Excessive Pricing in the Pharmaceutical Sector:

Recent European Cases

VAN BAEL & BELLIS

David Hull

European Pharma Law Academy

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Addressing Excessive Pricing in Pharma Sector: Policy Issues

Competition authorities have generally been **reluctant to launch cases**:

- High prices in a competitive market with low entry barriers are self-correcting
- Application of legal test raises very difficult questions (e.g. what is an "excessive" price)
- Interference with pricing could chill investment and innovation in a key sector – high prices are the carrot that encourages companies to invest in R&D
- Unnecessary in light of the strong buyer power exercised by national health authorities and other payors. Some Member States now considering joint buying arrangements.
- Pricing of medicines a national issue for Member States
- Difficulty of determining an appropriate remedy – competition authority ill-suited to be a price regulator

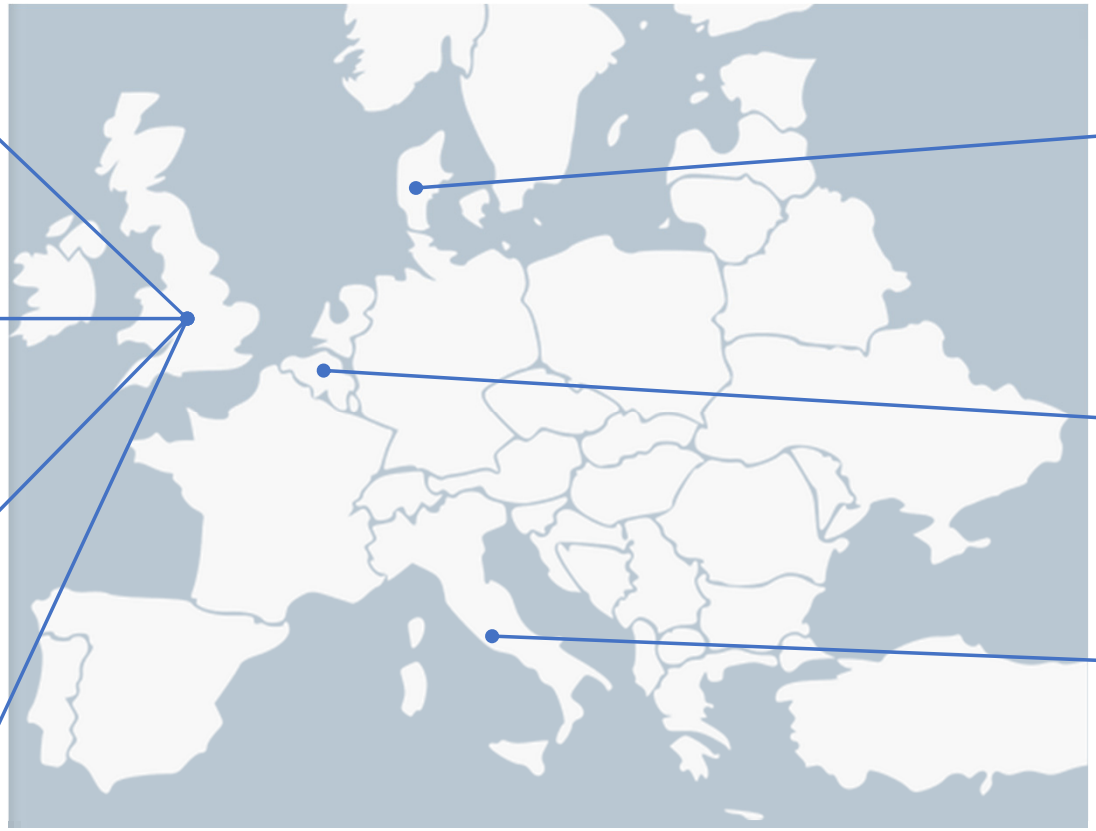
Excessive Pricing Cases in the Pharmaceutical Sector

Actavis (UK) – ongoing:
Investigation of unfair and excessive prices for hydrocortisone tablets.

Concordia (UK) – ongoing:
Investigation of unfair and excessive prices for liothyronine tablets.

Flynn / Pfizer (UK) – 2016:
£ 84.2 million fine
Unfair and excessive prices for phenytoin sodium capsules.

Napp (UK) – 2001:
£ 3.2 million fine
Hospital discounts and excessive community prices for morphine patches.



CD Pharma (Denmark) – 2018:
Referred to Prosecutor for Serious and Economic Crimes
Excessive price increases by exclusive country distributor of syntocinon.

Aspen (EU) – ongoing:
EU-wide investigation into excessive price increases for four cancer medications.

Aspen (Italy) – 2016:
€ 5.2 million fine
Excessive price increases for four cancer medications.

Common Features of the Cases

- Almost all cases are very recent
- Most are at national level, but there is one EU-level case
- All concern off-patent drugs
- None concern new, on-patent drugs
- None concern prices that went through an HTA process
- Typically based on (very) narrow market definitions

The Dilemma

- Excessive pricing is often seen as the quintessential evil of monopoly
- But recognition that high prices create incentives to innovate and invest and attract competition to the market
- How do you distinguish between acceptably high prices and excessive prices?

The Legal Test

Article 102(a) TFEU provides that an abuse may consist of "directly or indirectly imposing unfair purchase or selling prices …"

In ***United Brands*** (1978), the Court of Justice said that charging a price which is excessive because "*it has no reasonable relation to the economic value of the product*" is abusive. (¶250)

- Court set out a **2-pronged test**:
  - **STEP 1** *"[t]he questions therefore to be determined are whether the difference between the costs actually incurred and the price actually charged is excessive, and,*
  - **STEP 2** *"if the answer to this question is in the affirmative, whether a price has been imposed which is either unfair in itself or when compared to competing products."* (¶252)

- Court left open possibility of using **other tests**:
  - *"Other ways may be devised – and economic theorists have not failed to think up several – of selecting the rules for determining whether the price of a product is unfair."* (¶253)

Problems with the Legal Test

1. **Is difference between price / costs excessive?**
   - Difficult to determine costs
     - **Which costs?** Most significant costs for drugs are the R&D costs. How do you allocate them across products, time and geographies? How do you account for high failure rate in bringing a drug to market?
   - What is "excessive"?
2. **Is the price unfair?**
   - In itself? What is "in itself"?
   - When compared to competing products? Difficulty of making comparisons among different products, across different geographies, at different points in time.
     - Higher prices may reflect **superior efficacy** and **fewer side effects**, which reduces long-term costs to national health budgets – need to look at health technology assessments

Recent Clarification of *United Brands* Test: Cost/Price Only One Alternative

Application of the *United Brands* test discussed at length in Case C-177/16, ***AKKA/LAA*** (14 Sept. 2017) (reference from a Latvian court on licensing fees for musical works charged by national collecting society).

UNITED BRANDS STEP 1

- The benchmark for assessing whether prices are deemed "excessive" can be done by a number of methods (not only cost-price)
  - Comparison with prices charged in other Member States a valid method
  - Comparators must be chosen on bases of "objective, appropriate and verifiable" criteria
  - Comparisons must be made on a "consistent" basis
- *"Certain types of costs a given undertaking may have incurred may not be immediately evident or easily imputable to the supply of a given product or service (for example abortive research and development), but nonetheless may not be discounted"* (¶ 48)

Recent Clarification of *United Brands* Test: Cost/Price Only One Alternative

UNITED BRANDS STEP 2

Advocate General Wahl:

- Aim of Step 2 is to investigate whether the excessive price identified in Step 1 "*is merely the result of an abusive use of market power*" or "*the consequence of other legitimate reasons*" (¶ 21)
- Step 2 has two limbs:
  - Unfair in itself – "*is meant to cover those instances in which the unfairness of a price can be determined without the need to make any comparison with similar or competing products*" (¶ 121)
  - Unfair as against competing products – can often be a "*sanity-check of the assesment made with regard to the benchmark price*" insofar as it can reveal "*relevant factors which were either overlooked in that context or were consciously not taken into account because they were not easily quantifiable in financial terms*" (¶ 124)

Recent Clarification of *United Brands* Test: Cost/Price Only One Alternative

UNITED BRANDS STEP 2

- A "**significant and persistent**" difference from the benchmark price is "indicative of an abuse of the dominant position"
  - But dominant company can provide justification for higher prices
- Advocate General Wahl: it is only when there is "**no rational economic explanation**" that a high price will be abusive

> *"I would point out that the economic value of the goods or service supplied by a dominant undertaking may, in the eyes of the customers, be higher than the benchmark price. Again, there may be a variety of reasons for that: for instance, the goods or service in question may be (or be merely perceived to be, perhaps for reasons relating to advertising or branding investment costs) of superior quality. Some features of the product or service may be regarded as particularly valuable by customers (or certain groups of customers), in spite of the fact that they are not reflected on the cost side. In those cases, the additional benefits or advantages provided to customers justify a higher mark-up over costs*." (Opinion of AG Wahl, ¶128)

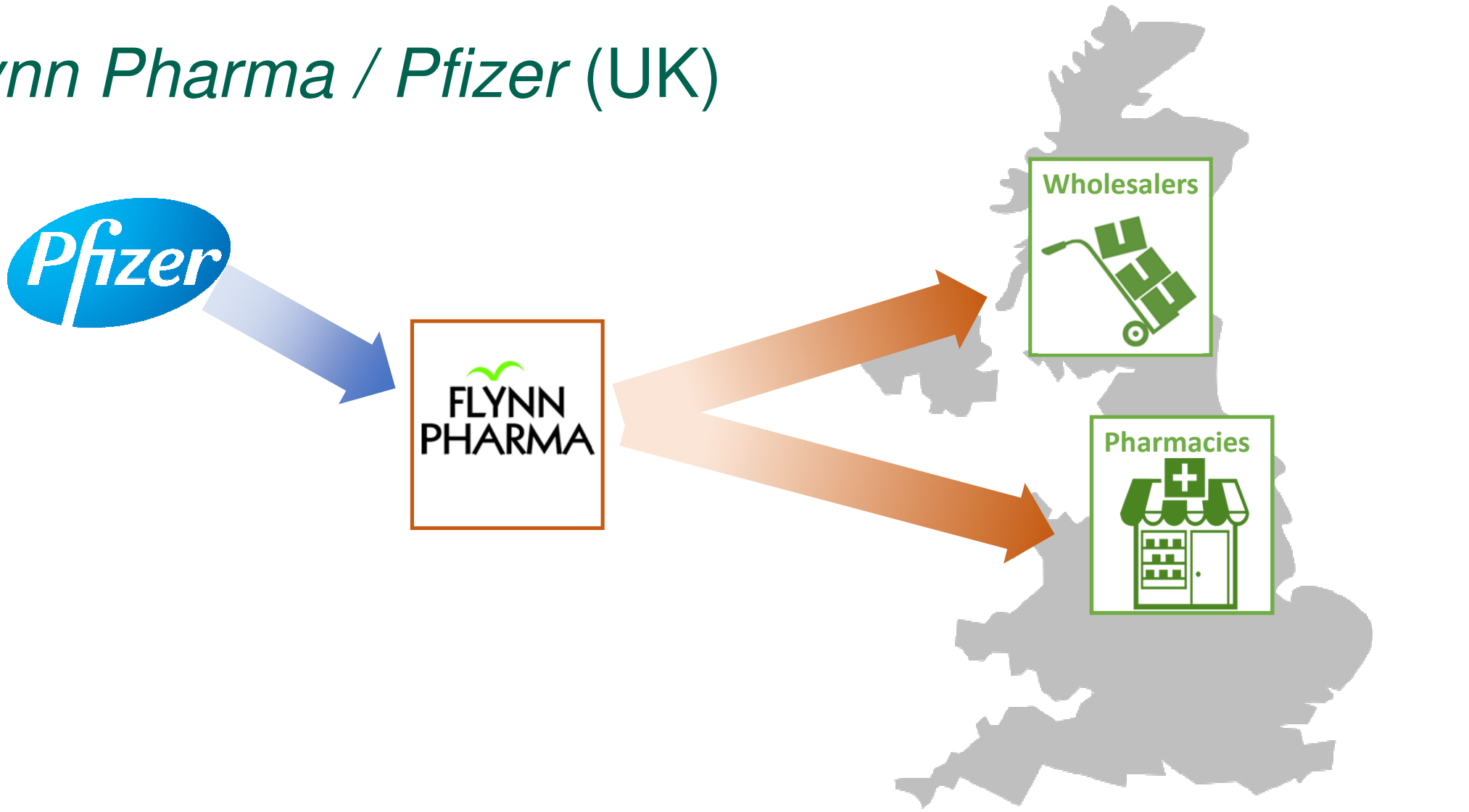
Flynn Pharma / Pfizer (UK)

- On 7 December 2016, the UK CMA (Competitions and Markets Authority) issued a decision finding Pfizer and Flynn Pharma had abused their dominant positions by imposing excessive prices for the anti-epilepsy drug phenytoin sodium
  - Fines of £84.2 million on Pfizer, and £5.2 million on Flynn
- The case was appealed to the CAT (Competition Appeals Tribunal), which overturned the CMA's decision on 7 June 2018
- CAT rejected the parties' requests to appeal; they may still seek leave to appeal directly from the Court of Appeal

Pfizer / Flynn's Pricing Conduct

- Prior to 2012, Pfizer manufactured and marketed the (**off-patent**) drug under the brand name Epanutin
- Pfizer then transferred the UK marketing rights to Flynn Pharma, which "genericised" the drug and started selling it in September 2012 at prices the CMA found to be **16 times higher** than Pfizer's historical prices

Flynn Pharma / Pfizer (UK)



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Flynn Pharma / Pfizer (UK)

Pfizer/Flynn's Phenytoin Sodium Capsules

- Pfizer's capsules had been subject to the UK "PPRS" which determines prices based on an average across the manufacturer's portfolio of products
- The PPRS had eroded the price of Epanautin to a loss-making level before 2012
- In 2012, Pfizer manufactured capsules are added to the UK Drug Tariff Category "C" for non-generics (reimbursement based on list price by manufacturer or supplier)

Capsules and tablets are clinically identical

Phenytoin Sodium Tablets

- Phenytoin in tablet form – such as Teva's – are classed in UK Drug Tariff Category "M" for products with available generics (reimbursement based on a weighted average price of multiple participating manufacturers)
- The health authorities had fixed a tablet price in the Drug Tariff in 2007, following a voluntary price reduction from Teva
- Drug Tariff price of tablets is roughly 2 times **higher** than Flynn's "excessive" capsule prices

Flynn Pharma / Pfizer (UK)

DOMINANCE

- CMA adopted a very narrow market definition to find the parties dominant:
  - the manufacture of Pfizer-manufactured phenytoin sodium capsules distributed in the UK; and
  - the distribution of Pfizer-manufactured phenytoin sodium capsules in the UK
- This is narrower than the molecule (excluding other brands and formulations such as tablets)
- CMA justifies this narrow definition based on:
  1) Clinical grounds –stable patients cannot switch between brands because of the drug's narrow therapeutic index (i.e. small dosage changes lead to therapeutic failure or toxicity)
  2) Limited actual switching – patients did not in fact switch to alternative products (though switching occurred at least until MHRA guidance in 2013 advised against it)
- CAT upholds this market definition

Flynn Pharma / Pfizer (UK)

UNITED BRANDS TEST – STEP 1

- CMA used "cost-plus" benchmark
  - Costs = Direct/indirect costs actually incurred
    - R&D costs not included (off-patent drug so costs recovered, Flynn did not develop Epanutin)
  - Plus = Reasonable rate of return
    - CMA sets a specific 6% ROS (Return on Sales)
- CMA determined that the price Flynn and Pfizer charged was excessive because it materially exceeded this cost-plus benchmark
- On appeal, the parties contended that the *United Brands* test requires determining what the price would normally be under conditions of effective competition, not determining a theoretically reasonable maximum price (such as a "reasonable rate of return")
- CMA argued all *United Brands* Step 1 requires is establishing a material difference between price and cost, not a comparison with a hypothetical benchmark under normal competitive conditions

Flynn Pharma / Pfizer (UK)

UNITED BRANDS TEST – STEP 1

- CAT held CMA erred in restricting its analysis to "cost-plus" only
  - While *United Brands* refers to a comparison of production costs as an example of a method to determine excessive price, it is neither required nor the only method possible
  - Cost-plus is not sufficient when other methods are available (and suggest different results)
  - A competition authority cannot simply choose the method most likely to result in an infringement
- What Step 1 seeks to establish is "*whether the dominant undertaking reaped trading benefits that it would not have earned under conditions of normal and sufficiently effective competition*"
  - CMA refers directly to the same approach in the Opinion of AG Wahl in *AKKA/LAA*
- CMA's cost-plus methodology (and reliance on a reasonable rate of return) produces a result that works under perfect competition, not in the real world
- Therefore must assess "excess" with reference to a benchmark for the normal competitive price
  - This requires a less rigid approach to the examination of comparators

Flynn Pharma / Pfizer (UK)

UNITED BRANDS TEST – STEP 2

- CMA finds price "unfair in itself"
  - CMA: "[*I*]*n the absence of relevant non-cost factors, the very excessiveness of a price could be sufficient*"
- CMA assigns no economic value (i.e. "benefits not reflected in costs of supply") beyond cost-plus:
  - Characteristics of product show no additional value (off-patent, older regimen)
  - CMA rejects parties' representations of additional added value (e.g. costs resulting from drug's withdrawal)
- CMA rejects demand-side value (value cannot be whatever the market will pay)
- CMA concludes it is not obliged to look at other limb of Step 2 (unfair in relation to comparators)
  - CMA rejects the Drug Tariff price for Teva tablets as a reasonable benchmark
    - Drug Tariff price for tables does not necessarily imply an endorsement of the tablet price as fair
  - Considers instead prices offered by Pfizer before 2012, as well as prices currently offered in other EU Member States

Flynn Pharma / Pfizer (UK)

UNITED BRANDS TEST – STEP 2

- CAT held CMA erred in relying exclusively on the "unfair in itself" limb of Step 2, without assessing the impact of relevant comparators (e.g. phenytoin tablets)
  - While the two limbs of *United Brands* Step 2 (unfair in itself vs. unfair as against comparators) do not both need to be satisfied, this does not give an authority complete discretion to pick only one
  - An authority cannot ignore a *prima facie* argument raised under the other alternative; it must consider whether such an argument undermines its conclusions (i.e. a "sanity check" per AG Wahl)
- CAT finds there were meaningful comparators giving rise to such a *prima facie* argument
  - Comparators within the meaning of *United Brands* Step 2 need not be products in the same market
  - Tablets were an "obvious" comparator, that the CMA should have investigated in greater depth
  - Other regimens were meaningful only to show how much a buyer might pay to treat epilepsy

Flynn Pharma / Pfizer (UK)

UNITED BRANDS TEST – STEP 2

- CAT found that the CMA had used prices in other EU Member States as a comparator without taking sufficient account of differences that might underlie those prices
  - CMA did underline that it seemed "significant" that Pfizer had only increased its prices in the UK due to its new marketing arrangement with Flynn
  - Nevertheless the CMA did not take into account other relevant factors (e.g. differing regulatory, economic or other conditions) to demonstrate unfairness with reference to other Member State prices
- CAT finds that *United Brands* Step 2 requires an analysis of the "economic value" of a product beyond cost-plus
  - Economic value is a legal, rather than economic concept
  - While it must not be whatever the the market can bear, it must take both supply and demand into account
  - Criticizes CMA's "outright rejection" of <u>any</u> value to dependent patients, as it is an effective treatment
  - CMA should have ascribed a value higher than zero, and should have looked to tablets as a comparator for what value to assign the product

Flynn Pharma / Pfizer (UK)

OTHER FACTORS

- CAT agrees that a dramatic change in price over time (i.e. the degree to which the parties had increased prices from previous levels) should be examined closely
  - However, CAT cautions that a dramatic increase in price "should not be confused with the test for unfair pricing itself"
  - Doing so would reverse the burden of proof, requiring a company to justify an increase in prices rather than an authority to find an infringement
- CAT concludes that excessive pricing may be found in this case, but that if the CMA chooses to apply the *United Brands* 2-step test, it must do so according to the framework laid out
  - CAT notes, however, that the 2-step test is not the only way to assess excessive pricing

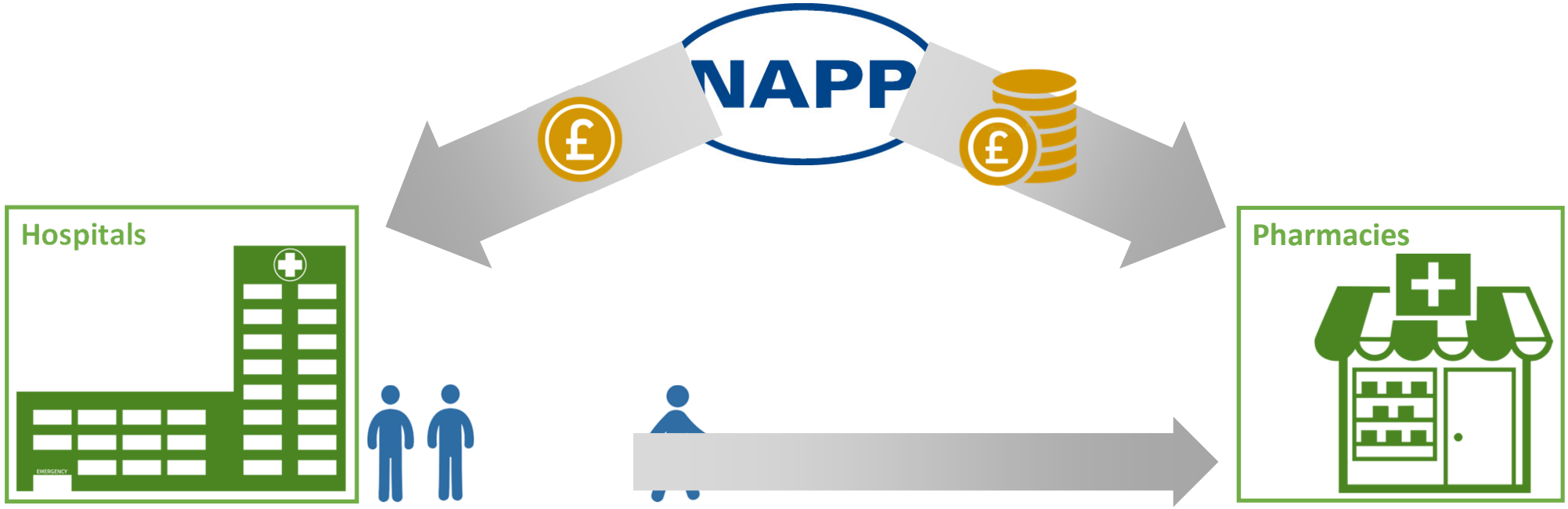
Napp (UK)

- In 2008 the CMA/OFT found that Napp had abused its dominant position by charging excessive prices on sustained release morphine.
- CAT upheld the OFT's decision

Napp's Pricing Conduct

- Napp sold this product at steep discounts to hospitals while charging much higher prices to pharmacies
- Exclusionary conduct in **hospital sector** linked to excessive pricing in **pharmacy sector**
- OFT found that the prices charged to pharmacies were excessive – above the level that would be charged in a competitive market

Napp (UK)



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Napp (UK)

- OFT looked at a range of comparators and factors other than production costs:
  - Prices were between 30 and 50% higher than competitors
  - List prices to pharmacies were, in some instances, more than 2000% higher than those in hospitals
  - Prices to pharmacies were 500% higher than those for export
  - Napp's gross margin was over 80%, while it was less than 70% for Napp's most profitable competitor

Aspen (Italy)

- On 29 September 2016, the Italian competition authority (ICA) fined Aspen Pharma €5.2 million for abusing its dominant market position by increasing the price of its cancer drugs
- Latium Regional Administrative Tribunal (TAR) upheld the ICA's decision on 26 July 2017

Aspen's Pricing Conduct

- These cancer products had been on the market for several decades and were **off-patent**
  - Aspen purchased the products from GSK in 2009, and then negotiated a substantial price increase with AIFA, the Italian medicines authority.
  - These price increases ranged from **300% to 1500%**
- Nevertheless, in its press release, AIFA noted that it was the lowest price in Europe for these drugs

Aspen (Italy)

aspen PHARMACARE
Marketing Authorization Holder

Refusal to supply

Drug reclassification

Agenzia Italiana del Farmaco
AIFA
Italian Medicines Agency

Aspen (Italy)

The ICA applied the 2-part *United Brands* test:

UNITED BRANDS – STEP 1

- The ICA found a significant difference between Aspen's new prices and its production costs
  - Did not take into account R&D costs because Aspen did not engage in R&D
  - Did not take into account purchase price of Aspen trademarks

Aspen (Italy)

UNITED BRANDS – STEP 2

- The ICA concluded these significant differences were not justified as:
  - The increased prices were not due to additional costs
  - Prices had not changed for decades
  - Aspen did not contribute to any increase in the drugs' quality
  - The price increases imposed a significant cost on national health expenditure (approx. 500% increase)
  - Rejected comparison to prices in other Member States because difficult to make comparisons due to differences in health systems and regulatory regimes
  - No consideration of demand for product – i.e. patients' willingness to pay – as you cannot put a price on a life-saving drug

Aspen (Italy)

- The ICA emphasized various **"plus" factors** in finding an abuse
  - Aspen had threatened to withdraw the product from the market if the health authority did not agree to the price increases
  - Aspen wanted to increase the prices in Italy up to the levels in other EU countries, in order to limit the levels of parallel trade of the product out of Italy
  - Aspen's business model was to buy drugs and exploit market niches by raising prices – no R&D investment

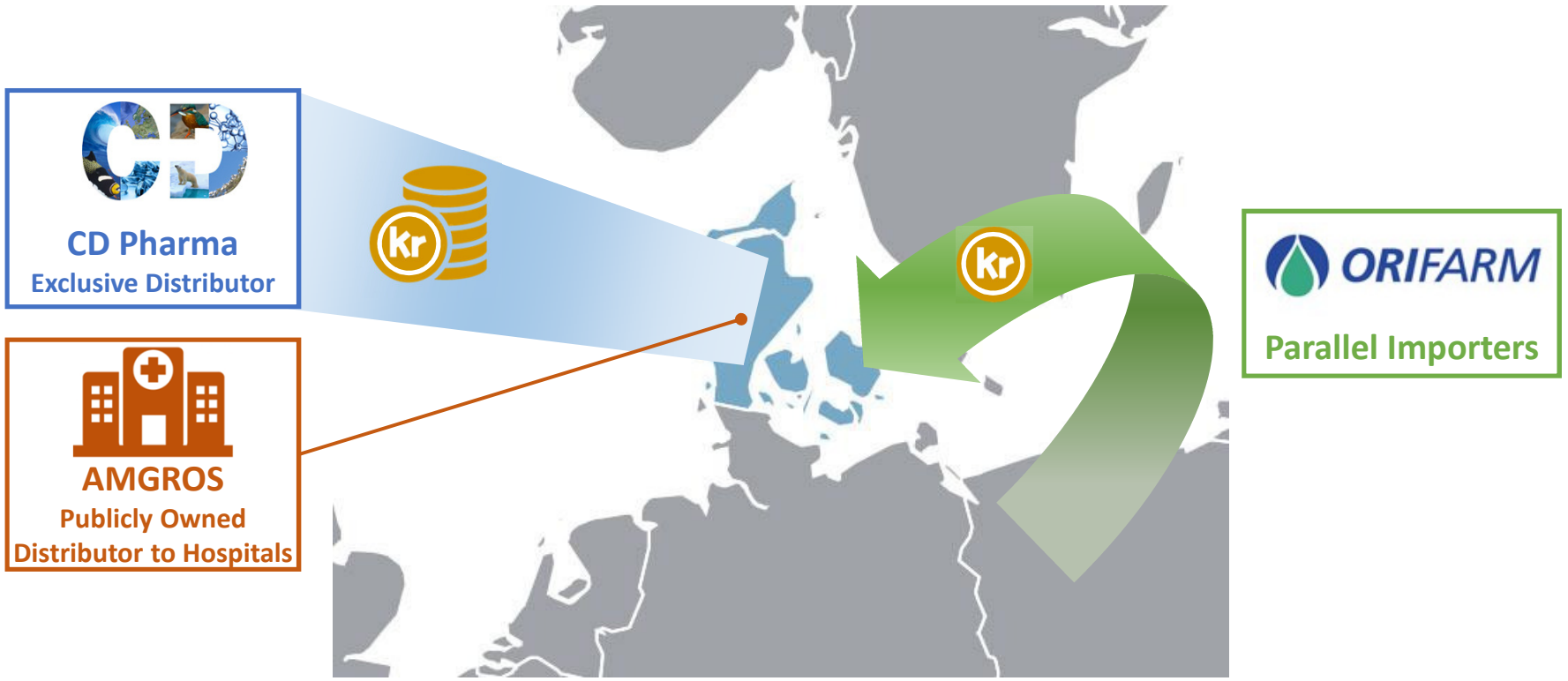
CD Pharma (Denmark)

- On 31 January 2018, the Danish Competition Council ruled that CD Pharma (a distributor) had abused its dominant position by charging excessive prices for Syntocinon

CD Pharma's Pricing Conduct

- Syntocinon contains oxytocin and is used in connection with childbirth. It has been on the market since the 1950's, has long been **off-patent** at a stable price
  - CD Pharma had an exclusive deal with the manufacturer to distribute in Denmark
  - AMGROS, the buyer for the national hospitals, issued a tender for the drug, which was won by Orifarm, a parallel trader
  - When Orifarm's supply was partially interrupted and it was no longer able to honor its commitment, it had to purchase its remaining requirements from CD Pharma (the only alternative supplier)
- Facing no competition from other suppliers, CD Pharma was able to raise its price by about **2,000%** between April and October 2014

CD Pharma (Denmark)



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CD Pharma (Denmark)

UNITED BRANDS – STEP 1

- Significant gap (80%) between cost and price

UNITED BRANDS – STEP 2

- Unfair in itself – when examining the financial value of the drug, the Authority found no non-cost related factors justifying the price increase (e.g. sunk costs or intangible value)
- Unfair as against a comparator – the Danish Authority found the price significantly above that of several comparators
  - CD Pharma's historical prices
  - Competitors' prices, including the price the hospital buyer had originally negotiated with Orifarm
  - The price CD Pharma charged for syntocinon in other countries

CD Pharma (Denmark)

- The Danish Authority emphasized another **"plus" factor**
  - The Authority found that CD Pharma's prices might have the effect of permanently raising prices even after prices for syntocinon had returned to previous levels
  - CD Pharma's price increase might have the effect of forcing parallel traders – who guarantee to cover loss due to delivery failures – to take into account the risk of compensation claims from buyers obliged to source elsewhere at much higher prices

Gilead (EU)

- On 22 December 2014, the European Commission declined to open an investigation into allegations of excessive prices for Gilead's Hepatitis C drugs, despite pressure from members of the European Parliament
- Commissioner Vestager responded to the Parliamentary Question (P-008636/2014) as follows:

Pursuant to Article 168(7) TFEU, Member States are responsible for health and medical care, including the allocation of resources assigned to these areas. Each Member State may therefore take measures to regulate or influence the prices in these areas.

For this reason, price-setting by pharmaceutical manufacturers and healthcare systems in general takes place on a national level, allowing Member States to exercise their bargaining power. …

Moreover … the market for hepatitis C drugs is a rapidly moving therapeutic area, with several new classes of direct-acting antivirals now in advanced stages of development. This would seem to suggest that this is a dynamic market.

Gilead (EU)

- On 15 March 2015, Commissioner Vestager responded to a follow-up Parliamentary Question (000261/2015) as follows:

Since the Commission's earlier response, as it can be ascertained from public sources, the factual situation surrounding this particular medicine has evolved further. For example, another novel medicine such as AbbVie's Viekira Pak has entered the market to compete with Sovaldi in addition to, for example, Janssen's Olysio. Furthermore, several Member States have concluded or are negotiating pricing and reimbursing agreements with respect to this group of novel Hepatitis C medicines.

ACM Working Paper (Netherlands)

- In May 2018, the President of the Dutch Competition Authority (ACM) co-authored a paper *"Lower drug prices can improve innovation"*
  - Premise is that competition law – including excessive pricing analysis – should be applied to patented drugs
- **Excessive pricing should be controlled even for drugs still under patent**
  - Authorities have traditionally not pursued such investigations for fear of chilling innovation incentives
  - However, where the price is higher than value to society (i.e. unreasonable relationship to its economic value) due to weak demand-side bargaining pressure from doctors/payors
  - This creates economic inefficiencies that negatively impact innovation incentives
- **The United Brands 2-step test is applicable to patented products**
  - The probability of success should be integrated into Step 1 as a production cost
  - An evaluation of whether the price exceeds the product's value to society (quality of life adjusted year) could allow for a meaningful comparison with other products under Step 2

Practical Guidance

- **High risks arise from drastic price increases after drug is on market:**
  - Cases in the UK and Italy concern drastic price increases (250% or more)
  - Cases involved drugs that were already on the market – easier to bring case as a "fair" price (i.e. the price prior to the increase) has already been established – no need to compare with competing products
  - Cases concerned off-patent medications no longer owned by their originators (i.e. the originating company is presumed to have already recuperated its R&D costs)
- **Such risks would not appear to arise in the context of:**
  - Initial price setting or pricing and reimbursement negotiations with the health authority
  - Moderate price increases

“Plus” Factors May Increase Risk

- ***Pfizer/Flynn***:
  - Exploitation of a regulatory loophole (now closed) that restricted the National Health Service’s ability to regulate the pricing of certain generics, leaving pricing subject to competitive constraints of the market
- ***Napp***:
  - Predatory/exclusionary pricing strategy to leverage sales in hospital market (by pricing below cost) in order to charge higher prices in the pharmacy market
- ***Aspen***:
  - Very aggressive negotiating posture with Italian Medicines Agency, including threats to reduce market supply and de-list products
- ***CD Pharma***:
  - Likely ongoing negative impact on parallel importers as a result of the increased prices, even after these prices were reduced

Questions?

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