Institution: University of East Anglia

Unit of Assessment: 16 - Economics and Econometrics

Title of case study: Combating anticompetitive and exploitative practices of pharmaceutical firms in the UK

Period when the underpinning research was undertaken: 2012-2020

Details of staff conducting the underpinning research from the submitting unit:

Name(s):	Role(s) (e.g. job title):	Period(s) employed by submitting HEI:
Dr Farasat Bokhari	Associate Professor in Economics	2012 to present
Professor Bruce Lyons	Professor of Economics	1994 to present
Dr Arnold Polanski	Associate Professor in Economics	2011 to present

Period when the claimed impact occurred: 2012-2020

Is this case study continued from a case study submitted in 2014? No

1. Summary of the impact

The marketing and pricing practices of pharmaceutical firms have restricted choice and increased costs to the NHS. UEA research was the catalyst for a series of award-winning investigative articles by [redacted] in *The Times* in June 2016. Citing these articles, Dr Sarah Wollaston MP wrote to the Health Secretary, who directed the Competition and Markets Authority (CMA) to investigate. The CMA launched an excessive pricing case against two large firms, Concordia in October 2016 and Actavis in December 2016. The *Times* article influenced the debate in Parliament on the Health Service Medical Supplies (Costs) Act, which was passed in 2017 to give the Health Secretary powers to lower the price of generic drugs (those no longer protected by patent) in cases of excessive pricing.

2. Underpinning research

Pharmaceutical firms engage in strategies that have implications for competition, prices, access to medicines, consumer/patient welfare, profits, as well as opportunity for growth and innovation. Some of these strategies are beneficial to efficiency in the long term, while others are anti-competitive and lead to consumer harm. *The Times* estimated, in an article published 22 April 2017, that anti-competitive practices cost the NHS GBP370,000,000 in 2016 alone. UEA research has focused on understanding when and how firms adopt these various strategies, and identifying their impact, positive or negative, on society.

Product and marketing innovations, "me-too" drugs and product hopping.

UEA research has focused on strategies that originators adopt regarding their original products near the end of their market exclusivity or end of patent life. For instance, originator firms may launch additional second-generation drugs, called "me-too" or follow-on drugs, with alternative dosage, formulations, or variation in pack sizes within the same therapeutic class and/or molecule. This innovation can be positive for firm growth if it meets some unmet demand or allows price discrimination. (R1) The "me-too" drugs can also be launched by competitors since the scope of the patent does not protect other formulations. These are criticized as undermining R&D incentives. Nonetheless, an additional variant of the original drug can benefit some patients who found the earlier version to be less than ideal for their condition. (R2) However, there are trade-offs in terms of implications for consumer welfare; additional variants by the originators come on the back of aggressive marketing campaigns and exclusivity periods and convince clinicians to switch patients to their new supposedly superior version, a practice called "product hopping". Thus follow-on drugs and product hopping can also be used to deter entry by generic competitors even when it does not lead to significant benefits for patients. (R3)

Pay-for-delay, de-branding and related anti-competitive strategies

A related area of UEA research has focused on strategies that are also problematic for competition law and are sometimes challenged by competition authorities. For instance, to prevent entry after the end of market exclusivity, an originator with a patent can pay a generic firm not to enter, thus maintaining its monopoly - and therefore the ability to charge higher prices - beyond the original exclusivity period. This practice, known as a pay-for-delay (P4D) deal, is prevalent in the UK, US and Europe. UEA research has investigated the welfare effects (R2), implications for prices on other related drugs (R4) and the reason such deals come about, including routes open to politicians and policymakers to tackle the practice (R5). This research strand also covers other anticompetitive actions such as excessive pricing and de-branding, where firms take advantage of small underlying market size where competitive entry is difficult, in combination with price regulation and loopholes that can be exploited to charge high prices. (R6)

3. References to the research

R1. "Innovation and growth in the UK pharmaceuticals: the case of product and marketing introductions"
Bokhari, F., Mariuzzo, F. and Bennato, A.R
Small Business Economics, **2020**, 2-32. DOI: 10.1007/s11187-019-00307-w (Initial draft circulated as 2016 CCP working paper 16-1 as "**Growth and returns to new products and pack varieties: The case of UK pharmaceuticals**") Available at tinyurl.com/yctxdzkv and held on file at UEA.

R2. "Entry in the ADHD drugs market: Welfare impact of generics and me-toos"
Bokhari, F. and Fournier, G.
Journal of Industrial Economics, **2013**, 61(2), 339-392. DOI: 10.1111/joie.12017.

R3. Product hopping as entry deterrence: the case of UK pharmaceuticals
Bokhari, F. and Yan, W (2019).
CCP Working paper 20-04, **2019.** Available at tinyurl.com/yygxqj82 and held on file at UEA.

R4. "What is the price of pay-to-delay deals?"
Bokhari, F.
Journal of Competition Law and Economics, **2013,** 9(3), 739-753.
DOI: 10.1093/joclec/nht016.

R5. "Entry limiting agreements: first mover advantage, authorized generics and pay-to-delay generic deals"
Bokhari, F., Mariuzzo, F. and **Polanski, A**.
Journal of Economics and Management Strategy, **2020**, 29(3) 516-542. DOI: 10.1111/jems.12351
(Initial draft circulated as 2015 CCP Working paper 15-5 as "**Entry limiting agreements for pharmaceuticals: pay-to-delay and authorized generic deals**". Working paper. Available at tinyurl.com/yb2vkl44 and held on file at UEA.

R6. "Can drug price hikes via debranding be prevented?"
Bokhari, F. and **Lyons, B**.
Prescriber, **2017**, 28(4). Held on file at UEA.

4. Details of the impact

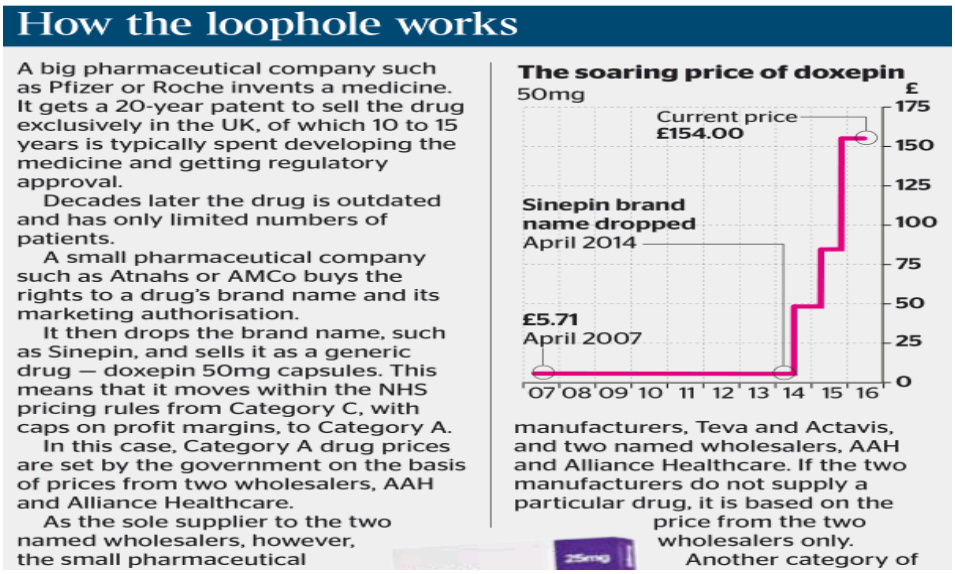
***The Times* investigation into excessive pricing in the pharmaceutical industry**

[redacted] of *The Times* approached Dr Bokhari in March 2016 regarding P4D deals, having become aware of Bokhari's research via his blog posts and media interviews. [redacted] wanted to understand better the background to the P4D strategies, and how they related to other anticompetitive and exploitative efforts to manipulate the market. In a series of email exchanges and telephone conversations throughout March 2016, Bokhari advised [redacted] on how pharmaceutical firms use P4D strategies and the implications of these strategies for pricing and

competition. Bokhari also broadened the conversation about the industry to point out other loopholes in UK law that were being exploited by pharmaceutical firms, including de-branding.

To bring out the practical effects of this exploitation of the gaps in UK legislation, Bokhari provided [redacted] with several examples using bespoke graphs and tables, as well as the sales and market shares of the relevant drugs. On 15-16 March 2016, Bokhari provided [redacted] the drug examples featured in *The Times* investigation, including the sales and shares for individual drugs for the molecule **Doxepin** (an antidepressant) and the shares for two specific drugs, **Sinepin** by Marlborough and **Sinequan** by Pfizer. (S1) Bokhari also provided his paper (R1) with background on pricing rules for branded vs generic drugs in the UK, pointing [redacted] to IMS as a source for additional data, and discussed the implications of the pricing rules for the ultimate cost of the drugs. (S1)

Figure 1. from The Times article 03rd June 2016



How the loophole works

A big pharmaceutical company such as Pfizer or Roche invents a medicine. It gets a 20-year patent to sell the drug exclusively in the UK, of which 10 to 15 years is typically spent developing the medicine and getting regulatory approval.

Decades later the drug is outdated and has only limited numbers of patients.

A small pharmaceutical company such as Atnahs or AMCo buys the rights to a drug's brand name and its marketing authorisation.

It then drops the brand name, such as Sinepin, and sells it as a generic drug — doxepin 50mg capsules. This means that it moves within the NHS pricing rules from Category C, with caps on profit margins, to Category A.

In this case, Category A drug prices are set by the government on the basis of prices from two wholesalers, AAH and Alliance Healthcare.

As the sole supplier to the two named wholesalers, however, the small pharmaceutical

The soaring price of doxepin

50mg

£

175

150

125

100

75

50

25

0

Current price £154.00

Sinepin brand name dropped April 2014

£5.71 April 2007

07 08 09 10 11 12 13 14 15 16

manufacturers, Teva and Actavis, and two named wholesalers, AAH and Alliance Healthcare. If the two manufacturers do not supply a particular drug, it is based on the price from the two wholesalers only.

Another category of

On 3 June 2016, *The Times* published the first of three investigative articles, *Brothers cost NHS millions by exploiting drug price loopholes*", drawing specifically upon Bokhari's examples (S3). In these articles, [redacted] highlights how drug prices are set for branded (category C) vs generics (Category A) and gives examples of **Sinepin (doxepin)** as a case of de-branding. *The Times* story gives **Doxepin** as an example and shows charts of price hikes of these drugs. This article and the follow-up stories in the next two days revealed how other drugs had recently registered large price hikes as a result of these de-branding strategies.

Following *The Times* investigation, [redacted] acknowledged the key contributions of Bokhari and his research to the development of the story:

> *Hi Farasat,*
> *Wanted to say thanks again for your help with the early stages of what became the price-hiking story. Was very useful to talk to you about pay-to-delay in the US and the UK and your research into the economics of that which you kindly shared. Of particular relevance were the two working papers -* ***'Entry limiting agreements for pharmaceuticals: pay-to-delay and authorized generic deals'*** *and* ***'Growth and returns to new products and pack varieties: The case of UK pharmaceuticals'*** *- and the blog post outlining the 'economics of pay to delay'.*
>
> *It was from the starting point of reading this research and considering its implications that I became interested in branded and generic drug prices and category changes in the NHS drug tariff which allowed companies to dramatically increase prices. You were very helpful in showing me EMC and other sites which made it possible to track changes in marketing authorisation ownership for various drugs and in pointing the way towards prescription data - which showed how much price rises were costing the NHS. It was with this understanding that I was then*

> *able to pull the relevant figures for the drugs I ultimately ended up focusing in on the articles of June 6, 2016.* (S2)

Subsequent impact of the investigation on UK policy debate and UK law

Parliament was particularly sensitive to *The Times* investigation into the loophole exploited by companies that profited by thousands of percent on drugs that had provided little innovation or had very small numbers of patients using them, simply by dropping their brand name. *The Times* investigation, encompassing three major articles between 3-6 June 2016, raised this issue's prominence in policy circles. For instance, in a letter from Dr. Sarah Wollaston MP, Chair Health Committee (13 June 2016) to Rt. Hon Jeremy Hunt MP, Secretary of State for Health:

> *"I write following the alarming story published on Friday 3 June by The Times regarding apparently extraordinary rises in drug prices (Brothers cost NHS millions by exploiting drug price loophole – 3 June 2016). As the story outlines, several medicines which have previously been marketed as a brand have been subsequently marketed as generic medication with a huge increase in price to the NHS."* --- Dr Sarah Wollaston (MP, Chair) (S4)

In his response, the then-Secretary of State wrote,

> *"Any concerns about possible anti-competitive behaviour by pharmaceutical companies should always be reported to the Competition and Markets Authority, and I have asked the Authority to look urgently at the evidence uncovered by The Times as part of its investigation into excessive drugs pricing."* --- Jeremy Hunt (Secretary of State for Health) (S5)

The CMA started several additional investigations regarding excessive pricing in late 2016 into companies who abused the system, including Concordia (now Advanz) in October 2016, and Activas in December 2016), both of which were named in *The Times* article. (The investigations are in progress as of this writing.)

The Times investigation also influenced the debate in the 2017 Health Service Medical Supply Act (Costs) Bill which was introduced to address concerns that some companies abuse their position as a monopoly. References to *The Times* investigation in the debate include: (S6)

1. "As highlighted by the investigation conducted by *The Times* earlier this year, there are companies that ..." Mr Hunt (S6, 1a, p.24).
2. "An investigation in *The Times* highlighted how a small number of companies …" Mr. Madders (S6, 1b, p.24)
3. "… That was highlighted by *The Times* investigation a few months ago, … In effect, the Bill will allow the Government to require companies to reduce the price of an unbranded generic drug, even if the company is in the voluntary scheme … the NHS unreasonably high prices for them, as highlighted by the investigation by The Times." Sir Simon Burns (S6, 1c, p.24)
4. "… I pay tribute to *the Times* for the investigation that it began on 3 June. We often have cause …" Mr Selous (S6, 1d, p.24)
5. "My first point is that it took quite a while for this to be exposed. It took the campaign from *the Times* to bring this to the forefront …" Lord Young (S6, 3a, p.25).

The Act's measures include allowing the government to increase the statutory price regulation scheme for *branded* medicines, which effectively brings it closer to the Pharmaceutical Price Regulation Scheme (PPRS). It also closed the loophole that previously barred the government from controlling the prices of *unbranded* generics if the firm already participated in the PPRS scheme. Powers were granted to allow the government to intervene, via competition market authorities, to control price increases in unbranded generics as well as implementing statutory powers to force manufacturers, distributors, and suppliers to pass over sales data and other information.

In recognition of his investigation, in 2017 [redacted] was named the Science and Health Journalist of the Year at the British Press Awards, and won the Medical Journalists' Association Award for Outstanding Contribution to Health or Medical Journalism, for his "world-class

investigation, with extensive biographies of the culprits, which led to a change in the law". He was also short-listed for the Orwell Foundation's 'Exposing Britain's Social Evils' Prize, and for *Private Eye*'s Paul Foot Award for investigative and campaigning journalism.

5. Sources to corroborate the impact

Documented Evidence

S1. Email exchanges between Bokhari and Investigative Reporter for The Times, March 2016.

S2. Email from Investigative Reporter for The Times, 7 October 2019 acknowledging Bokhari's help with the price hike story and raising his interest in branded to generic switches.

S3. Copy of The Times news articles, 3, 4, and 6 June 2016.

S4. Copy of the letter from Dr Sarah Wollaston MP, Chair to Secretary of State for Health, Jeremy Hunt, 13 June 2016.

S5. Copy of the response letter from Secretary of State for Health, Jeremy Hunt to Dr Sarah Wollaston MP.

S6. Text of debates in the House of Commons and the House of Lords.