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SCIENCE MEDICINES HEALTH

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Committee for Veterinary Medicinal Products (CVMP)

CVMP assessment report

Procedure under Article 141(1)(i) of Regulation (EU) 2019/6

Scientific advice for quarter-based selective antibiotic dry cow therapy

Procedure number: EMA/REF/0000285673

Note: assessment report as adopted by the CVMP with all information of a commercially confidential nature deleted.

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1. Information on the procedure

1.1. Request for a CVMP scientific advice

On 9 July 2025, Germany presented to the European Medicines Agency a request for a scientific advice under Article 141(1)(i) of Regulation (EU) 2019/6 from the Committee for Veterinary Medicinal Products (CVMP) on whether quarter-based selective antibiotic dry cow therapy could be used to reduce antibiotic use and thus likely antimicrobial resistance, without compromising animal health and without contradicting national policies.

2. Scientific discussion

2.1. Introduction

Combatting antimicrobial resistance (AMR) is a top priority for the European Medicines Agency (EMA) and the European medicines regulatory network, as recently outlined in the European Medicines Agencies Network Strategy to 2028. In alignment with this objective, the European Commission is actively contributing to the aspirational target of reducing overall European Union antibiotic sales for farmed animals and aquaculture by 50% between 2018 and 2030 (European Commission 2020b). Notably, the latest JIACRA Report (ECDC, EFSA, EMA, 2024) has documented early success in this strategy, demonstrating that countries with reduced antibiotic consumption in both humans and animals have experienced a corresponding decline in antibiotic-resistant bacteria.

A significant share of antibiotic use in dairy farming is due to administration at dry-off. In the past, blanket antibiotic dry cow therapy (BDCT) was the gold standard, in which all cows were routinely administered antibiotics at dry-off. This approach has the advantage that cows and quarters subclinically infected with mastitis pathogens received treatment, and the risk of new intramammary infections (IMI) was reduced for healthy quarters during the dry period. In addition, no cow- or quarter-level diagnostics were necessary.

However, over the past 30 years, and in light of the prudent use of antimicrobials, selective antibiotic dry cow therapy (SDCT) has become increasingly widespread. Selective antibiotic dry cow therapy means that only cows or quarters that are infected or at risk of infection receive antibiotics at dry-off. This approach, especially the cow-based SDCT is well researched and it is shown in several publications that antibiotic usage at dry-off can be significantly lowered when applying a cow-based SDCT regimen compared to BDCT, without compromising udder health and animal welfare (Patel *et al.,* 2017; Rowe *et al.,* 2020; Kabera *et al.,* 2020; D´Amico *et al.,* 2024). A cow-based SDCT means that the decision to administer antibiotics at dry-off is made individually for each cow. If a cow fulfils certain criteria (e.g. at least one quarter with subclinical mastitis), all four quarters receive antibiotics, irrespective of infection status. Following, the potential for reduction of the risk for new IMI substantially varies depending on farm conditions and management practices, the pathogens involved, and other factors. Especially the usage of internal teat sealants in those cows that do not receive antibiotics generally reduces the risk of new IMI and thus enhances the advantages of the selective approach. Nevertheless, if a cow-based selective approach is chosen, all four quarters of the respective cow will receive antibiotics, i.e. the infected quarters for treatment of subclinical infections and healthy quarters for prevention of new IMI.

In this regard, the German Ministry of Food and Agriculture funded the national study "MinimA" (sustained minimisation of antibiotic use through quarter-based selective dry cow therapy in dairy cows) to explore the potential for further reducing antibiotic use in dairy cows by selectively

administering antibiotics only to those udder quarters with subclinical mastitis instead of to all quarters of a cow. This quarter-based SDCT derives from the observation that, in many cases, only one or two udder quarters of a cow are infected before drying off and thus require treatment (McDougall et al., 2022). Individually treating with antibiotics only those subclinically infected mastitis quarters at drying off, without administering antibiotics to healthy quarters for prevention of new IMI, is likely to result in a further reduction in antibiotic use at dry-off. The outcomes from the above-mentioned German national study indicated such benefits of a quarter-based approach compared to a cow-based selective dry cow therapy (Beckmann et al., 2025). However, this study did not assess the impact of reduction in antibiotic use on AMR development. While available data regarding the impact of antibiotic dry cow therapy in reducing AMR are sparse, some data indicate that antibiotic use at drying off may contribute to antibiotic resistance in both mastitis pathogens (Okello et al., 2023) and intestinal bacteria (Vasco et al., 2023). In conclusion, a quarter-based SDCT approach could be a relevant option for dairy farmers and responsible veterinarians.

According to Article 106(1) of Regulation (EU) 2019/6, veterinary medicinal products (VMPs) shall be used in accordance with the terms of the marketing authorisation. In many cases, the product information (PI) (summary of product characteristics, package leaflet, and labelling) for intramammary antibiotic VMPs authorised for use at drying-off requires the administration of antibiotics at dry-off to all four quarters of a cow, without distinguishing between healthy and infected quarters. This wording allows only cow-based SDCT or a BDCT but is potentially restricting farmers and veterinarians from implementing a quarter-based approach in farms where such an approach could be appropriate.

In the context of prudent antibiotic use, it was considered necessary to determine whether it is scientifically justifiable to generally allow quarter-based SDCT with intramammary antibiotic VMPs. Allowing such an approach would enable veterinarians to make case-specific decisions, potentially reducing overall antibiotic use with possible benefits regarding the risk of antimicrobial resistance development.

This scientific advice under Article 141(1)(i) of Regulation (EU) 2019/6 addresses the following aspects:

- Considering all available scientific data, the CVMP was asked to assess whether quarter-based selective antibiotic dry cow therapy could be considered consistent with the latest scientific knowledge aimed at reducing antibiotic use, without compromising animal health.
- If quarter-based selective antibiotic dry cow therapy is deemed an effective strategy to reduce antibiotic use, the CVMP was asked to advise on how this approach could be reflected in the product information of the relevant intramammary antibiotic VMPs. This would enable veterinarians and farmers to practice quarter-based selective antibiotic dry cow therapy in accordance with the terms of the marketing authorisation.

2.2. Critical evaluation

2.2.1. Literature research

In this procedure, the Committee was to consider whether quarter-based selective antibiotic dry cow therapy could be used as a tool to reduce antibiotic use and thus likely antimicrobial resistance, without compromising animal health.

To support the CVMP considerations, a literature review of the available English-language scientific bibliography on quarter-based selective dry cow therapy was carried out to identify evidence on its efficacy, advantages and potential risks. A search strategy was developed to ensure a broad and

standardised approach using the Medical Subject Headings (MeSH) thesaurus, a controlled and hierarchically organised vocabulary produced by the National Library of Medicine.

The selection criteria included clinical trials, meta-analyses, systematic reviews, and randomised controlled trials published from 1990/01/01 to 2025/10/31 in PubMed. Letters, editorials, case studies and commentaries were excluded.

Details on the keywords used and on the search strategies are listed below:

- **STRING SEARCH A** – Core QBSDCT (Quarter-based selective dry cow therapy)

("Mastitis, Bovine/therapy"[Mesh] OR "Anti-Bacterial Agents/therapeutic use"[Mesh] OR "Anti-Bacterial Agents/veterinary use"[Mesh] OR intramammary[tiab] OR IMM[tiab])

AND ("Dry Period"[Mesh] OR dry-off[tiab] OR "dry cow"[tiab])

AND (quarter[tiab] OR "quarter-level"[tiab] OR "quarter based"[tiab] OR "quarter-based"[tiab] OR "individual quarter"[tiab])

AND (selective[tiab] OR targeted[tiab] OR "selective therapy"[tiab] OR "selective treatment"[tiab])

- **STRING SEARCH B** – Culture-guided Quarter-based Selection (Cult-QBSDCT)

("Mastitis, Bovine/therapy"[Mesh] OR "Anti-Bacterial Agents/therapeutic use"[Mesh] OR "Anti-Bacterial Agents/veterinary use"[Mesh] OR intramammary[tiab])

AND ("Dry Period"[Mesh] OR dry-off[tiab])

AND (quarter[tiab] OR "quarter-level"[tiab] OR "quarter-based"[tiab])

AND (culture[tiab] OR "on-farm culture"[tiab] OR Petrifilm[tiab] OR "Minnesota Easy Culture"[tiab])

AND (selective[tiab] OR targeted[tiab])

- **STRING SEARCH C** – Internal Teat Sealant (ITS) and Selective Strategies

("Teat"[Mesh] OR "Teat Diseases/prevention and control"[Mesh] OR teat[tiab])

AND ("Dry Period"[Mesh] OR dry-off[tiab] OR "dry cow"[tiab])

AND ("sealant"[tiab] OR "sealer"[tiab] OR "internal teat sealant"[tiab] OR "bismuth subnitrate"[tiab])

AND (selective[tiab] OR targeted[tiab] OR "quarter-level"[tiab] OR "quarter-based"[tiab])

- **STRING SEARCH D** – Historical Quarter Interdependence

("Mastitis, Bovine/epidemiology"[Mesh] OR "Mastitis, Bovine/prevention and control"[Mesh] OR "Mastitis, Bovine/therapy"[Mesh])

AND ("Dry Period"[Mesh] OR dry-off[tiab] OR "dry cow"[tiab])

AND (quarter[tiab] OR "quarter-level"[tiab] OR "quarter-based"[tiab] OR "interdependence"[tiab] OR "dependency"[tiab])

AND (cow-level[tiab] OR "cow level"[tiab] OR "treat all quarters"[tiab] OR "whole cow"[tiab]).

The duplicated references were discarded, and the remaining references were assessed for relevance and selected based on the following additional criteria: the availability of quantitative information on a quarter-based selective dry-off approach and data on efficacy and risk factors associated with the dry-off regimen. Although studies conducted in Europe were preferred, the limited number of such studies

meant that geographical origin was not used as an exclusion criterion. This step was carried out by checking the title and abstract of each individual reference.

2.2.2. Could quarter-based selective antibiotic dry cow therapy be considered consistent with the latest scientific knowledge aimed at reducing antibiotic use, without compromising animal health?

The literature search yielded eleven original research articles and one review article that met the search criteria and addressed quarter-based SDCT. Since only a limited number of studies have assessed quarter-based SDCT – both within and outside the EU – all relevant publications were included. The selected studies are described and assessed below, presented in chronological order by year of publication.

One of the earliest and largest field studies addressing quarter-based SDCT was conducted by Browning *et al.* (1990) in 12 dairy herds in Victoria, Australia. A total of 1,044 cows (4,176 quarters) were sampled just before dry-off, within two days after calving, and again three to five months postpartum. Cows were classified as infected or uninfected at dry-off, and four groups were formed: uninfected cows with no treatment (NI-NT), or antibiotic treatment of all quarters (NI-AT) equal to BDCT; infected cows with antibiotic treatment of all quarters (I-AT), which represents a cow-based SDCT approach or only in the infected ones (I-QT), which represents a quarter-based SDCT approach. Outcomes included new IMI rate, persistence of infection, and clinical mastitis after calving. The results showed that uninfected cows did not benefit from blanket treatment, as new IMI rates were similar to untreated animals (3.8% for NI-NT vs. 2.1% for NI-AT) during the dry period. In infected cows, however, quarter-only treatment resulted in nearly four times as many new IMI (15.3% vs. 4.1%), particularly caused by *Staphylococcus aureus* and *Streptococcus uberis*. The authors concluded that treating all quarters of uninfected cows "does not appear to reduce" infection risk, but that quarter-only treatment in infected animals carries a significant risk of new IMI. Of note, unlike in other published studies, no internal teat sealant was used in healthy quarters in this study. Thus, there was no prevention of new IMI in those quarters that did not receive antibiotics.

Berry *et al.* (2003) re-analysed data from two field trials evaluating selective dry cow strategies at the cow level, comparing long-acting intramammary antibiotics and an internal teat sealant to untreated cows. Treatments in both trials were allocated at the cow level, but infection status at drying off and calving was determined at the quarter level, with foremilk samples collected 1 week prior to drying off, at drying off, and within 24 hours of calving, as well as 7 to 14 days after calving, according to International Dairy Federation (1981) recommendations. Both interventions significantly reduced the risk of new IMI at calving (odds ratios ~0.23–0.30) compared with untreated controls. Importantly, the study demonstrated that the infection status of different quarters within a cow was not independent, as untreated cows with one infected quarter were more likely to have additional infected quarters at calving. Based on this interdependence, the authors concluded that "*The application of dry-cow strategies at the cow level and not the quarter level is [also] supported*".

In the same line, Robert *et al.* (2006) analysed 624 cows from 28 French herds managed under selective dry cow therapy to investigate whether udder quarters behave independently or interdependently with respect to new IMI during the dry period. Quarter samples were collected at drying-off and on day 3 postpartum. The overall incidence of new IMI was 17.7%, with slightly higher rates in untreated cows (19.0%) than in treated cows (15.5%). The most common pathogens were coagulase-negative staphylococci and *Corynebacterium spp.* Observed distributions of newly infected quarters per cow significantly deviated from expectations under an independence model, with more cows either uninfected or affected in multiple quarters than anticipated. This pattern was consistent

across pathogen types and in both treated and untreated groups. The authors concluded that "*interdependence of quarters during the dry period supports selective therapy at the cow level rather than at the quarter level*". Although the results of these two studies suggest that quarters left untreated during the dry period are not independent of the risk of new IMI, quarter-based SDCT was not evaluated in either study.

Patel *et al.* (2017) carried out a pilot randomised controlled trial at the University of Minnesota, enrolling 56 Holstein cows at dry-off. Cows were assigned to BDCT or quarter-based SDCT. Regardless of whether antibiotic treatment was administered, all quarters received a teat sealant. Outcomes included bacteriological cure, new IMI, and clinical mastitis up to 30 days in milk. Quarter-based SDCT reduced antibiotic use at dry-off by 48% compared to BDCT, without significant differences in cure rate (82.3% vs. 88.0%), new IMI (40.2% vs. 41.5%), or mastitis incidence (42.2% vs. 39.6%). This study examined the practical applicability of quarter-based SCDT and provided evidence that quarter-based SDCT in combination with internal teat sealants can safely reduce antimicrobial exposure, without significant disadvantages to udder health compared to BDCT, as there were no significant differences in cure rates, new IMI, or mastitis incidence.

The study by Rowe *et al.* (2020) comes to a similar conclusion. They conducted a large multi-site randomised clinical trial across seven commercial dairy farms in the United States, enrolling 1,211 cows that were followed up to 120 days in milk. Cows were randomly allocated to one of three groups: BDCT (all four quarters treated with ceftiofur and an internal teat sealant), quarter-based SDCT (only quarters testing positive on a rapid culture system after 30–40 hours incubation received antibiotic treatment, with all quarters receiving a teat sealant), and algorithm-guided cow-based SDCT (alg-SDCT, where all four quarters received antibiotic treatment if the cow met at least one of the two following criteria: a somatic cell count (SCC) >200,000 cells/mL in any Dairy Herd Improvement Association (DHIA) test during the lactation, or ≥2 cases of clinical mastitis during the current lactation. Cows not meeting the criteria still remained in the algorithm-guided cow-based SDCT group but only received teat sealant). Clinical mastitis incidence and removal from the herd (culling or death), as well as test-day milk yield and SCC during the first 120 days in milk, were recorded. The authors found no significant differences in mastitis risk, removal from the herd, SCC, or milk yield between BDCT and either selective approach. Importantly, they emphasised that either selective approach "reduced antibiotic use at dry-off by 55%, without causing any negative effects." These findings provide evidence that quarter-based SDCT can reduce antimicrobial use while maintaining udder health and production performance under commercial conditions using teat sealants.

Similar results were reported by Kabera *et al.* (2020) in a randomised controlled trial involving 568 Holstein cows from nine Canadian herds, representing 2,247 quarters. Four groups were compared: BDCT, BDCT plus an internal teat sealant, quarter-based SDCT with infected quarters treated with antibiotics and healthy quarters receiving a teat sealant, and quarter-based SDCT where infected quarters received antibiotics plus sealant and healthy quarters received sealant only. Milk samples were collected at dry-off and postpartum, and mastitis events and milk yield were recorded up to 120 days in milk. Antibiotic use was reduced by 58% in the quarter-based SDCT groups, with no significant differences in new IMI, persistence of infection, clinical mastitis, SCC, or milk yield. The authors concluded that a "*very substantial reduction in antimicrobial use*" can be achieved "*without negative effects on udder health or milk production*," further confirming the practicality of quarter-based SDCT under field conditions if a teat sealant is used to prevent new IMI in healthy quarters. There was no significant difference in the use of antimicrobials alone versus the combination with an internal teat sealant in those quarters with subclinical mastitis at dry-off.

Swinkels *et al.* (2021) conducted a randomised controlled field trial in six UK herds with 807 cows, which were stratified by SCC from the preceding three months of lactation into high (≥200,000 cells/ml) and low (<200,000 cells/ml) SCC groups. Within each stratum, cows were allocated to cow-level SDCT (all quarters of high-SCC cows treated with antibiotic and teat sealant; low-SCC cows with sealant only) or to quarter-based SDCT with a California Mastitis Test (CMT) threshold at the time of dry-off of ≥1 or ≥2. All cows received a teat sealant in all 4 quarters and additional antibiotic treatment into CMT positive quarters. In high-SCC cows, the quarter-based SDCT approach led to a reduced antibiotic use by 31% (CMT ≥1) or 55% (CMT ≥2), with no significant differences in cure, new IMI, or clinical mastitis. In low-SCC cows, however, the potential for further reduction of antibiotic use by a quarter-based SDCT instead of a SDCT on cow basis was limited, as few quarters required antibiotic treatment under these conditions. The authors concluded that quarter-level selection is effective and safe in high-risk cows but less efficient in low-risk herds, where cow-level approaches may be preferable.

A somewhat contrasting perspective emerged from New Zealand, where McDougall *et al.* (2022) compared two selective strategies in 1,775 cows across four pasture-based herds. Cows were ranked by their most recent production-recording SCC before dry-off and randomly assigned in sequential pairs either to an SCC-based cow-level strategy (SCC-group) or to a CMT-based quarter-level strategy (CMT-group). In the SCC-group, all four quarters were treated with antibiotics if the maximum SCC during lactation exceeded 200,000 cells/mL, whereas in the CMT-group, only quarters with a score of ≥ trace (i.e., slight thickening of test reactants) at dry-off were treated. All cows also received an internal teat sealant into all quarters. Quarter-level selection achieved higher cure rates (95% vs. 90%), fewer new IMI cases (3.2% vs. 4.4%), and lower postpartum prevalence of IMI (3.7% vs. 5.4%), but at the cost of 63% greater antibiotic use. 63.9% of quarters in the quarter-based CMT-group received an antibiotic compared to 26.7% in the SCC-group. The authors attributed this paradox to the high sensitivity of the CMT, which classified more quarters as requiring antibiotics. Thus, while quarter-based SDCT improved udder health outcomes in this context, it failed to achieve the goal of antimicrobial stewardship because of the diagnostic threshold employed.

D'Amico *et al.* (2024), a randomised, controlled trial evaluating BDCT, cow-based SDCT, and quarter-based SDCT in a large U.S. herd of 5,200 Holsteins, with 840 cows randomised to the three treatment groups. In BDCT, all four quarters received ceftiofur and a teat sealant. In cow-based SDCT, all quarters of cows with a last test-day SCC >200,000 cells/mL were treated with antibiotics, while cows below this threshold received sealant only. In quarter-based SDCT only quarters testing positive for Gram-positive pathogens were treated with antibiotics, and all quarters received a teat sealant. Antibiotic use was reduced by 44% in cow-based SDCT and 74% in quarter-based SDCT compared with BDCT. At enrolment, cows in the cow-based selective group had slightly higher linear SCC scores and a greater proportion of infected quarters than the quarter-based SDCT group ($P = 0.008$ and $P = 0.03$). After calving, no significant differences were observed among treatment strategies in new IMI, cure rate, clinical mastitis, or milk production. Both selective strategies showed a transiently higher SCC at the first DHIA test postpartum, but this difference resolved by the second test, with no subsequent divergence between groups. It can be concluded that although antibiotic use has been significantly reduced, caution should be exercised when implementing selective antibiotic dry cow programmes based on SCC or culture results, as these can temporarily elevate linear SCC scores observed at the first test postpartum.

Boloña *et al.* (2024) drew a similar conclusion while focusing on cows with only one infected quarter in three Irish research herds, enrolling 96 animals. Cows were randomised either to all-quarter treatment with cefalonium plus a teat sealant or to selective treatment of only the infected quarter, while healthy quarters received a teat sealant. Cure rates in infected quarters were similar between groups (around

95%), but new IMI in previously healthy quarters were significantly higher in the quarter-based selective group (11% vs. 4%), and SCC remained higher throughout the following lactation. Nevertheless, antibiotic use at dry-off was reduced by 78%. Consequently, the authors concluded that "*quarter-level treatment resulted in higher SCC in the full new lactation and higher odds of new infections*," illustrating that strict quarter-only approaches yield large savings but with trade-offs for udder health.

Beckmann *et al.* (2025) investigated the effectiveness of quarter-based SDCT in reducing antibiotic usage on 16 commercial dairy farms in Germany between 2021 and 2022. All farms initially used SDCT at the cow level, primarily based on SCC of milk at the last or the last three milk recordings before drying off. All farms changed to a quarter-based SDCT strategy with treatment decisions based on bacteriological findings, with antibiotics administered only to quarters infected with major pathogens, while minor pathogens were not treated. All quarters received an internal teat sealant irrespective of the infection status. A total of 1,155 dry periods from 4,530 quarters were analysed. The study found a significant reduction in antibiotic use, with only 8.1% of quarters receiving antibiotics at dry-off, compared to 42.2% under previous cow-based SDCT practices. This corresponds to an 81% reduction in antibiotic use. Despite this reduction, bacteriological cure rates remained high, at 97.1% for major pathogens in antibiotic-treated quarters. Untreated quarters infected with minor pathogens had an 81.6% self-cure rate for non-aureus staphylococci (NAS) and 83.0% for *Corynebacterium* spp. Furthermore, the incidence of new IMI after calving was 14.6%, with the majority of new infections caused by environmental pathogens. The study concluded that quarter-based SDCT is a viable strategy for reducing antibiotic use on dairy farms without compromising udder health, provided appropriate hygiene measures, up-to-date farm management, and the consistent use of internal teat sealants are ensured.

A recent review by Ut *et al.* (2025) provides an in-depth assessment of SDCT with a particular focus on the level of selection, i.e., whether treatment decisions should be made at the cow or quarter level. Based on a systematic search in the Web of Science Core Collection, the authors included English-language, peer-reviewed studies that compared BDCT with selective strategies using criteria such as bacteriological culture, SCC, or CMT. Among the studies included in the review were those by Browning *et al.* (1990), Patel *et al.* (2017), Rowe *et al.* (2020), Swinkels *et al.* (2021), and McDougall *et al.* (2022), which have been summarised above. The outcomes evaluated included IMI prevalence at calving or early lactation, clinical mastitis (CM), SCC, milk yield, antibiotic usage, and economic impact. The authors discussed the frequently reported high levels of interdependence between quarters, with significantly increased incidence of new IMIs in previously uninfected quarters if one quarter is infected. It was agreed that the use of internal teat sealants can be used as a risk reduction strategy and moreover that the overall risk of new IMI is increased in herds with a high prevalence of contagious mastitis pathogens. Thus, in well-managed herds with low herd bulk tank SCC, a lower prevalence of contagious pathogens, and utilisation of internal teat sealants interdependence may be mitigated, and a selective dry cow regimen can be effectively implemented at either the quarter or cow level. An SDCT on a by cow level is primarily warranted in herds where contagious pathogens have a high prevalence and represent the dominant cause of IMI.

Summary and conclusions

In conclusion, several peer-reviewed scientific publications address the advantages and risks of a quarter-based selective antibiotic dry cow therapy.

The study conditions differ in terms of farm conditions and herd management, overall health status of the herd, infection pressure, predominant mastitis pathogens, overall dry-off management and

selection criteria for the quarters to be treated, as well as in the simultaneous administration of teat sealants.

While all authors agreed that the cure rates for subclinical mastitis are comparable irrespective of the dry-off strategy applied (i.e. BDCT, cow-based SDCT, quarter-based SDCT), Browning *et al.* (1990) and Boloña *et al.* (2024) showed higher risks of new IMI in the quarter-based SDCT groups compared to a cow-based SDCT approach, while Rowe *et al.* (2020), Kabera *et al.* (2020), Swinkels *et al.* (2021), McDougall *et al.* (2022) and D'Amico *et al.* (2024) found no difference between quarter-based SDCT and cow-based SDCT. This difference can be explained by the interdependence of quarters within cows and the positive effects of internal teat sealants. As discussed in the review by Ut *et al.* (2025), there is a quarter interdependence persisting during the dry period, and thus cow-level susceptibility may influence infection risk in untreated quarters with significantly increased incidence of new IMIs in previously uninfected quarters if one quarter is infected. The use of internal teat sealants as done in the latter studies that showed no difference between quarter-based and cow-based SDCT can serve as an effective risk-reduction strategy. Additional factors that increase the risk of new IMI in a quarter-based SDCT herd include a high prevalence of contagious pathogens and an overall high bulk tank SCC. Unlike the studies by Patel *et al.* (2017) and Kabera *et al.* (2020), which based decisions on the use of quarter-based SDCT on culture-based methods and concluded that the use of quarter-based SDCT during dry-off can minimise antibiotic use without compromising udder health, Swinkels *et al.* (2021) and McDougall *et al.* (2022) based their decision on whether to use quarter-based SDCT on a CMT instead of bacteriological findings. However, available evidence does not allow for a definitive conclusion on whether one approach is more appropriate and suitable for all scenarios that could be relevant for the different farms in the European Member States.

It should be underlined that the reduction of antibiotic use was not the focus of most of the presented studies and in general only antibiotic use at dry-off was considered. Compared to BDCT, a reduction between 44% and 81% for quarter-based SDCT or a cow-based SDCT was shown by the following authors - Patel *et al.* (2017); Rowe *et al.* (2020); Kabera *et al.* (2020); Swinkels *et al.* (2021); McDougall *et al.* (2022); D'Amico *et al.* (2024); Boloña *et al.* (2024) and Beckmann *et al.* (2025). Differences between a cow-based and a quarter-based approach, however, seem to depend on the parameters used to select for treatment, as seen in McDougall *et al.* (2022), and the efficacy of controlling new IMI which would otherwise require antibiotic treatment in the next lactation period. Reducing antibiotic administration during the dry period should not be accompanied by an increase in antibiotic use after calving to treat clinical mastitis cases originating from the dry period.

As the risk of new IMI depends strongly on controlling for the interdependence of quarters, e.g. by concomitant usage of internal teat sealants, as well as on the major pathogens relevant in a herd and the bulk tank SCC, the CVMP concluded that no general recommendation for a quarter-based instead of a cow-based selective approach can be given. Both options may be advantageous depending on the individual farm and herd. As summarised by Ut *et al.* (2025), in well-managed herds with low herd bulk tank SCC, a lower prevalence of contagious pathogens, and utilisation of internal teat sealants, a selective dry cow regimen can be effectively implemented at either the quarter or cow level. In this setting and depending on the selection criteria, a quarter-based SDCT approach may enable an even greater reduction of antimicrobial usage compared to a cow-based SDCT approach. An SDCT at cow level is primarily warranted in herds with a high prevalence of contagious pathogens.

This conclusion is further supported by long-term experience in Nordic countries, showing that it is possible to maintain a low incidence of clinical mastitis and acceptable SCC levels with prudent use of antibiotics and selective DCT based on bacteriologic diagnosis of intramammary infections in a region

with high milk production (Rajala-Schultz *et al*., 2021). Also, recent reviews by Ut *et al.* (2025) and McCubbin *et al.* (2022) support the benefits and safety of SDCT over BDCT.

2.2.3. CVMP deliberations on how quarter-based SDCT could be reflected in the product information of the relevant intramammary antibiotic VMPs

If quarter-based selective antibiotic dry cow therapy is deemed an effective strategy to reduce antibiotic use without compromising animal health, the CVMP was asked to advise on how this approach could be reflected in the product information of the relevant intramammary antibiotic VMPs. This would enable veterinarians and farmers to practice quarter-based selective antibiotic dry cow therapy in accordance with the terms of the marketing authorisation.

Discussion

Current evidence does not indicate that either a quarter-based or a cow-based selective approach is generally more advantageous for udder health. No differences in antimicrobial use for the treatment of subclinical mastitis at dry-off were found. Although the efficacy of preventing new IMI may be lower with a quarter-based approach, this can be compensated for under certain farm conditions by the concurrent use of internal teat sealants. Depending on the individual farm and herd, a quarter-based SDCT strategy may nevertheless contribute to reducing overall antibiotic consumption. To date, the PIs for most intramammary antibiotic VMPs authorised for use at drying off require the administration to all four quarters, without distinguishing between healthy and infected ones. Since Article 106(1) of Regulation (EU) 2019/6 requires that VMPs shall be used in accordance with the terms of the marketing authorisation, a quarter-based SDCT approach would not be feasible for these VMPs. Hence, to allow the responsible veterinarian to choose an appropriate dry-off approach, including a quarter-based selective antibiotic dry cow regimen for a specific cow/herd, the CVMP considered that the PIs for intramammary antibiotics indicated for dry cow therapy should not preclude such an approach.

Summary and conclusions

In conclusion, the PIs of intramammary antibiotic dry cow products should permit for a selective antibiotic dry cow therapy including both a cow-based and a quarter-based approach, allowing the responsible veterinarian to decide on the best approach depending on the conditions of a specific cow and herd.

3. Stakeholders' input

Written submissions were received from a research institute, an independent research and innovation company, a veterinarians organisation, a marketing authorisation holder, and a VMP manufacturers' association. All data submitted were considered by the CVMP in reaching its conclusions.

A total of five stakeholders provided relevant information to the procedure in response to the request made by the CVMP.

Max Rubner-Institut, Institut für Sicherheit und Qualität bei Milch und Fisch - veterinary healthcare professional, Academia - Germany

The Max Rubner-Institut submitted a manuscript with a study from Germany titled *"Investigation of quarter-selective dry cow therapy based on bacteriological outcomes on dairy farms"* which had been accepted for publication by the Journal of Dairy Research on May 28, 2025. It was subsequently published on 27 October 2025. This study is already considered in section 2.2.2 and is therefore not repeated here.

SEGES Innovation - independent research and innovation company - Denmark

SEGES Innovation provided (mainly unpublished) data from two ongoing initiatives in Denmark. They are set to deliver data and best-practice recommendations on SDCT in 2026. SEGES Innovation regards those initiatives as highly relevant to the evaluation of SDCT from a Danish and broader European/global context. According to the data provided, Denmark has seen a reduction in the use of veterinary medicines, bulk tank SCC and new infection rates, all while maintaining an improved udder health.

The first initiative/research project has been conducted with the University of Copenhagen from 2022 to 2025 and it is expected to be completed in 2027. The final DNA results are still pending, the data provided are preliminary and not published.

The second activity of SEGES is to create an international best-practice guideline on how to properly select cows for SDCT, considering geographic diversity and national regulatory distinctions. This project has not been finalised yet.

The final conclusion/recommendation from SEGES is that quarter-based SDCT should be permitted and even advised, provided the criteria of selection for a specific dry cow product are fulfilled.

The Federation of Veterinarians of Europe (FVE) - Veterinary practitioners - EU

The FVE welcomed the initiation of the review on quarter-based selective antibiotic dry cow therapy, recognising its foundation in field experience and evidence-based benefits, particularly its role in reducing unnecessary antibiotic use, safeguarding animal welfare, and supporting the EU's AMR objectives.

They provided a position paper on SDCT recommending that BDCT should be replaced by SDCT, except under exceptional circumstances. They further stated that SDCT should be implemented on the basis of the animal’s clinical history of mastitis, suspicion of intramammary infection and relevant individual cow or farm risk factors.

The FVE further expressed that preventive animal health visits play a crucial role in early disease detection and in the implementation of key preventive measures, e.g. biosecurity protocols, milking hygiene, targeted surveillance and strategic vaccine planning. In their report from April 2024, the FVE concluded that the implementation of these visits varies significantly between EU Member States.

The shift toward SDCT requires that veterinarians be afforded sufficient prescribing flexibility, guided by clinical judgment, risk assessment, and prudent use principles, in order to protect animal welfare and combat antimicrobial resistance. However, no remarks or recommendations have been made by the FVE regarding the implementation of quarter-based SDCT specifically.

Zoetis Belgium SA - Marketing authorisation holder

Zoetis was unable to identify proprietary data relevant to this procedure. However, a review of publicly available sources revealed that the most relevant information concerns the limitations of SDCT (on both cow and quarter level), along with some practical considerations. Zoetis pointed out that there are several challenges that come with SDCT, as mentioned below.

The approach requires accurate identification of infected quarters, typically through microbiological testing, which can be costly and time-consuming. It increases labour and diagnostic costs, which may offset potential savings from reduced antibiotic use. If not implemented correctly, SDCT can lead to an

increase in the number of infected cows, which in turn may raise the use of antibiotics during lactation for treating subclinical or clinical mastitis. There is also a risk of increased milk contamination, milk waste, and animal welfare issues due to clinical mastitis.

Zoetis also mentioned a review and meta-analysis of controlled studies from 2020 which found that SDCT resulted in a higher level of IMI compared to BDCT (Winder CB *et al.,* 2020). This finding suggests that SDCT may not be as effective as BDCT in controlling IMI, particularly when the implementation is not rigorous or diagnostics are not accurate. Zoetis emphasised that SDCT is only effective in herds with good management practices, accurate diagnostics, and careful implementation guided by an experienced veterinarian. The transition from BDCT to SDCT should be tailored to the specific needs of each farm, taking into account responsible antibiotic use, farm economics, and the limitations of SDCT.

AnimalhealthEurope - association representing manufacturers of animal medicines - EU

AnimalhealthEurope stated that most clinical and regulatory studies for antibiotic intramammary dry-off veterinary medicines treat the entire udder, meaning that specific data to support quarter-based SDCT is likely very limited or non-existent. AnimalhealthEurope cited the CVMP Guideline on the conduct of efficacy studies for intramammary products for use in cattle (EMA/CVMP/344/1999). The previous version of this guideline (EMA/CVMP/344/1999-Rev.2) indicated that *"At drying off, all four quarters of animals should be treated."* However, the updated version (EMA/CVMP/344/1999-Rev.3) from 21 February 2025 states: *"For treatment of subclinical mastitis at the time of drying-off, only the confirmed positive quarter(s) are to be treated. The other non-infected quarters may receive an intramammary veterinary medicinal product in respect to prophylaxis of new intramammary infections."* This change reflects a shift toward more targeted treatment strategies.

Consistent with the findings reported by Zoetis, AnimalhealthEurope considers that SDCT can contribute to reducing antibiotic use, but emphasises that its success depends on the accurate identification of infected quarters, proper implementation, and good management practices. Microbiological testing is currently the most reliable method for identifying infections, though it is costly and impractical for many farms. They argue that the implementation of SDCT requires veterinary guidance, proper diagnostics, trained personnel, and the use of teat sealants. It also involves additional costs that must be weighed against potential savings. Their findings further suggest that cow-based SDCT is generally more practical and effective for most European farms, while quarter-based SDCT may be suitable for well-managed herds with low infection rates and reliable diagnostics.

In their conclusion, AnimalhealthEurope outlined that data supporting quarter-based SDCT may be limited, but adding this approach as an additional, non-exclusive option to the PI of respective VMPs would provide veterinarians greater flexibility in choosing the most appropriate treatment regimen. They commented further that this addition should not require generating new data, and regulations should prioritise flexibility, science-based approaches, and continuous education to support effective mastitis control.

3.1. Summary and conclusions of stakeholders' input

There is an overall agreement that cow-based or quarter-based SDCT is a meaningful measure for reducing antibiotic use at dry-off compared with BDCT, provided they are implemented under appropriate conditions. Nevertheless, there are also some concerns, particularly regarding the potential increase in costs and workload if the (quarter-based) SDCT approach was to be established as the standard method. While economic considerations are understandable, especially the Nordic countries

have shown that SDCT is a competitive management practice, especially on farms succeeding in keeping their IMI risk low. Overall, however, stakeholders would also welcome if the PIs of those dry cow VMPs would offer more flexibility in the applicability to individual quarters.

4. Overall conclusions

Overall, the CVMP concluded that blanket administration of antibiotics at dry-off to all animals in the herd and to all four quarters has no advantage in terms of efficacy or safety of intramammary veterinary medicinal products compared with selective antibiotic dry cow therapy. In contrast, a selective approach may provide benefits by reducing antimicrobial use. Moreover, antimicrobial VMPs shall neither be administered routinely nor used to compensate for factors such as poor hygiene, inadequate animal husbandry practices, insufficient care, or to compensate for deficient farm management. As those aspects may apply to a BDCT regimen, an SDCT should always be favoured.

Besides a cow-based SDCT, a quarter-based SDCT can be aligned with current principles of reducing antimicrobial use without jeopardising udder health, provided that its implementation is adapted to contemporary herd conditions including precise diagnostics, good herd management, and the use of internal teat sealants. A decision on whether a cow-based or a quarter-based approach is more suitable for an individual farm can only be made on a case-by-case basis by the responsible veterinarian and in close cooperation with the farmer, considering different parameters, e.g. regular dairy herd improvement system results, bulk tank and individual cow SCC, individual quarter CMT, prevalence of new IMI during the dry period and major causative pathogens. Considerations regarding the workload and the necessary organisational efforts accompanying a quarter-based SDCT approach might also be relevant.

In the context of this scientific advice request and based on the assessment of the currently available scientific evidence, the CVMP considered quarter-based selective dry cow antibiotic therapy to be consistent with the latest scientific knowledge aimed at reducing antibiotic use, without compromising animal health.

The CVMP deliberated on how this approach could be reflected in the product information (summary of product characteristics, labelling, and package leaflet) of the relevant intramammary antibiotic dry cow veterinary medicinal products, so that the approach may be used in accordance with the terms of the markething authorisation. This may assist the responsible veterinarian and farmer to choose a cow-based or quarter-based selective antibiotic dry cow regimen for a specific herd, where appropriate. To this end, the CVMP considered the following changes to the product information (Summary of Product Characteristics and package leaflet) to be relevant.

Deletion of any reference to blanket or routine administration of intramammary antibiotic dry cow VMPs to all cows or all four quarters of the cow in all sections of the product information.

Addition of the following advice to SPC section 3.4 Special warnings (QRD template v9.1) / 4.4 Special warnings for each target species (QRD template v8.2) (and corresponding section of the package leaflet) to all antibiotic veterinary medicinal products administered before dry-off:

"*A routine administration of the veterinary medicinal product to all udder quarters to be dried-off should not be applied.*

The dry-off treatment strategy for an individual farm and each cow should be determined on a case-by-case basis by the responsible veterinarian, based on herd-level risk assessment and professional judgement.

This decision should also consider whether cow-based selective dry cow therapy or quarter-based selective dry cow therapy is the most appropriate approach."

Deletion of any reference to administering the VMP to all four quarters of the cow, if such wording appears in SPC section 3.9 Administration routes and dosage (QRD template v9.1) / 4.9 Amounts to be administered and administration route (QRD template v8.2) (and corresponding section of the package leaflet) of intramammary antibiotic VMPs administered at dry-off, and amendment as follows:

"*Infuse the entire content of one syringe into each quarter to be treated via the teat canal directly after the last milking before dry-off.''*

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