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**Global Forum on Competition**

**Competition in the Healthcare Sector – Contribution from Sweden**

**- Session II -**

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This contribution is submitted by Sweden under Session II of the Global Forum on Competition to be held to be held on 1-2 December 2025.

More documentation related to this discussion can be found at: [oe.cd/chthc](https://oe.cd/chthc).

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## Sweden

1. The pharmaceutical sector has been identified as a particular focus area for the Swedish Competition Authority (SCA) in its 2025 operational plan. This contribution describes two cases investigated by the SCA related to pharmaceutical markets. Both cases were closed without a finding of an infringement in 2025, but the issues raised in the cases are nonetheless informative as regards competition law enforcement in the healthcare sector and in the context of the Global Forum on Competition's broader discussion of competition in the sector.

### 1. Suspected collusion within the system for generic substitution of medicines<sup>1</sup>

#### 1.1. Case background

2. During 2024 - 2025, the SCA investigated suspicions that certain pharmaceutical companies had colluded in the pricing and allocation of generic drugs within the system known as "product of the month".<sup>2</sup>

3. Product of the month is the product appointed by the Swedish Dental and Pharmaceutical Benefits Agency (TLV)<sup>3</sup> that pharmacies offer their customers when the pharmacies have to substitute medicines subject to generic competition. Products are appointed one month at a time through an auction-like procedure. To be appointed, the product has to be the least expensive within the package size group it belongs to and the pharmaceutical company has to confirm that it can supply the product to all pharmacies in Sweden for the entire month with a sufficient expiration date.<sup>4</sup>

4. The investigation originated from a tip-off by the TLV. The TLV had received email correspondence suggesting a possible rotation arrangement among several suppliers of generic medicines within a specific packaging group of the product of the month system. One email from a representative of one of the suppliers stated that, according to the rotation system, it was not the company's turn to have the product of the month until three months later. The representative also wrote that the company only held the product of the month appointment four times a year. Price data showed that the companies involved had held the product of the month in a recurring order for approximately one and a half years.

5. These observations prompted the SCA to suspect potential anti-competitive agreements between the suppliers. The SCA also observed similar pricing patterns in groups other than the one referred to in the tip-off.

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<sup>1</sup> Case reference 236/2024.

<sup>2</sup> In Swedish, "periodens vara".

<sup>3</sup> TLV is the Swedish authority responsible for deciding whether a medical drug shall be subsidised by the state, determining the retail margin for all pharmacies and regulating the generic substitution of medicines.

<sup>4</sup> The Dental and Pharmaceutical Benefits Agency, <https://www.tlv.se/in-english/pharmacy/substituting-medicines-at-the-pharmacy/product-of-the-month.html>, accessed on 28 October 2025.

## 1.2. The SCA's investigation

6. The SCA conducted inspections at company premises in Sweden and coordinated with the Danish Competition and Consumer Authority to perform inspections in Denmark. The investigation focused on whether the companies had engaged in direct or indirect agreements to coordinate pricing or market allocation by alternating being designated the product of the month, thereby maintaining a higher price than if the companies had individually decided what price to apply for to the TLV.

7. The price data analysis in the case revealed that from late 2022 to early 2024, four companies alternated sequentially in holding the product of the month appointment in one exchange group, each taking a turn every third month. Before that, between 2018 and 2022, two companies had alternated in a similar pattern, with some interruptions to the pattern.

8. Further internal documentation that the SCA reviewed supported the view that the companies themselves considered that they had arrangements to take turns with their competitors in certain groups.

## 1.3. The SCA's assessment of the conduct

9. Swedish and EU law prohibits agreements and concerted practices between companies that have the object or effect of preventing, restricting or distorting competition in the market in an appreciable manner. Therefore, it is prohibited for competing companies to coordinate prices through direct or indirect contacts.

10. However, companies are not prevented from unilaterally adapting to the prevailing and expected behaviour of other market participants. For parallel behaviour (in this case, the observed order of turns) to constitute evidence of unlawful coordination, coordination through direct or indirect contacts must be the only reasonable explanation for the parallel behaviour. In making this assessment, it is not sufficient to consider the parallel behaviour in isolation; it is crucial to also examine the specific conditions of the market in question.<sup>5</sup>

11. The SCA's investigation did not provide any evidence of direct or indirect contacts between the parties with the aim of coordinating price levels or turn-taking arrangements within the product of the month system. The question then became whether there was any other reasonable explanation for how the observed price patterns could have arisen.

## 1.4. Other explanations for the price patterns

12. The product of the month system exhibits several conditions which, according to economic theory, can lead to competitors maintaining prices higher than those that would have applied under perfect competition, even without contact with each other. By observing each other's prices and adapting to each other, price competition is avoided, which benefits all competitors in the long run. This is sometimes referred to as "tacit coordination" or "parallel behaviour". Since such behaviour is based on the competitors' independent decision-making and is not preceded by contacts between them, it is not normally covered by the prohibition in Swedish law.<sup>6</sup> From the outside, it can be difficult to distinguish such permissible tacit coordination from impermissible coordination since the result may be the same.

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<sup>5</sup> Case C-89/85, etc., *Ahlström Osakeyhtiö v Commission* ('Wood Pulp II') [1993] ECR I-1307, EU:C:1993:120, pp. 71–72.

<sup>6</sup> Chapter 2, Section 1 of the Swedish Competition Act (2008:579).

13. Among other things, the following conditions in the product of the month system may make it easier for competitors to maintain higher prices than would be the case under perfect competition: (i) the same competitors meet repeatedly in identical repeated “auctions”; (ii) authorisation from the Swedish Medical Products Agency (Läkemedelsverket) is required to sell medicines and thus establish oneself in a group, (iii) several groups have few competitors, (iv) prices are published by the TLV (historical and for the coming month), which means that companies can immediately observe if a competitor deviates from an established price pattern, (v) the price ceiling creates a clear point of coordination, and (vi) the competitor who wins the “auction” receives a large share of sales for the coming month.

14. Taken together, these conditions can create an environment where simple and relatively obvious strategies for tacit coordination emerge and where it becomes advantageous for companies to avoid price competition and increase prices.

## 1.5. Outcome of the investigation

15. The SCA concluded that there was no evidence to suggest that the parties agreed through direct or indirect contacts on price levels or order of precedence within the product of the month system. The investigation also showed that there may have been a reasonable alternative explanation for how the observed price patterns may have arisen. Against this background, the SCA found that there were no grounds for continuing the investigation.

16. The SCA has continued its dialogue with the TLV about an appropriate design of the product of the month system from a competition point of view.

## 2. Suspected abuse of a dominant position – excessive pricing of orphan drugs

### 2.1. Case background

17. In 2024 - 2025, the SCA investigated a suspected abuse of a dominant position by way of excessive pricing of the repurposed orphan drug Namuscla.<sup>7</sup> The case had its background in a pre-study that the SCA launched in 2023 to study the pricing of so-called repurposed orphan drugs (i.e. drugs originally developed for another use or indication). These are drugs with an active substance for which patent protection have expired, but which have been registered for a rare indication under EU rules.<sup>8</sup>

18. The pre-study identified patterns of very large price increases when such products obtained new exclusive market authorisation rights. Based on the results of the pre-study, the SCA initiated an investigation into the pricing of Namuscla. The medicine, whose active substance mexiletine had long been used for cardiac arrhythmia, was re-approved for the treatment of adult patients with non-dystrophic myotonia (NDM or IDM) within the European Economic Area (EEA). IDM is a rare disease that causes, among other things, involuntary muscle stiffness.

19. One of the investigated companies has held a European marketing authorisation and associated exclusive rights to market Namuscla for IDM in the EEA since 2018.

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<sup>7</sup> Case reference 341/2024

<sup>8</sup> Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products.

Namuscla entered the Swedish market in 2021, and, since 2018, has been the only drug that may be marketed for the treatment of adult patients with IDM in Sweden.

## 2.2. Findings regarding the pricing of the orphan drug

20. The SCA found that the general problem indicated by its pre-study had been confirmed by the investigation. The investigation indicated that the launch of Namuscla in Sweden in 2021 had led to an increase in the cost of treating IDM with mexiletine of between 8 and 11 times compared with previously licensed mexiletine.

21. The SCA also noted that most European countries apply so-called international reference pricing, which limits pharmaceutical companies' incentives to differentiate prices between countries. This means that pharmaceutical companies may have incentives to maintain a uniform price level even though it negatively affects sales in individual countries. The SCA's understanding is that this has also been the case for the pricing of Namuscla in Sweden and other EU countries. Some customers in Sweden have been able to purchase Namuscla at a more favourable price than others. However, even this price is several times higher than the price paid for mexiletine under licence prior to the introduction of Namuscla.

## 2.3. The legal assessment of excessive pricing

22. A very large price increase may indicate that the pricing is unreasonable, but cannot automatically be taken as evidence that the price is excessive as stipulated by competition law. Under both Swedish and EU competition law, proving abuse of a dominant position requires demonstrating two elements: first, that the company holds a dominant position in a relevant market; and second, that the dominant position is abused.

### 2.3.1. Assessment of market dominance

23. The SCA found that the circumstances of the case pointed to the holder of orphan drug status and marketing authorisation for Namuscla having a dominant position in a preliminarily defined market. The preliminary market definition the SCA considered in the investigation was medicinal products with the active substance mexiletine that have marketing authorisation for the treatment of adult IDM patients in Sweden.

24. Due to the regulatory exclusivity, licensing prescriptions could no longer be issued for the same indication after the launch of Namuscla in Sweden 2021, making Namuscla the only lawful mexiletine product for IDM. Although another mexiletine-based product, Dopital, later appeared on the market in autumn 2024, it was authorised solely for arrhythmia, not for myotonia, and thus any use for IDM would not be a viable alternative during the exclusivity period. Although the price of Dopital was significantly lower than that of Namuscla, the pricing of Namuscla was not affected by the launch of Dopital in Sweden. Nor did products with other active substances than mexiletine appear to exert sufficient competitive pressure to discipline the pricing of Namuscla.

25. In the course of its investigation the SCA also considered whether the exclusive distributor of Namuscla in Sweden also held such a market position. However, as the SCA reached the overall conclusion that the investigation into the matter should not be continued, no final assessment of the relevant market or dominance was made.

### 2.3.2. Assessment of pricing

26. Under EU and Swedish law, an abuse may consist of directly or indirectly imposing unfair purchase or selling prices or other unfair business conditions on someone. Such

abuse may consist of applying an excessively high price that has no reasonable relation to the economic value of the product supplied.<sup>9</sup>

27. EU case law, particularly the United Brands judgment, establishes a two-tier test to assess whether an “excessive price” constitutes an abuse. The first step of the assessment concerns whether there is an excessive difference between the actual price charged by the dominant undertaking and the costs actually incurred. If this is the case, the second step is to assess whether there is an imposition of an unfair price, either in terms of the price itself or in relation to the prices of competing products. There are also other possible methods for assessing whether a price is excessively high and therefore unfair.

28. In order to investigate whether Namuscla had been supplied at an excessively high price that was not reasonably related to the economic value of the product, the SCA carried out a price and cost analysis of Namuscla, among other measures. The SCA’s analysis and forecasts of costs and revenues that could be attributed to Namuscla’s sales on the Swedish market did not yield clear results.

29. The SCA did note that the costs that the authorisation holder stated it had incurred in connection with its application for marketing authorisation appeared to be remarkably high. It was also uncertain whether the benefits of Namuscla for customers, for example in terms of availability, had improved within the EU as a whole, or in individual countries, in a way that justified these costs. In Sweden, the price of Namuscla appeared to have led to fewer IDM patients being prescribed mexiletine. This, in turn, contributed to sales of Namuscla in Sweden not being as high as the market authorisation holder and the exclusive distributor in Sweden had forecasted.

## 2.4. Outcome of the investigation

30. In light of the findings of the investigation, the SCA’s overall conclusion was that the investigation into the matter should not be continued. The SCA notes that this does not prevent it from initiating a new review of the pricing of Namuscla or other orphan drugs in the future, based on market developments.

## 3. Concluding remarks

31. The pharmaceutical sector is characterised by complex regulatory frameworks operating at both national and supra-national levels. The investigations carried out by the SCA demonstrate different ways in which regulation interacts with and affects both competitive conditions and competition law enforcement in the sector.

32. The product of the month investigation highlights the evidentiary limits of competition law in cases involving tacit collusion within highly transparent and regulated market settings. Meanwhile, the investigation of the orphan drug case highlights the need to balance the regulatory objectives of pharmaceutical innovation and fair pricing and access in markets for orphan drugs. As this case demonstrates, a competition authority, when assessing a case, must take due account of the fact that both regulation and the companies involved may operate at a supra-national level (in this case the EU).

33. Traditional competition rules have proven to be robust and flexible enough to address competition problems in many situations. However, the complex interaction

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<sup>9</sup> Case 27/76, United Brands Company and United Brands Continentaal BV v. Commission of the European Communities, EU:C:1978:22, para. 250.

between regulation and competition in these cases reinforces the fact that there are also potential competition problems that cannot sufficiently be addressed solely within the framework of traditional competition enforcement. In some cases, it may be more appropriate for a competition authority to advocate policymakers to address competition issues through improved regulation.