

**DIRECTORATE FOR FINANCIAL AND ENTERPRISE AFFAIRS  
COMPETITION COMMITTEE**

**Excessive Pricing in Pharmaceutical Markets - Note by Denmark**

**28 November 2018**

This document reproduces a written contribution from Denmark submitted for Item 9 of the 130<sup>th</sup> OECD Competition Committee meeting on 27-28 November 2018.

More documents related to this discussion can be found at  
[www.oecd.org/daf/competition/excessive-pricing-in-pharmaceuticals.htm](http://www.oecd.org/daf/competition/excessive-pricing-in-pharmaceuticals.htm)

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## Denmark

### 1. Excessive Pricing

1. According to section 11(3)(i) of the Danish Competition Act, exploitative pricing by a dominant firm may be considered abusive.
2. In cases concerning excessive pricing, the Danish Competition Council (“DCC”)<sup>1</sup> can impose a number of sanctions. The undertaking involved can be ordered to refrain from similar abusive behaviour in the future. The DCC can also submit excessive pricing cases to the Danish State Prosecutor for Serious Economic and International Crime for a criminal assessment, potentially resulting in a fine.
3. As addressed by the Competition Committee, excessive pricing is typically viewed as a temporary and self-correcting market failure, or, conversely, as a problem to be addressed through sector-specific regulation. Therefore, the Danish Competition and Consumer Authority (“DCCA”) has only adopted decisions related to excessive pricing in a limited number of cases.
4. The most recent case on excessive pricing was adopted in a case concerning pharmaceuticals, case no.: 14/08469, *CD Pharma’s pricing of Syntocinon* cf. below.<sup>2</sup>

### 2. The CD Pharma case

#### 2.1. Background

5. On 31 January 2018, the DCC adopted a decision concerning a pharmaceutical distributor’s (CD Pharma) abuse of dominance by charging an excessive and unfair price for the drug Syntocinon.
6. Syntocinon contains oxytocin, an active substance given to pregnant women during childbirth. This drug has been marketed since the 1950’s and the patent expired many years ago.
7. From 2007-2014, the price of Syntocinon in Denmark was stable at approximately DKK 44 (EUR 5.9).
8. Amgros (the pharmaceutical procurement service for the five regional authorities in Denmark) carried out a tender on Syntocinon for the period of 1 April 2014 to 31 March 2015, which Orifarm (a parallel importer and competitor to CD Pharma) won.

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<sup>1</sup> Together the DCC and the DCCA form an independent competition authority.

<sup>2</sup> Apart from this case, the DCC has only adopted one decision concerning pharmaceuticals in recent years, case no.:12/07423: Nomeco A/S and Tjellesen Max Jenne A/S’ coordination of fees and other trading conditions. On 26 November 2014, the DCC adopted a decision concerning the two largest wholesale distributors of pharmaceuticals on the Danish market. The two distributors restricted competition by agreeing to a joint set of fees and other terms of delivery to all pharmaceutical manufacturers and pharmacies on the Danish market.

9. Orifarm, however, proved incapable of supplying the full amount of Syntocinon requested by Amgros and it was therefore necessary for Amgros to buy the residual amount from CD Pharma, the only other supplier of Syntocinon on the Danish market.

10. During the contract period, Orifarm tried to supply Syntocinon in accordance with the contract, but was, as a parallel importer, unable to procure a sufficient amount from other countries to cover Amgros' full demand.

11. Contrary to parallel importers such as Orifarm, CD Pharma was guaranteed supply due to an exclusive distribution agreement with the producer of Syntocinon, Sigma-Tau.

12. CD Pharma had entered into the exclusive agreement with Sigma-Tau with effect from February 2014.

13. Before February 2014, Sigma-Tau had an exclusive distribution agreement with another distributor in Denmark. From at least 2009 to 2014, the distributor having the exclusive distribution agreement with Sigma-Tau held a monopoly-like position in Denmark with a market share of 100 pct.

14. CD Pharma held a dominant position on the Danish market for the sale of oxytocin during at least the period from 1 April 2014 to 31 March 2015, but also in the subsequent period from 1 April 2015 to 31 March 2016 where Amgros carried out a new tender. This was primarily caused by CD Pharma's special position on the market given the exclusive distribution agreement with Sigma-Tau.

15. From 28 April 2014 to 27 October 2014, i.e. during the period when CD Pharma acted as a residual supplier to Amgros, CD Pharma increased its price on Syntocinon from DKK 45 (approx. EUR 6) to DKK 945 (approx. EUR 127), corresponding to a price increase of approx. 2,000 pct.

## 2.2. The assessment of CD Pharma's pricing

16. In the assessment of CD Pharma's pricing, the DCC followed the test set out by the Court of Justice in *United Brands*<sup>3,4</sup>

17. The United Brands test consists of two steps:

1. Whether the difference between the costs actually incurred and the price actually charged is excessive, and,
2. if the answer to this question is affirmative, whether a price has been imposed which is either unfair in itself or when compared to competing products.<sup>5</sup>

18. In practise, it may be difficult to assess excessive pricing conduct. Especially the first step of the test, where the profit margin of the undertaking involved is assessed, can be challenging as it requires access to internal information about actual costs – or a solid basis for making cost estimates

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<sup>3</sup> Case 27/76 *United Brands and United Brands Continental v Commission* ("United Brands") [1978] ECR 207.

<sup>4</sup> This methodology will also be applied when assessing excessive pricing in sectors other than pharmaceuticals.

<sup>5</sup> Case 27/76 *United Brands*, paragraph 252.

19. This difficulty also arose in the CD Pharma case when assessing CD Pharma's profit margin on Syntocinon. The DCC was unable to obtain documentation of the relevant costs. The DCC therefore conducted 7 sensitivity analyses in order to estimate CD Pharma's profit margin. 6 out of these 7 analyses resulted in a profit margin of 80-90 pct.

20. CD Pharma was unable to justify the price increase from DKK 45 (approx. EUR 6) to DKK 945 (approx. EUR 127) with, for instance, increased costs or special considerations related to research and development. All tests conducted by the DCC confirmed that CD Pharma's price on Syntocinon was excessive and unfair.

21. CD Pharma thereby exploited its dominant position making Amgros (i.e. the Danish hospitals) pay an excessive and unfair price on Syntocinon. Consequently, the DCC ordered CD Pharma to refrain from similar abusive behaviour in the future.

22. The DCC is currently awaiting a decision from the Danish Competition Appeal Tribunal. If the decision is upheld by the Danish Competition Appeal Tribunal, the DCC will submit the case to the Danish State Prosecutor for Serious Economic and International Crime with the aim of a criminal assessment possibly resulting in a fine.

### 2.3. Why the case was prioritised

23. When deciding whether to pursue a possible infringement, the DCC/DCCA considers the trade-off between the expected effects of the case in relation to improving competition and creating better-functioning markets and the expected required use of resources to investigate the case. More specifically, the assessment is based on the following criteria:

- The gravity of the infringement of the Act
- The expected impact on the market, the competition culture and the economy as a whole
- The legal importance, i.e. whether the case involves an issue which has not previously been clarified in legal practice
- The expected use of working hours

24. In addition to these general criteria, the DCC, in relation to the case concerning *CD Pharma's pricing of Syntocinon*, also took into account the characteristics of the relevant market. The DCC considered that:

- Syntocinon was no longer patented and hence there was no need for protection of innovation
- There were no generic or substitutable pharmaceuticals available on the Danish market
- The buyer, Amgros, observed delivery failure from tender-winners as a growing problem in tenders with few bidders
- The high price on Syntocinon had weakened future incentives to compete instead of attracting entry.

25. The DDC found that CD Pharma's behaviour had greatly affected the hospitals' procurement of pharmaceuticals (funded by public finances). Beside CD Pharma's behaviour being exploitative, the behaviour could lead to a permanently higher price level

in the post-abuse period. As the contract with Amgros states that a supplier is obliged to cover Amgros' loss in case of delivery failure, suppliers in the post-abuse period must take into account the risk of a significant claim for compensation and CD Pharma's behaviour may therefore also be exclusionary.

### 3. Sector specific regulation in Denmark

26. In Denmark, sector-specific regulation concerning pharmaceuticals poses certain challenges for effective competition. Below is a non-exhaustive list of some of the rules:

- Pharmaceutical suppliers in Denmark have free pricing. However, pharmaceuticals are sold at the same price from all pharmacies. In relation to suppliers, the Danish Association of the Pharmaceutical Industry (Lif) (a trade association for the researching pharmaceutical industry), the Danish Ministry of Health, the Ministry of Finance and the Danish Regions have an agreement on price reductions and a cap on prices for both hospital pharmaceuticals and pharmaceuticals sold at pharmacies.<sup>6</sup> The price-cap applies to areas with limited competition as a result of the patents of original products as well as areas subject to competition in which Lif's members market generic products.
- Prices on pharmaceuticals distributed to pharmacies are adjusted frequently through 14-days price auctions. Here, pharmaceutical suppliers have free access to knowledge concerning historic bids submitted by competitors in the auction system via [medicinpriser.dk](http://medicinpriser.dk).

It is not uncommon for prices to increase/decrease on a regular basis for pharmaceuticals exposed to generic competition, and the DCCA often receives inquiries/complaints from citizens who experience increases in the price of their pharmaceuticals. These inquiries/complaints are often without additional information about the market or other conditions which points to anti-competitive behaviour. In most cases, the increase in prices stem from the 14-days fixed price auctions and the subsequent price cycles and hence, do not lead to further investigations.

- Regulation in the pharmacy sector limits the scope for competing on a number of parameters. For instance, on pharmaceuticals exclusively sold at pharmacies<sup>7</sup>, both purchase prices and sales prices are fixed, meaning that pharmacies are unable to compete on prices. In addition, the number of pharmacies is regulated by means of a licensing system determining the rules of ownership and location.
- The scope for price competition among wholesalers is limited by regulation which, in practice, prevents wholesalers from competing on the pharmaceutical prices offered to pharmacies and on the rebates granted on the pharmaceuticals.

<sup>6</sup> The price-cap agreement for pharmaceuticals sold to hospitals runs from 1 April 2016 to 31 March 2019. The price-cap agreement for pharmaceuticals sold at pharmacies runs from 1 July 2016 to 15 December 2018.

<sup>7</sup> That is prescription-only pharmaceuticals and certain over-the-counter pharmaceuticals which are only permitted for sale in pharmacies.

27. The Danish Competition Act, Section 2 (2), states that the prohibition against anti-competitive agreements shall not apply where an anti-competitive practice is a direct or necessary consequence of public regulation.

28. However, from Section 2 (5) it follows that if the DCC finds a public regulation likely to restrict competition, the DCC may deliver a reasoned opinion to the relevant minister and to the Minister for Business, pointing out its potentially adverse effects on competition, and present recommendations for promoting competition in the area concerned.

29. However the DCC has no power to change the anticompetitive rules. Instead the DCC and the DCCA draws attention to sector-specific regulation limiting competition through a number of different activities.

#### 4. Initiatives other than antitrust enforcement in pharmaceutical markets

30. The DCCA is working actively to promote competition in many ways besides antitrust enforcement. Below is a non-exhaustive overview of some of the activities, in which the DCCA is involved concerning the pharmaceutical markets:

##### 4.1. Inter-ministerial working groups

31. The DCCA works closely with other ministries and regulators. For instance, the DCCA participates in different kinds of inter-ministerial working groups. Since the DCC and the DCCA has no authority to change anticompetitive regulation, this close collaboration is an important opportunity for the DCC and the DCCA to draw political attention to undesirable sector-specific regulation and to work for changes to the regulation leading to more competitive markets.

##### 4.2. Article: ‘Regulatory issues and price cycles in the market for prescription medicine after patent expiry’

32. Smaller publications are another advocacy tool commonly used by the DCCA. By drawing attention to different competitive issues, articles help create public debate and thereby serve as a platform for potential political action.

33. In November 2017, the DCCA published an article on regulatory issues and price cycles in the market for prescription medicine after patent expiry. The article is based on a market study performed by two guest authors/researchers from the University of Copenhagen.

34. The article focused on the challenges arising from the 14-days fixed price auctions. Among other things the authors found that for prescription medicine where the patent has expired, prices often show a marked cyclical pattern, where the price rises very strongly and then only slowly decreases again.

35. Moreover, the authors/researchers highlight three specific challenges in the 14-day price auctions:

1. The medical suppliers have easy and free access to knowledge about the bids that competitors have submitted in the auction system via [medicinpriser.dk](http://medicinpriser.dk).

2. After the auctions, delivery failures are very common and there is no penalty for not delivering.
  3. The winner of the auction only sells about 70 percent of the medicine during the 14 day period. The rest is sold by competitors at higher prizes.
36. In conclusion, the article includes a number of actions, which could help deal with the challenges listed above and potentially reduce the price cycles, thereby improving competition in the market for prescription medicine.

#### **4.3. Report: ‘Competition in the distribution of pharmaceuticals’**

37. In October 2016, the DCCA published a report analysing competition in the distribution of pharmaceuticals. The focus was a number of regulatory issues and the fact that the Danish market structure is characterized by two major wholesalers who handle almost all supplies.

38. The conclusion of the report is that competition in the distribution of pharmaceuticals to pharmacies can be more effective by changing regulation. In the report, the DCC set forward a list of recommendations aimed at increasing competition.

39. Summary of report in English: <https://www.en.kfst.dk/media/3296/141016-competition-in-the-distribution-of-medicines.pdf>

#### **4.4. Conference on ‘Well-functioning Markets’**

40. Another advocacy tool used by the DCCA is the organization of conferences, where academics, stakeholders, politicians and other relevant individuals are invited to join e.g. discussions on relevant topics.

41. The DCCA is currently planning a conference on ‘Well-functioning Markets’ to be held on 20 November 2018, where one of the topics will be on pricing and regulation within pharmaceutical markets.