	8,64	11,27	10,80	9,57	9,18	8,12	8,09	30,5%	-4,2%	-11,4%	-4,0%	-11,5%	-0,4%	9,25
Polymyxins	3,89	2,74	2,25	2,03	1,76	1,69	1,50	-29,6%	-17,6%	-9,9%	-13,3%	-4,1%	-11,2%	1,72
Aminosides	3,99	4,34	4,47	4,48	4,49	3,93	4,71	8,8%	3,1%	0,2%	0,3%	-12,6%	20,0%	5,39
Quinolones	1,64	1,69	1,92	0,82	0,29	0,44	0,48	3,2%	13,7%	-57,5%	-64,2%	50,0%	10,0%	0,55
Other**	0,90	0,61	0,57	0,55	0,50	1,05	0,82	-32,3%	-6,1%	-3,8%	-9,4%	109,5%	-21,4%	0,94
Phenicols	0,75	0,78	0,99	1,46	1,50	1,59	1,56	4,6%	26,5%	47,3%	3,0%	6,1%	-1,8%	1,79
Cephalosporins 1° & 2° G	0,35	0,39	0,37	0,44	0,41	0,37	0,52	12,7%	-4,4%	16,3%	-6,7%	-7,8%	38,1%	0,59
Cephalosporins 3° & 4° G	0,41	0,38	0,35	0,25	0,09	0,07	0,07	-7,0%	-9,5%	-28,3%	-65,9%	-19,2%	-2,6%	0,08
Total mg/kg biomass	128,02	129,42	123,39	117,43	108,40	94,50	87,43	1,09%	-4,66%	-4,83%	-7,69%	-12,83%	-7,48%	100
Total biomass cfr. Grave et al., 2010)*	2.026.565	2.068.815	2.109.520	2.065.040	2.052.300	2.087.735	2.022.450	2,08%	1,97%	-2,11%	-0,62%	1,73%	-3,13%	

Table 4. The evolution of use (mg/kg biomass) per antimicrobial class since 2011.

\*\* zink bacitracin,

rifaximin, metronidazol,

tiamulin

In 2019, the use of the three main compounds (penicillins, sulphonamides and tetracyclines) all continued to decrease. Especially the reduction of tetracycline use in 2019 is remarkable. Only in three antimicrobial classes an increase was seen this year. First of all an increase of 20,0% in use of aminosides. This is in contrast to 2018 where a decrease in use of this molecule of almost 13% was observed. Also the use of cephalosporines of the 1° and 2° generation grew substantially (+38,1%). This is entirely due to an increase in the use of cefalexine registered for use in dogs and cats and in intramammary products for cattle. And finally the use of quinolones increased for the second year in a row (+10%). The latter is worrisome as the quinolones are categorized as "red" antimicrobials. The use of these molecules decreased very substantially in 2016 and 2017, however it increased again in 2018 and continued at this level in 2019. The increase in 2018 was entirely due to an increase in the use of flumequine stayed more or less at the same level in 2019, the further increase in 2019 is largely due to an increase in use of enrofloxacin. The cephalosporines of the 3<sup>rd</sup> and 4<sup>th</sup> generation (the second group of "red" molecules), continue to decrease in use again driven by a continued substantial decrease in use of ceftiofur (table 5).

The decreased use of polymyxins (almost entirely colistin sulphate) is observed for the seventh year in a row with a decrease of -11,2% in 2019. This is a positive trend given the simultaneous decrease in use of ZnO as an alternative for colistin in the treatment of post-weaning diarrhoea in piglets, meaning that alternative treatments without use of antibiotics or ZnO may have been used more frequently. When comparing to 2012 (before authorization of ZnO products), polymyxin use has dropped with 66,4%.

AMCRA (centre of expertise on AntiMicrobial Consumption and Resistance in Animals)<sup>15</sup> published its first guidelines on responsible antibacterial consumption in 2013 and made them online available since 2016. In these guidelines, the different antibacterial classes available in veterinary medicine are given a colour to differentiate them in terms of importance for human and animal health. The ranking of importance is based on the WHO list on antibacterial with importance for human health<sup>16</sup> and the lists produced by the World Animal Health Organization (OIE) indicating the importance of antibacterials for veterinary health<sup>17</sup>. When producing these lists, priority was given to human health.

The group of yellow products contains the antibacterial classes with the lowest importance for human medicine in terms of resistance selection and transfer and therefore no additional restrictions, on top of the legal requirements, are suggested for the use of these compounds. The yellow group contains the majority of the penicillins, the sulphonamides (and diaminopyrimidines), the cephalosporins of the first generation and the phenicols.

The group of orange products are of higher importance for human medicine and should therefore be used restrictively and only after good diagnostics allowing to target the therapy. The orange group contains the highest amount of different molecules including all available macrolides, the polymyxins, the aminoglycosides, the tetracyclines and the aminopenicillins.

The **red** group of products are the products of the highest importance for human medicine and therefore their use should be avoided in veterinary medicine as much as possible. AMCRA advises to use these molecules only under very strict regulations. This group contains the cephalosporins of the 3<sup>rd</sup> and 4<sup>th</sup> generation and the quinolones.

In figure 19, the evolution of use of the different colour groups of antibacterials over the last 4 years is presented. From this figure it can be seen that the orange group remains the most widely used group whereas the red molecules are only limitedly used when expressed in mg active substance per kg biomass. Yet the red molecules are generally more modern molecules with a high potency and therefore a low molecular weight in relation to their treatment potential. In 2019, a substantial decrease in the yellow (-7 %) and orange (-8%) groups is observed, whereas the red group shows an increase of +8%. The latter increase is entirely due to the increased use in the quinolone group as was discussed already before. In comparison to 2011 (reference year) the reduction of red molecules is still -77,3% which remains below the aim of minus 75% by 2020.

<sup>&</sup>lt;sup>15</sup> www.amcra.be

<sup>&</sup>lt;sup>16</sup> <u>http://apps.who.int/iris/bitstream/10665/77376/1/9789241504485\_eng.pdf</u>

<sup>&</sup>lt;sup>17</sup> <u>http://web.oie.int/downld/Antibacterials/OIE\_list\_Antibacterials.pdf</u>



Figure 19: Evolution in the antibacterial consumption (mg/kg) per antibacterial colour group between 2014 and 2019.

A similar graph with products exclusively registered for dogs and cats (Fig. 20) shows an increase in use in every category. As the biomass of dogs and cats in Belgium is unknown it is difficult to relate this data to any change in biomass of these species.



Figure 20: Evolution in the antibacterial consumption (kg active compound) per antibacterial colour group for compounds exclusively registered for use in dogs and cats between 2014 and 2019.

## b) Antibacterial pharmaceuticals





Figure 21. Use of antibacterial pharmaceuticals per class of antibacterials between 2011 and 2019.

## c) Antibacterial premixes



In Figure 22 the consumption of antibacterials per class (ATC level 3 or 4) is presented for the antibacterial premixes.

Figure 22. Use of antibacterial premixes per class of antibacterials between 2011 and 2019.

# Antibacterial use per active substance

Table 5 gives the amounts used per individual active substance, grouped per class of antibacterials.

## Table 5. Antibacterial use per active substance.

											->	Madicated promises (kg)				
	Antimicrobiol			total Kg			A	ntimicrobia	ai pharmac	euticais (K	5)		Iviedic	ated prem	ixes (kg)	
Class	compound	2015	2016	2017	2018	2019	2015	2016	2017	2018	2019	2015	2016	2017	2018	2019
cephalosporins 1G	cefalexine	740,4	837,3	763,0	720,2	993,2	740,4	837,3	763,0	720,2	993,2					
cephalosporins 1G	cefalonium	12,8	12,2	10,2	9,3	8,7	12,8	12,2	10,2	9,3	8,7					
cephalosporins 1G	cefapirine	20,7	31,7	44,3	45,3	41,3	20,7	31,7	44,3	45,3	41,3					
cephalosporins 1G	cefazoline	15,6	17,7	16,0	7,3	3,2	15,6	17,7	16,0	7,3	3,2					
fenicols	chlooramfenicol	-	-	-	-	-	-	-	-	-	-					
fenicols	florfenicol	2.084,5	3.006,5	3.077,5	3.320,7	3.159,5	1.984,1	2.632,3	2.816,2	3.041,5	2.916,5	100,5	374,1	261,3	279,2	243
other	metronidazol	92,5	100,5	96,7	234,4	254,5	92,5	100,5	96,7	234,4	254,5					
other	tiamuline	1.032,3	994,2	879,0	1.901,6	1.362,2	548,3	640,4	624,6	1.236,0	1.007,8	484,0	353,8	254,4	665,6	354,4
other	valnemuline	11,2	-	0,3	-	-	-	-	-	-	-	11,2	-	0,3	-	0
other	zink bacitracine	48,6	23,3	28,9	28,2	25,4	48,6	23,3	28,9	28,2	25,4					
penicillines	benethamine penicilline	10,2	22,1	33,7	38,2	58,6	10,2	22,1	33,7	38,2	58,6					
penicillines	cloxacilline	337,7	286,9	260,0	257,2	183,8	337,7	286,9	260,0	257,2	183,8					
penicillines	fenoxymethylpenicilline	537,0	796,4	864,2	1.078,4	1.424,4	537,0	796,4	864,2	1.078,4	1.424,4					
penicillines	nafcilline	7,2	6,3	6,0	6,0	7,3	7,2	6,3	6,0	6,0	7,3					

penicillines	penethamaat	146,1	184,8	235,2	202,0	198,6	146,1	184,8	235,2	202,0	198,6					
penicillines	procaïne benzylpenicilline	10.508,4	10.359,3	9.426,0	9.583,8	7.013,7	10.508,4	10.359,3	9.426,0	9.583,8	7.013,7					
sulphonamides	sulfachloorpyridazine natrium	1.098,2	1.094,5	1.176,4	1.050,7	458,5	1.098,2	1.094,5	1.176,4	1.050,7	458,5					
sulphonamides	sulfadiazine	59.403,3	51.631,2	33.703,6	27.303,7	25.602,3	37.954,0	37.350,2	32.971,4	27.266,8	25.602,3	21.449,3	14.281,0	732,3	36,9	0
sulphonamides	sulfadimethoxine natrium	-	-	-	37,7	32,0	-	-	-	37,7	32,0					
sulphonamides	sulfadimidine natrium	_	-	-	-	-	_	-	-	-	-					
sulphonamides	sulfadoxine	587.9	922.8	1.174.1	1.238.4	816.4	587.9	922.8	1.174.1	1.238.4	816.4					
sulphonamides	sulfamethoxazol	557.6	785.4	810.8	792.6	1.222.8	557.6	785.4	810.8	792.6	1.222.8					
sulphonamides	sulfanilamide	-		-	-	-	-									
sulphonamides	trimethoprim	12,351.8	10.906.3	7.390.8	6.092.7	5.632.4	8.061.9	8.050.1	7.244.4	6.085.3	5.632.4	4,289,9	2.856.2	146.5	7.4	0
amino(glyco)sides	anramycine	97.9	79.5	49.5	34.0	102.1	37.0	26.3	12 5	0.2		60.9	53.2	37.0	33.8	102.05
amino(glyco)sides	dihydrostreptomycine	7.2	63	131 7	6.0	85	72	63	131 7	6.0	85			01)0	00,0	
amino(glyco)sides	framycetinesulfaat	63	11 3	16.3	17.8	24.3	63	11 3	16.3	17.8	24.3					
amino(glyco)sides	gentamicine	129.2	136.1	141 7	172.9	170.7	129.2	136.1	141 7	172.9	170.7					
amino(glyco)sides	kanamycine	23.7	22.7	25.3	53.2	102.0	223,2	230,1	25.3	53.2	102.0					
amino(glyco)sides	neomycine	336.0	683.8	672.9	17.7	34.0	336.0	683.8	672.9	47.7	34.0					
amino(glyco)sides	naromomycina	2 269 1	1 979 /	1 907 1	2 5 1 0 2	2 502 5	2 269 1	1 979 /	1 907 1	2 5 1 0 2	2 502 5					
amino(glyco)sides		6 /71 5	6 /27 2	6 200 4	5 261 0	6 500 0	6 217 7	6 220 9	6 260 6	5 256 6	6 500 2	2527	116 /	10.0	A A	0 5 5
macrolides	clindamycine	1/1/1,5	1/10 7	121 2	125 0	126.2	1// 1	1/10 7	121 2	125 0	126.2	200,7	110,4	19,8	4,4	0,55
amino(glyco)sides amino(glyco)sides macrolides	neomycine paromomycine spectinomycine clindamycine	336,0 2.368,1 6.471,5 144,1	683,8 1.878,4 6.437,2 142,7	672,9 1.807,1 6.380,4 121,2	47,7 2.510,2 5.361,0 135,8	34,0 2.502,5 6.589,9 136,3	336,0 2.368,1 6.217,7 144,1	683,8 1.878,4 6.320,8 142,7	672,9 1.807,1 6.360,6 121,2	47,7 2.510,2 5.356,6 135,8	34,0 2.502,5 6.589,3 136,3	253,7	116,4	19,8	4,4	0,

Macrolides	erythromycine	0,9	-	-	-	-	0,9	-	-	-	-					
Macrolides	gamithromycine	20,3	32,9	29,8	39,3	36,7	20,3	32,9	29,8	39,3	36,7					
Macrolides	lincomycine	5.631,8	4.582,0	4.990,6	4.378,7	5.066,7	5.378,0	4.465,6	4.970,8	4.374,3	5.066,2	253,7	116,4	19,8	4,4	0,55
Macrolides	pirlimycine	0,4	0,2	-	-	-	0,4	0,2	-	-	-					
Macrolides	spiramycine	248,0	195,4	183,7	160,0	187,0	248,0	195,4	183,7	160,0	187,0					
Macrolides	tildipirosine	44,5	48,9	48,5	49,2	47,2	44,5	48,9	48,5	49,2	47,2					
Macrolides	tilmicosine	4.159,7	3.785,5	3.160,2	2.824,7	2.918,8	2.540,3	2.637,1	2.344,6	2.113,7	2.372,8	1.619,4	1.148,4	815,6	711,0	546
Macrolides	tulathromycine	111,1	133,1	142,2	128,1	119,5	111,1	133,1	142,2	128,1	119,5					
Macrolides	tylosine	12.041,0	10.581,1	9.839,8	9.181,1	7.808,5	11.151,5	10.149,1	9.600,2	9.040,3	7.674,8	889,5	432,0	239,5	140,9	133,75
Macrolides	tylvalosin	377,9	259,8	330,2	60,5	39,2	377,9	259,8	330,2	46,2	37,5				14,4	1,7
other	rifaximin	24,8	21,4	20,7	21,3	22,3	24,8	21,4	20,7	21,3	22,3					
penicillines	amoxicilline	68.574,8	74.840,9	72.929,0	63.182,0	60.561,2	55.025,1	64.267,8	61.549,1	53.406,1	50.420,3	13.549,7	10.573,1	11.380,0	9.775,9	10140,8325
penicillines	amoxicilline-clav	222,2	244,3	257,6	230,0	279,3	222,2	244,3	257,6	230,0	279,3					
penicillines	ampicilline	233,3	297,8	302,8	356,3	312,0	233,3	297,8	302,8	356,3	312,0					
polymyxins	colistinesulfaat	4.755,6	4.195,0	3.613,9	3.524,9	3.033,4	4.060,3	3.719,4	3.156,1	3.134,9	2.961,9	695,3	475,6	457,8	390,0	71,54
polymyxins	polymyxine B sulfaat	0,9	0,8	0,8	0,7	1,0	0,9	0,8	0,8	0,7	1,0					
tetracyclines	chloortetracycline	588,2	717,2	664,9	738,5	634,8	526,1	680,1	664,9	738,5	634,8	62,1	37,1	-	-	0
tetracyclines	doxycycline	49.134,3	38.130,4	46.540,0	39.843,2	30.687,1	42.364,9	33.120,0	41.705,1	34.070,8	25.872,1	6.769,4	5.010,4	4.834,9	5.772,4	4815
tetracyclines	oxytetracycline	10.369,3	11.052,0	9.552,0	9.448,8	5.786,7	10.199,8	10.926,9	9.448,0	9.444,8	5.786,7	169,5	125,1	104,0	4,0	0

(fluoro)quinolones	danofloxacine	60,0	42,5	12,0	8,4	6,5	60,0	42,5	12,0	8,4	6,5			
(fluoro)quinolones	difloxacine	-	-	-	-	-	-	-	-	-	-			
(fluoro)quinolones	enrofloxacin	1.280,7	719,3	306,5	305,4	375,7	1.280,7	719,3	306,5	305,4	375,7			
(fluoro)quinolones	flumequine	2.197,5	610,6	176,0	519,5	516,5	2.197,5	610,6	176,0	519,5	516,5			
(fluoro)quinolones	ibafloxacine	-	-	-	-	-	-	-	-	-	-			
(fluoro)quinolones	marbofloxacine	504,0	306,6	99,0	75,3	70,2	504,0	306,6	99,0	75,3	70,2			
(fluoro)quinolones	orbifloxacine	3,1	3,0	2,7	2,9	3,2	3,1	3,0	2,7	2,9	3,2			
(fluoro)quinolones	pradofloxacine	3,4	2,9	2,5	2,1	1,8	3,4	2,9	2,5	2,1	1,8			
cephalosporins 3G	cefoperazon	6,5	5,9	5,0	5,4	4,2	6,5	5,9	5,0	5,4	4,2			
cephalosporins 3G	cefovecin	9,1	9,3	9,0	9,1	9,4	9,1	9,3	9,0	9,1	9,4			
cephalosporins 3G	cefquinome	179,9	132,6	89,2	75,6	75,3	179,9	132,6	89,2	75,6	75,3			
cephalosporins 4G	ceftiofur	537,1	366,6	71,4	53,3	46,4	537,1	366,6	71,4	53,3	46,4			

## **ANTIMICROBIAL USE DATA**

## **Notifications in Sanitel-Med**

Table 6 shows the number of notifications (incl. ZnO) in Sanitel-Med in 2019, the number of farms for which notifications were done and the number of veterinarians that did the notifications, in total and per species. The pig sector remained the largest sector in all terms and the veal sector remained the smallest sector in terms of active veterinarians and number of farms, yet equalling the poultry sector in terms of notifications. The sum of the veterinarians per species does not equal the total number, meaning that some veterinarians did notifications for multiple species.

······································												
	TOTAL PIG								POULTRY		VEAL	
	n	AB n	%	ZnO n	%	Total n	%	AB n	%	AB n	%	
Notifications	169 616	124 888	74	7 984	5	132 872	78	18 304	11	18 440	11	
Farms	5 293	4 204	79	618	12	4 210	80	826	16	257	5	
Veterinarians	302	250	83	102	34	252	83	56	19	23	8	

Table 6. Number of notifications and farms and veterinarians with notifications per animal species in Sanitel-Med in 2019.

## Sanitel-Med coverage of sales data

## a) General

The mass antimicrobials calculated from all Sanitel-Med notifications in 2019 covered 80% of the mass according to the 2019 Belgian sales data as presented above. The coverage was 79% for pharmaceuticals and 93% for premixes medicated with antibacterials (Figure 23), which is quite similar to the results of 2018. Yet, the difference between the sales and use data amounted to 34,6 tonnes in 2019, which was 19% lower than the difference in 2018 (42,5 tonnes) (Figure 24).





It must be noted that the coverage result is slightly confounded because Sanitel-Med accepts notifications from products not authorised for sale in Belgium (notified as Self Defined Products – SDPs). The part SDPs make up from the Sanitel-Med total tonnes remained stable on approx. 1,3 tonnes in the last two years (Figure 24). Only one product is involved: Neosol 100%.



Figure 24. Comparison of tonnes active substance used (Sanitel-Med) in 2018 and 2019 with the corresponding Belgian sales data for those years, distinguishing based on authorisation of the products for sale in Belgium. The part of the sales data not covered by Sanitel-Med data is also shown.

In the following analyses, SDPs are always included in the Sanitel-Med data unless stated otherwise.

## b) Per species/animal category

In 2019, fatteners and weaned piglets remained the animal categories with the largest mass of antimicrobials used, together accounting for 68% of tonnes used (Figure 25). As in 2018, weaners used the highest total mass of antimicrobials in 2019 when including ZnO.



Figure 25. Tonnes active substance of pharmaceuticals, medicated premixes and ZnO used in 2019 per Sanitel-Med animal category.

Total use of ZnO was 0,9 tonnes higher in 2019 (37,6 tonnes) compared to 2018 (36,7 tonnes); its use in weaned piglets slightly decreased, but the use of ZnO in sucklers dramatically increased with 250% in 2019. Remarkably, the tonnes ZnO notified in Sanitel-Med in 2019 exceeded the ZnO sales data for 2019 as presented above (33,6 tonnes). This might indicate that part of the ZnO used in Belgian pig farms is imported from other member states.

## c) Per antimicrobial class

When breaking down the total used tonnes in the different antimicrobial classes, coverage of sales data was above 80% for penicillins, tetracyclines, macrolides and polymyxins (Table 7). In contrast, coverage was very low for cephalosporins and below 50% for quinolones, showing that these molecules are predominantly used in animal species currently not covered in Sanitel-Med.

	Sales 2019	Sales 2019 Use 2019									
	Tonne	Total tonne	% sales	Pig tonne	% sales	Poultry tonne	% sales	Veal tonne	% sales		
Penicillins	70,0	57,9	83	44,0	63	9,5	13	4,4	6		
Tetracyclines	37,1	33,6	91	26,3	71	1,6	4	5,7	15		
Trim-sulfa	33,8	22,7	67	17,8	53	3,9	12	1,0	3		
Macrolides	16,4	15,8	97	7,1	43	5,0	30	3,8	23		
Aminosides	9,5	6,5	68	2,8	30	2,5	26	1,1	12		
Polymixins	3,0	2,6	84	2,3	76	0,2	6	0,1	3		
Phenicols	3,2	1,6	51	1,4	45	<0,1	<1	0,2	5		
Other	1,7	1,1	65	1,1	65	0	0	0	0		
Quinolones	1,0	0,4	36	<0,1	<1	0,3	33	<0,1	3		
Cephalosporins	1,2	<0,1	<1	<0,1	<1	0	0	<0,1	<1		

 Table 7. Total tonnes per antibacterial class sold in 2019 (Sales 2019) and total tonnes used in pigs, poultry and veal calves

 (Use 2019). Next to the tonnes used by each species the % this covers of the sales data (% sales) is shown.

## Use of critical substances in the Sanitel-Med animal species

Poultry remained the Sanitel-Med species with the largest use of (fluoro)quinolones (Figure 26a), although the used mass as well as the % of farms with notifications using these critical substances decreased compared to 2018. Used mass as well as the % of farms using (fluoro)quinolones also decreased in veal calves and pigs. Pigs remained the single species with use of cephalosporins 3G/4G (Figure 26b), albeit virtually zero.



Figure 26a. Kg used of the (fluoro)quinolones in pigs, poultry and veal calves in 2018 and 2019, and the % of farms with notifications using these critical substances.



Figure 26b. Kg used of the 3<sup>rd</sup> and 4<sup>th</sup> generation cephalosporins in pigs, poultry and veal calves in 2018 and 2019, and the % of farms with notifications using these critical substances.

Figure 27 illustrates that pigs remained the species with the largest use of colistin, although the used mass as well as the % of farms with notifications using this substance decreased compared to 2018. Used mass as well as the % of farms using colistine also decreased in veal calves but it drastically increased in poultry, almost tripling the mass used and doubling the % of farms with notifications.



Figure 27. Kg used of polymyxins (colistin) in pigs, poultry and veal calves in 2018 and 2019, and the % of farms with notifications using colistin.

## Species-level antimicrobial use

## a) BD<sub>100</sub>-species

The  $BD_{100}$ -species, expressing the treatment days out of 100 days based on the total amount of antimicrobials used per species and the total mass animals at risk per species, shows a decrease in the use for all three species between 2018 and 2019 (Table 9). Use in veal calves remained far higher than that in pigs and poultry.

	Species-level DDDA <sub>bel</sub> *LA <sub>bel</sub> (x10 <sup>6</sup> )		Specie kg at ris	s-level k (x 10³)	BD <sub>100</sub> -	species	%∆ 18-19
	2018	2019	2018	2019	2018	2019	
PIGS	8 300	7 646	318 867	311 901	7,13	6,72	-5,8%
POULTRY	1 140	1 092	54 921	55 860	5,69	5,36	-5,8%
VEAL CALVES	1 408	1 115	13 629	13 717	28,31	22,27	-21,3%

Table 9. Antimicrobial use (BD<sub>100</sub>-species) in 2018 and 2019 in pigs, poultry and veal calves.

## Farm-level antimicrobial use

## a) 2019 reference populations for benchmarking

Table 10 shows the number of farms per Sanitel-Med animal category that, after applying the farm-level quality controls, were found eligible to be included in the 2019 reference populations for benchmarking. This amounted to a total of 3904 pig farms, 938 poultry farms and 241 veal calf farms.

Table 10. Number of farms and zero-use farms per Sanitel-Med animal category that were part of the 2019 reference populations for benchmarking.

		Pl	GS	POL	VEAL			
	Sucklers	Weaners Fattener		Breeders	Broilers	Laying hens	CALVES	
n farms	1 508	1 562	3 621	1 508	740	199	241	
n zero-use farms <sup>1</sup>	122	72	291	122	110	132	1	

<sup>1</sup> For pigs, zero-use relates to the species-level, whereas for poultry and veal calves, it relates to the animal category.

#### b) Farm-level antimicrobial use in 2019

Below the distribution of the farm-level BD<sub>100</sub> in the 2019 reference population of each Sanitel-Med animal category is shown as a box-plot with the median and average use indicated. Note that the zero-use farms in each reference population (see Table 10) were excluded to produce the box-plots. As in 2018, use was highest in weaners, veal calves and broilers. The distribution in veal calves approached a normal distribution, with the average and median close to each other, illustrating a (high) basic level of antimicrobial use in this category, in contrast to the other categories were the distribution was right-skewed, meaning there is a 'tail' of high users.



Figure 28. Box-plots representing the BD<sub>100</sub>-distribution in the 2019 reference population of each Sanitel-Med animal category. Outliers are not shown, zero-use farms were excluded. The median values are provided next to the lines in the boxes, and the average values next to the crosses.

## c) 2018-2019 core reference populations for benchmarking

Table 11 shows the number of farms per Sanitel-Med animal category that were part of the reference populations for benchmarking in 2018 as well as 2019, hence forming the 2018-2019 core reference populations for benchmarking. This amounted to a total of 3590 pig farms, 869 poultry farms and 241 veal calf farms.

	-	PI	GS	РО	VEAL		
	Sucklers	Weaners	Fatteners	Breeders	Broilers	Laying hens	CALVES
n farms	1 481	1 405	3 350	1 481	689	181	241
n zero-use farms <sup>1</sup>	121	78	351	121	110	143	2

Table 11. Number of farms and zero-use farms per Sanitel-Med animal category that were part of the 2018-2019 core reference populations for benchmarking.

<sup>1</sup> Zero-use farms in either 2018, 2019 or both. For pigs, this relates to the species-level, whereas for poultry and veal, it relates to the animal category.

## d) Evolution of farm-level antimicrobial use from 2018 to 2019

## i. Summary

The evolution of the median farm-level  $BD_{100}$  in the 2018-2019 core reference populations shows that use decreased in most Sanitel-Med animal categories between 2018 to 2019, with highest reductions in sucklers and veal calves. Use slightly increased in breeders and strongly increased in laying hens. However, use in the latter category is generally very low, with almost 80% of zero-use farms (Table 11) which were excluded for the analysis shown in Figure 29. Note that the  $BD_{100}$  values for 2019 slightly differ from those shown in Figure 28, which is explained by the slightly different composition of the 2018-2019 core reference populations, comprising two years, and the 2019 reference populations, looking only at 2019.



Figure 29. Evolution of the median of the BD<sub>100</sub>-distribution in the 2018-2019 core reference population of each Sanitel-Med animal category. Zero-use farms were excluded for the analysis. The following figures show per animal category the distribution of the BD<sub>100</sub>-values per farm in the core reference population for 2018 (blue) and 2019 (red), together with some important descriptive parameters of the distributions (Figures 30-36).

#### i. Suckling piglets

In 2019, antimicrobial use in suckling piglets showed a further general decrease (Figure 30).



Figure 30. Distributions of the farm-level antimicrobial use in the 2018-2019 core-reference population for benchmarking of suckling piglets in 2018 (blue) and 2019 (red), descriptive parameters of the distributions and % difference (% diff) between 2019 and 2018.

#### ii. Weaned piglets

In 2019, antimicrobial use in weaned piglets showed a further general decrease (Figure 31). The decrease was most pronounced towards the high-users. Weaned piglets remained by far the category with the highest number of treatment days, with 10% of farms raising weaned piglets treating these animals >60% of their weaning period.



Figure 31. Distributions of the farm-level antimicrobial use in the 2018-2019 core-reference population for benchmarking of weaned piglets in 2018 (blue) and 2019 (red), descriptive parameters of the distributions and % difference (% diff) between 2019 and 2018.

## iii. Fattening pigs

In 2019, antimicrobial use in fatteners showed a further general decrease, with the reduction evenly spread across the population. As fatteners represent the largest group of all animals in terms of mass antimicrobials used and mass animals at risk or biomass produced, the result in this category is of mayor importance for the general result of antimicrobial use in animals in Belgium.



Figure 32. Distributions of the farm-level antimicrobial use in the 2018-2019 core-reference population for benchmarking of fatteners in 2018 (blue) and 2019 (red), descriptive parameters of the distributions and % difference (% diff) between 2019 and 2018.

#### iv. Breeding pigs

In contrast to the other pig categories, certain parameters of the distribution in breeders increased in 2019, whereas other parameters decreased. This might indicate that the breeders are not a focus group in farm-level antimicrobial management.



Figure 33. Distributions of the farm-level antimicrobial use in the 2018-2019 core-reference population for benchmarking of breeders in 2018 (blue) and 2019 (red), descriptive parameters of the distributions and % difference (% diff) between 2019 and 2018.

#### v. Broilers

The farm-level broiler use in the 2018-2019 core reference population for benchmarking showed a clear reduction between 2018 and 2019. This is remarkable, as the total mass used in broilers has not appeared to change over time in the last two years, and the species-level mg/kg (largely determined by broilers) showed an increase for the second consecutive year. it might be an illustration of the fact that a small group of farms, falling outside the core reference group, spoils the result for the sector. This should be looked at in more detail and should be a focus point for the sector. It might furthermore illustrate that benchmarking, which came at full force in 2019, does start paying off, which might be a reassuring result.



Figure 34. Distributions of the farm-level antimicrobial use in the 2018-2019 core-reference population for benchmarking of broilers in 2018 (blue) and 2019 (red), descriptive parameters of the distributions and % difference (% diff) between 2019 and 2018.

#### vi. Laying hens

In contrast to the broilers, the farm-level use for laying hens dramatically increased in the 2018-2019 core reference population for benchmarking. Evidently, this is partly explained by the very low basic use in this sector, where even a small increase in absolute numbers can lead to a high relative increase. Likewise, it must again be stressed that this sector is generally characterized by a majority of zero-users, as noted above, meaning the observed increase is a phenomenon playing in a minority of farms. These zero-use farms have been left out of the distribution shown in Figure 35, in order to be uniform over all animal categories. In conclusion, while remarkable and meriting closer attention from the sector, the result should not be overexposed.



Figure 35. Distributions of the farm-level antimicrobial use in the 2018-2019 core-reference population for benchmarking of laying hens in 2018 (blue) and 2019 (red), descriptive parameters of the distributions and % difference (% diff) between 2019 and 2018.

#### vii. Veal calves

As noted, veal calf farms have the highest basic level of antimicrobial use, with almost no farms without use of antibacterial products. However, the most clear reduction of all animal categories was achieved in veal calves, which is a reassuring result. The narrowing of the use curve, approaching a normal distribution, is clearly visible.



Figure 36. Distributions of the farm-level antimicrobial use in the 2018-2019 core-reference population for benchmarking of veal calves in 2018 (blue) and 2019 (red), descriptive parameters of the distributions and % difference (% diff) between 2019 and 2018.

#### e) Farm-level use of the various antimicrobial classes

Figure 37 shows, for the three animal species, the number of treatment days with the different antimicrobial classes and the proportions this represent in the total treatment days per species, in 2018 and 2019.

This illustrates on the one hand that each species has its own specificities in terms of variety of classes used. For example, lincomycine-spectinomycine is of relatively highest importance in poultry, even though it must be noted that the calculated treatment days are clouded by the fact that this antimicrobial class is used predominantly the first week after the start of the growing period, when the chicks have a weight that is far below the standard used 1 kg. In veal calves, the importance of the tetracyclines, macrolides and aminoglycosides is remarkable, the latter being made up in a large part of the SDP neosol 100%.

On the other hand, the data proof that the variety of classes used has remained comparable over time. This is important to be able to assess the reduction paths that may be established in the different sectors.



Figure 37. Number of treatment days with the different antimiocrobial classes and percentage of the total number of treatment days per species in 2018 and 2019. Numbers/percentages not shown are classes where use was below 1% of treatment days in 2018 and 2019.

## **DISCUSSION**

In the context of the increasing (awareness on) antimicrobial resistance development, comparable data and evolutions of antimicrobial consumption (AMU) are of utmost importance. This annual BelVet-SAC report is now published for the eleventh time and describes the antimicrobial use in animals in Belgium in 2019 and the evolution since 2011. For the second year this report combines sales data (collected at the level of the wholesaler-distributors and the compound feed producers) and usage data (collected at farm level). This allows to dig deeper into AMU at species and farm level in Belgium.

As always, in the sales data, the dependency on the biomass factor may influence the result. This means that changes regarding the net import or export of slaughter animals (increasing or decreasing biomass in BE) will have an influence on the outcome. Furthermore, we have to take into account that it is not 100% sure that all products sold in Belgium by the wholesaler-distributors are also used in Belgium. Veterinarians living near the country borders may also use medicines bought in Belgium to treat animals abroad. However, also the contrary may happen, i.e. veterinarians from neighbouring countries using products in Belgium that are not included in the BelVet-SAC sales data. The usage data might help to shed some light on this. Indeed, cascade use ('import') is requested to be registered in Sanitel-Med as 'Self Defined Products' and in 2019 approximately 1,3 ton of SDPs (predominantly Neosol 100%) was registered. In 2019, sales data were 34,6 tons higher than usage data (not corrected for SDPs), which is a substantial improvement in comparison to 2018 where the difference was still 42,5 tons. As the usage data do not cover all animal species, most of this difference will be explained by usage in the non-included species, most importantly bovines but also companion animals, horses,... It can also not be excluded that some usage is not registered in Sanitel-Med for the currently obliged animal categories. The data-collection is still relatively new and it likely takes time to get all veterinarians involved, especially those who have small practices. Adequate sensibilisation and controls should therefore further ensure the completeness of the collected usage data.

With a **consumption of 87,4 mg antimicrobial/kg biomass a** decrease of **-7,6%** in comparison to 2018 is achieved in 2019. This marks the fifth year in a row where an important decrease of antimicrobial usage in animals is observed resulting in a cumulative reduction of **-40,3% since 2011.** As last year, the reduction in 2019 is balanced over a **reduction in pharmaceuticals (-7,8% mg/kg) and antimicrobial premixes (-5,1% mg/kg).** In absolute values the observed reduction in antimicrobial sales is even larger (-10,5%) yet this is partially nullified by the substantial decrease in biomass in Belgium in 2019. This effect may reflect a reduced size of the national herd, yet it might also be influenced by increased export of live animals for slaughter abroad. In that latter case the observed reduction expressed in mg/kg biomass is even an underestimation of the reality.

When looking at the **evolution in the number of treatment days (BD**<sub>100</sub>), as calculated from the SANITEL-MED use data, comparable **reductions of -5,8% for pigs and poultry and -21,3% for veal calves** are observed. The fact that both data sources are showing comparable trends is reassuring with regard to the data validity and the representation of reality.

As in 2018 the total AMU in animals in 2019 is in large part determined by the pig sector and more specifically, by the fatteners and the weaners. Together, they accounted for 68% of tonnes used. Broilers and veal calves accounted for 16% and 12% of tonnes used, respectively, and the remaining animal categories (sows/boars; sucklers; layers) for only 4%.

In 2019, on a median pig farm fatteners were treated with antimicrobials for around 3% of their livetime, sucklers for around 2% and pigs for breeding for around 0,4%. All but the breeders are reductions in comparison to 2018. These are encouraging results for the pig sector, which has already put a lot of efforts in reducing their antimicrobial since many years, starting with a private data-collection system (AB Register) already in 2014 and having also bore the entire weight of the antimicrobial premix reduction up to 2017. Yet, challenges remain: despite the achieved reductions, the weaners remain a problem, being among the three highest using categories with a median BD<sub>100</sub> of 17,9. Yet also in this animal category a reduction of 10% in comparison to 2018 is observed. Being the sector with the largest portion of total AMU, it will be important that pig producers and veterinarians sustain their efforts in the coming years, especially in weaners.

Also in the broiler (-4%) and especially in the veal calve sector (-21%) the median BD<sub>100</sub> was reduced in 2019 in comparison to 2018. Especially the very substantial reduction in the veal calf production is remarkable and can likely be linked to the enhanced actions organized in this production sector through the development of a "10 point program" aiming at reducing the use in this sector. However, even after this important reduction the median use in the veal production still is at 21,4% of the production period which remains the highest value of all sectors and therefore needs to be further reduced. Also in the broiler production a moderate improvement is observed. Yet this is partially superseded by the continued high use of

fluoroquinolones in this production. An issue that urgently should be resolved. Therefore the broiler sector is urged to take measures in the coming years. The results obtained in veal calves and pigs may serve as a source of inspiration.

For other species such as cattle, horses and companion animals no herd or animal level use date are yet available in Sanitel-Med. Yet the BelVet-SAC sales data do allow to get a rough estimate of the antimicrobial use evolutions in these species. In dairy cattle it is disturbing to see that since 2015 there is a steady increase in the use of antimicrobial dry cow applicators which shows that there is no indication of a further implementation of selective dry cow therapy. Also the number of applicators used for the treatment of mastitis cases has steadily increased over the last 3 years. Also in dogs and cats the volume of antimicrobial use has again increased in 2019 with +13,0% in comparison to 2018. Compared to 2014 the total increase of antimicrobial substances used in dogs and cats is +24,3%. These results clearly demonstrate, as has been already mentioned in previous years, that the sector of companion animals urgently needs to take actions to start to bend the curve.

The details of the use of the different antimicrobial classes show – as in previous years – that penicillins (39,6%) form the largest group of consumed antimicrobials, followed by tetracyclines (21,0%) and the sulphonamides (19,1%). For the majority of the antimicrobial classes, a decrease in sales was observed in 2019. Especially the reduction of tetracycline use in 2019 is remarkable. Only in three antimicrobial classes an increase was seen this year. First of all an increase of 20,0% in use of aminosides. This is in contrast to 2018 where a decrease in use of this molecule of almost 13% was observed. Also the use of cephalosporines of the 1° and 2° generation grew substantially (+38,1%). This is entirely due to an increase in the use of cefalexine registered for use in dogs and cats and in intramammary products for cattle. And finally the use of quinolones increased for the second year in a row (+10%). The latter is worrisome as the quinolones are categorized as "red" antimicrobials. The use of these molecules decrease of fluoroquinolones in 2019 is largely due to an increase in use of enrofloxacin. The cephalosporines of the 3<sup>rd</sup> and 4<sup>th</sup> generation (the second group of "red" molecules), continue to decrease in use again driven by a continued substantial decrease in use of ceftiofur. The decreased use of polymyxins is observed for the seventh year in a row with a decrease of -11,2% in 2019. When comparing to 2012 polymyxin use has dropped with 66,4%.

Comparing the Belgian sales data with the results of other European countries and especially our neighbouring countries clearly shows there is still a substantial gap to be bridged. Yet it should be taken into account that the European data (ESVAC) are published with a two year delay (latest EU data are from 2017) and therefore do not take into account the very substantial reductions achieved in 2018 and 2019 in Belgium.

When comparing the overall results achieved in 2019 with the three AMCRA 2020 reduction targets, the **goal of reducing the overall AMU in animals with 50% by 2020 has not been achieved yet**, however the objective becomes in range with still 9,7% to reduce in the final year (corresponding to an additional reduction of 16,2% compared to the data of 2019). It is anticipated that the herd level data-collection and benchmarking through the Sanitel-Med and AB register systems, in combination with multiple other initiatives such as herd health plans, continuous education, increased biosecurity,.... will provide invaluable support to achieve this goal. Moreover, AMCRA has in the meantime also already communicated further reduction goals up to 65% by 2024 (compared to the reference year 2011)<sup>18</sup>, indicating that even after 2020 the efforts will need to be continued. It is also very promising to see that again in 2019, even after largely achieving the goal of reducing the use of **antimicrobial premixes** with 50% by 2017, a further reduction in the use of antimicrobial premixes is achieved, now already **resulting in a cumulative reduction of -71,1% in comparison to 2011**. In regard to the different AMCRA colour classes, use of "yellow" (-7%) and "orange" (-8%) classes substantially reduced. Yet the use of the "**red" products** increased for the second year in a row (+8%) after a very spectacular drop in 2016 and 2017. Fortunately, this increase does not yet put at risk the reduction target of -75% by 2020 (which was already achieved in 2017) as there **still is a reduction of -77,3% in comparison to 2011**. However it is certainly an evolution that requires close surveillance.

<sup>&</sup>lt;sup>18</sup> <u>https://www.amcra.be/nl/visie-2024/</u>

## **CONCLUSION**

This report shows several promising results with a continued reduction of the total use and the achievement of two out of the three quantitative goals (use of premixes and use of critically important antimicrobials). These evolutions strengthen us in the believe that also the third and overarching objective of a 50% reduction in use remains feasible, yet substantial efforts will be required from all stakeholders to obtain this goal. The pig and veal sector is encouraged to sustain their efforts, while the broiler, dairy and companion animal sector are urged to increase their efforts.

## **ACKNOWLEDGEMENTS**

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# **APPENDIX**

APPENDIX A. ATC-VET CODES INCLUDED IN THE DIFFERENT CLASSES OF ANTIBACTERIAL PRODUC
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Class of Antibacterials	ATCvet codes included
	QJ01FF01
	QJ01GB03; QJ01GB90
	QS01AA11
	QD06AX04
Aminoglycosidos	Q\$02AA14; Q\$02AA57
Anniogrycosides	QG51AA04
	QA07AA06
	QJ51RG01
	QJ51CE59
	QJ01XX04
	QJ01XX10
Othor	QJ01XQ01; QJ01XQ02
Other	QJ51XX01
	QJ01RA04
	QJ01DB01
	QJ01DD90; QJ01DD91
	QJ51DB01; QJ51DB04; QJ51DB90
Conhalosporins	QJ01DE90
Cephalospornis	QJ51DE90
	QG51AX02
	QJ51DD12
	QJ51RD01
Amphonicols	QJ01BA90
Amphenicois	QS01AA01
	QJ01FA02; QJ01FA90; QJ01FA92; QJ01FA91; QJ01FA94; QJ01FA95
Macrolidos	QJ01FF02; QJ01FF52
Macronides	QJ51RF03
	QJ51FF90
	QJ01CA01; QJ01CA04; QJ01CA51
	QJ51RC26
Penicillins	QJ01CR02
r enicinins	QJ51CF02
	QJ01CE02; QJ01CE09; QJ01CE30; QJ01CE90
	QJ51CA51
Polymyxins	QJ01XB01

	QA07AA10					
	Q\$02AA11					
Pyrimidines	QJ01EW10; QJ01EW13					
rymmunes						
Quinclones	QJ01MA90; QJ01MA92; QJ01MA93; QJ01MA94; QJ01MA95; QJ01MA96					
Quinoiones	QJ01MB07					
Sulphonomides and trimethonrim	QJ01EW09; QJ01EW11; QJ01EW12					
Supronamides and trimethophin	QJ01EQ03					
totracyclinos	QJ01AA02; QJ01AA03; QJ01AA06					
ten acyclines	QD06AA02; QD06AA03					