Competition Commission SINGAPORE

Section 57 of the Competition Act (Cap. 50B)

Grounds of Decision issued by the Commission

Notification for Decision: Proposed Acquisition by GSK Trading Services Limited of the right to distribute and market selected pharmaceutical products from UCB SA.

23 March 2009

Case number: CCS 400/002/09

Confidential information in the original version of this Decision has been redacted from the published version on the public register. Redacted confidential information in the text of the published version of the Decision is denoted by [✂]

I. INTRODUCTION

1. On 13 February 2009, the Competition Commission of Singapore ("CCS") received a notification for decision pertaining to an anticipated transaction (the "Transaction"), by which GSK Trading Services Limited ("GSK") will acquire certain rights to distribute and market selected pharmaceutical products in certain emerging markets from UCB SA ("UCB"), by way of a Sale and Purchase Agreement.[1] GSK and UCB are collectively referred to as "the Parties".

2. The Parties have informed CCS in their submission that they have made filings or will be filing in various jurisdictions/authorities.[2]

II. THE PARTIES

3. GSK, which is incorporated in Ireland, is a wholly owned subsidiary of GSK plc. GSK plc and its subsidiary, and associated companies constitute a major

[1] GSK will not be acquiring any of UCB's manufacturing facilities. Instead, it will be entering into a supply agreement with UCB pursuant to which UCB will continue to supply the business acquired by GSK

[2] *I.e.* Columbia (Superintendence of Industry and Commerce), Jordan (Competition Directorate in the Ministry of Industry and Trade), Pakistan (Competition Commission of Pakistan), South Africa (Competition Commission), Taiwan (Fair Trade Commission) and Tunisia (Ministry of Commerce). The Parties also informed CCS on 9 March 2009 that the Transaction has been approved in Jordan and Taiwan on 3 March 2009 and 5 March 2009 respectively.

global healthcare group engaged in the creation, discovery, manufacture and marketing of pharmaceutical and consumer health-related products. GSK plc is a publicly limited company incorporated in the UK whose shares are listed on the London Stock Exchange and New York Stock Exchange. GSK plc operates in Singapore as a pharmaceutical company specialising in medicines which treat asthma, viral infections, mental health, diabetes and digestive conditions. Within Singapore, GSK plc works with and sells to both the private and public market. GSK plc also markets non-pharmaceutical consumer products such as Lucozade and Aquafresh.

4. UCB is a Belgian-based biopharmaceutical company that specialises in providing therapy for certain central nervous system disorders (including epilepsy, diabetic neuropathic pain, sclerosis and Parkinson's disease). It also provides therapy in the areas of oncology, immunology, inflammation, allergy and respiratory diseases. Together with its subsidiaries, UCB has research and development facilities in Belgium, Germany, Japan, the United Kingdom and the United States, and operations spanning more than forty countries. UCB is listed on the Euronext Brussels Stock Exchange.

III. THE MERGER

5. The Transaction involves the anticipated acquisition by GSK of certain rights to distribute and market selected pharmaceutical products in certain emerging markets from UCB by way of a Sale and Purchase Agreement entered into between GSK and UCB on 23 January 2009.

6. In Singapore, GSK will acquire the UCB subsidiary, UCB Singapore Pte Ltd, as well as certain rights to distribute and market the following products ("relevant UCB products"):

i) Keppra;
ii) Elantan;
iii) Isoket;
iv) Nitrocine;
v) Xyzal;
vi) Zyrtec;
vii) Cirrus;[3]
viii) Atarax; and
ix) Nootropil.

7. Based on the information furnished by and submissions of the Parties, the Transaction constitutes a merger pursuant to section 54(2)(b) and (c) of the Act.

[3] Also known as Zyrtec-D.

IV. COMPETITION ISSUES

8. The businesses of GSK and UCB overlap horizontally in the supply of certain categories of pharmaceutical products (described below). CCS therefore examined whether the Transaction potentially leads to substantially lessening of competition in the market(s) in which these categories of pharmaceutical products are supplied, whether by way of non-coordinated or coordinated effects.

9. There are no vertical concerns arising from the Transaction.

V. RELEVANT MARKETS

Product market definition

Parties' submission

10. In defining the product market, the Parties refer to the "Anatomical Therapeutic Chemical" classification ("ATC"), devised by the European Pharmaceutical Marketing Research Association ("EPhMRA") and maintained by EPhMRA and Intercontinental Medical Statistics. The ATC classification is hierarchical and has four levels. The ATC-1 level of categorisation is most general, and comprises 16 categories (A, B, C, D, etc.).[4] At the second level, each ATC-1 category is further subdivided into different ATC-2 categories. At the third level, each ATC-2 category is further subdivided into different ATC-3 categories. At the fourth and most detailed level, each ATC-3 category is divided into different ATC-4 categories. Of the four levels of classification, the ATC-3 classification allows medicines to be grouped according to their therapeutic indications, *i.e.* their intended use. The Parties thus submit that it is realistic to use the ATC-3 classification as an operational approach towards defining the relevant product markets for the purposes of the Transaction.[5]

11. The ATC-3 classifications of the relevant UCB products, as well as the corresponding products sold by GSK within Singapore, are described below:

[4] Some of the ATC-1 categories include "C" for the cardioardiovascular system, "N" for the nervous system and "R" for the respiratory system.
[5] Paragraphs 6.1.1 to 6.1.3 of Part 2B of Form M1 submitted on 13 February 2009.

ATC-3 Category	Description of ATC-3 Category[6]	Relevant UCB products in this category	GSK products in this category sold in Singapore
N3A (Anti-epileptics)	This class of drugs is used for the treatment of epilepsy. It is used in conjunction with other drugs or alone as single treatment depending on the type of epilepsy	Keppra	Lamictal
C1E (Nitrites & Nitrates)	These are prescription-only preparations of the short-acting vasodilator and anti-angina drug. They can be used to treat and prevent angina pectoris (ischaemic heart pain). They work by dilating the blood vessels returning blood to the heart and so reducing the heart's workload. They are administered by aerosol spray, intravenous injection or infusion.	i) Elantan ii) Isoket iii)Nitrocine	Anginine
R6A (Anti-histamines)	These are products used for the treatment of allergic reactions. Anti-histamines act to prevent or relieve typical symptoms of allergic reactions.	i) Xyzal ii) Zyrtec	i) Piriton ii) Semprex
R1B (Systemic Nasal Preparations)	This includes all preparations indicated primarily for rhinitis, allergic rhinitis, sinusitis, catarrh, nasal congestion and other similar conditions.	Cirrus	Actifed
N5C (Hypnotics and Sedatives)	These are used to relieve allergic symptoms, such as itching and rashes, and also for short-term treatment of anxiety.	Atarax	N.A.
N6D (Anti-Dementia)	These are preparations of the anti-epileptic drug piracetam. These can be used in treatment of involuntary spasmic contractions of muscles of the body.	Nootropil	N.A.

12. The Parties submit that there are three relevant markets, in their businesses where horizontal overlap occurs:

i) N3A (anti-epileptics);
ii) C1E (nitrites and nitrates); and
iii) R6A(anti-histamines).

As explained below, these product markets have been confined to products which are distributed and marketed in Singapore.

13. In relation to the ATC-3 category R1B (systemic nasal preparations), the Parties submit that this is not a relevant market, albeit that both UCB and GSK sell products within this category (*i.e.* Cirrus and Actifed respectively). Cirrus is a

[6] "The Avery Complete Guide to Medicines" Dr. Ian Morton and Dr Judith Hall (ed) Penguin Putnam Inc. New York 2001.

systemic nasal preparation that is used for treatment of blocked nose, sneezing, and runny nose associated with allergic rhinitis. Actifed is indicated for nasal and respiratory congestion, common cold, acute sinusitis, allergic rhinitis and vasomotor rhinitis. The Parties argue that although both products belong to the same ATC-3 category (R1B), they are not substitutable. Specifically, the parties point out that Actifed causes drowsiness and insomnia. On the other hand, Cirrus has fewer side effects compared to Actifed. The Parties submit that during the treatment of allergic rhinitis, physicians would usually elect to use Actifed for preliminary stages and to treat patients subsequently with Cirrus only when symptoms are not alleviated and have become more severe. As such, the Parties submit that there is no horizontal overlap insofar as both these products are concerned.

14. The Parties also point out that all the GSK and UCB products falling within the relevant markets are non-OTC,[7] being either prescription products or pharmacy-only[8] products. The Parties submit that based on data from IMS Health Inc. ("IMS") which the Parties have access to, there are no sales of OTC products in the relevant markets in Singapore.[9]

CCS' assessment

15. CCS agrees with the Parties that the ATC-3 classification, reflecting the pharmaceutical product's therapeutic use, is indeed a useful starting point when defining relevant product markets, albeit that it may in certain cases be necessary to deviate from the ATC-3 classification when defining relevant markets for competition analysis (e.g. further subdivision may, depending on the facts, be necessary). CCS also notes that the European Commission has in previous decisions also classified the relevant product market according to the ATC-3 category.[10] On the facts of the present case, the parties submit that the ATC-3 classifications N3A (anti-epileptics), C1E (nitrites & nitrates) and R6A (anti-histamines) each form a separate product market. CCS's investigations have not yielded any results that would justify a different conclusion.

16. As regards the R1B product category (systemic nasal preparations), there was third party feedback supporting the Parties' claim that Cirrus and Actifed are not substitutable, so that there is no horizontal overlap in the Parties' business in relation to these products. They cater to the needs of different patients. Actifed causes drowsiness and is short acting. Cirrus does not cause drowsiness and is

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[7] Over-The-Counter ("OTC") medications refer to non-prescription medications that are sold legally over the counter in a retail pharmacy store. OTC medicines can be bought in any quantity without restrictions at the retail store level.

[8] According to the parties, pharmacy-only medicines are medicines which do not require a prescription but can only be sold under the supervision of a pharmacist (*i.e.* can only be bought from pharmacies): see footnote 2 on page 9 of the Parties' response to CCS' request for additional information, dated 19 February 2009.

[9] Paragraph 6.4 of the parties' response to CCS' request for additional information, dated 19 February 2009.

[10] COMP M.3544 – *Bayer Healthcare/Roche*, COMP M.3354 – *Sanofi-Synthelabo/Aventis* and COMP M.3751 – *Novartis/Hexal*.

long acting. Nevertheless, as will be explained below, even if R1B does constitute a relevant product market, including both Cirrus and Actifed, no competition concerns arise. It is therefore not necessary to decide whether Cirrus and Actifed are from separate product markets.

17. In relation to N5C (hypnotics and sedatives) and N6D (anti-dementia) products, there were no overlapping products supplied by GSK in Singapore.

Geographic market definition

Parties' submission

18. The Parties submit that the relevant geographic market for this merger is Singapore, in view of the local regulatory restrictions, *i.e.* physicians and pharmacies are only able to supply products that are registered with the Health Sciences Authority of Singapore ("HSA").

CCS' assessment

19. CCS' investigations revealed that pharmaceutical products supplied in Singapore must be the subject of a Product Licence from the Health Sciences Authority (HSA). According to the Parties, the product registration process requires, on average, 12 to 15 months.[11] HSA also has a "special import permit" which allows distributors to bring in specialised products should a physician make a special request for it. Depending on factors such as the critical nature of the drug and the safety level of the drug, this "special import permit" can be processed between 3 days to 3 months. Thus, although specialised products can be imported, the usage is still subject to licence registration with HSA.

20. CCS thus agrees that the geographical scope of the relevant market is Singapore.

VI. MARKET STRUCTURE

Market share and market concentration

21. According to reports furnished by the parties, their Singapore market shares in Singapore for products falling within the four ATC-3 categories are as follows:

[11] Paragraph 3.2.29 of Part 2A of Form M1, submitted on 13 February 2009.

Table 1: Market shares in Singapore for 2005-2008

	Sales Value				Sales Volume			
	2005	2006	2007	2008	2005	2006	2007	2008
N3A Anti-epileptics								
GSK	[10-20]%	[10-20]%	[10-20]%	[10-20]%	[0-10]%	[10-20]%	[10-20]%	[10-20]%
UCB	[0-10]%	[0-10]%	[10-20]%	[10-20]%	[0-10]%	[0-10]%	[0-10]%	[0-10]%
GSK+UCB	[10-20]%	[20-30]%	[20-30]%	[20-30]%	[10-20]%	[10-20]%	[10-20]%	[10-20]%
Pfizer	[30-40]%	[20-30]%	[30-40]%	[30-40]%	[20-30]%	[10-20]%	[20-30]%	[20-30]%
Sanofi-Aventis	[20-30]%	[20-30]%	[20-30]%	[20-30]%	[40-50]%	[40-50]%	[40-50]%	[40-50]%
Johnson&Johnson	[0-10]%	[10-20]%	[10-20]%	[0-10]%	[0-10]%	[0-10]%	[0-10]%	[0-10]%
C1E Nitirites/Nitrates								
GSK	[20-30]%	[20-30]%	[20-30]%	[20-30]%	[20-30]%	[20-30]%	[20-30]%	[20-30]%
UCB	[20-30]%	[20-30]%	[10-20]%	[0-10]%	[10-20]%	[0-10]%	[0-10]%	[0-10]%
GSK+UCB	[40-50]%	[40-50]%	[40-50]%	[30-40]%	[30-40]%	[30-40]%	[30-40]%	[20-30]%
CCM Pharma	[0-10]%	[20-30]%	[20-30]%	[30-40]%	[0-10]%	[40-50]%	[50-60]%	[50-60]%
AstraZeneca	[30-40]%	[10-20]%	[10-20]%	[10-20]%	[50-60]%	[20-30]%	[10-20]%	[10-20]%
Hospira	[0-10]%	n.a.	[0-10]%	[0-10]%	[0-10]%	n.a.	[0-10]%	[0-10]%
R6A Anti-histamines								
UCB	[40-50]%	[40-50]%	[40-50]%	[40-50]%	[30-40]%	[30-40]%	[30-40]%	[30-40]%
GSK	[0-10]%	[0-10]%	[0-10]%	[0-10]%	[0-10]%	[0-10]%	[0-10]%	[0-10]%
GSK+UCB	[40-50]%	[50-60]%	[50-60]%	[40-50]%	[30-40]%	[40-50]%	[30-40]%	[30-40]%
Schering Plough	[20-30]%	[20-30]%	[20-30]%	[20-30]%	[10-20]%	[10-20]%	[10-20]%	[0-10]%
Sanofi-Aventis	[0-10]%	[0-10]%	[0-10]%	[0-10]%	[0-10]%	[0-10]%	[0-10]%	[0-10]%
Strides Arcolab	[0-10]%	[0-10]%	[0-10]%	[0-10]%	[10-20]%	[10-20]%	[10-20]%	[10-20]%
Xepa Holdings	[0-10]%	[0-10]%	[0-10]%	[0-10]%	[0-10]%	[0-10]%	[10-20]%	[20-30]%
R1B Systemic Nasal Preparations								
UCB	[10-20]%	[20-30]%	[10-20]%	[20-30]%	[0-10]%	[0-10]%	[0-10]%	[0-10]%
GSK	[10-20]%	[10-20]%	[10-20]%	[0-10]%	[50-60]%	[50-60]%	[30-40]%	[30-40]%
GSK+UCB	[30-40]%	[30-40]%	[20-30]%	[30-40]%	[50-60]%	[50-60]%	[40-50]%	[40-50]%
Schering Plough	[40-50]%	[30-40]%	[30-40]%	[30-40]%	[0-10]%	[0-10]%	[0-10]%	[10-20]%
Sanofi-Aventis	[0-10]%	[0-10]%	[0-10]%	[0-10]%	[0-10]%	[0-10]%	[0-10]%	[0-10]%
Wyeth	[0-10]%	[0-10]%	[0-10]%	[0-10]%	[20-30]%	[20-30]%	[30-40]%	[20-30]%
Pre-acquisition CR3								
N3A Anti-epileptics	[70-80]%	[60-70]%	[60-70]%	[70-80]%	[70-80]%	[70-80]%	[70-80]%	[70-80]%
C1E Nitrites/Nitrates	[60-70]%	[60-70]%	[60-70]%	[80-90]%	[80-90]%	[80-90]%	[80-90]%	[90-100]%
R6A Anti-histamines	[70-80]%	[70-80]%	[70-80]%	[70-80]%	[50-60]%	[50-60]%	[50-60]%	[40-50]%
R1B Systemic Nasal Preparations	[70-80]%	[70-80]%	[60-70]%	[60-70]%	[60-70]%	[60-70]%	[50-60]%	[50-60]%
Post-acquisition CR3								
N3A Anti-epileptics	[80-90]%	[70-80]%	[70-80]%	[80-90]%	[70-80]%	[70-80]%	[70-80]%	[80-90]%
C1E Nitrites/Nitrates	[80-90]%	[90-100]%	[80-90]%	[80-90]%	[90-100]%	[90-100]%	[90-100]%	[90-100]%
R6A Anti-histamines	[70-80]%	[80-90]%	[70-80]%	[70-80]%	[50-60]%	[50-60]%	[50-60]%	[40-50]%
R1B Systemic Nasal Preparations	[80-90]%	[80-90]%	[70-80]%	[70-80]%	[60-70]%	[60-70]%	[50-60]%	[60-70]%

Source: IMS Ethical + OTC MAT September 2008

22. As mentioned in CCS' Guidelines, CCS is generally of the view that competition concerns are unlikely to arise in a merger situation unless:

- the merged entity has a market share of 40% or more; or
- (where the merged entity has a market share of between 20% to 40%) the post-merger CR3[12] is 70% or more.

[12] The CR3 refers to the concentration ratio arrived at by combining the market shares of the three largest

23. The post-merger share of the Parties exceeds the indicative threshold in the CCS Guidelines (*i.e.* 40%), based on the estimated market shares of the Parties for 2008, in respect of two ATC-3 categories:

i) R6A (anti-histamines): for value only; and

ii) R1B (systemic nasal preparations): for volume only.

CCS also examined (see below) whether the Transaction might possibly raise concerns of non-coordinated effects in these product categories within Singapore.

24. CCS also notes that the post-merger CR3, in those instances where the post-merger market share of the parties is between 20% and 40%, exceeds the indicative thresholds in the CCS Guidelines (*i.e.* 70%), based on the estimated market shares of the Parties for 2008, in respect of all four ATC-3 categories, *i.e.*

i) N3A (anti-epileptics): for value only;

ii) C1E (nitrites & nitrates): for both value and volume;

iii) R6A (anti-histamines): for value only; and

iv) R1B (systemic nasal preparations): for value only.

CCS examined (see below) whether the Transaction might possibly raise concerns of coordinated effects in these product categories within Singapore.

Barriers to Entry and Expansion

25. The parties submit that the patent protection for the molecules of the GSK and UCB products in the relevant markets have expired, and that this lowers the barriers to entry. CCS agrees, as patent expiry paves the way for the entry of generics by competitors. CCS also notes that there are decisions of the European Commission that barriers to entry are low once the patent for the relevant product's molecule expires.[13]

26. In addition, CCS received feedback from third parties that regulatory approval in Singapore does not constitute a high barrier to entry. As mentioned above, the Parties submit that the product registration process requires, on average, 12 to 15 months. For generic drugs, the registration process is shorter. For example, the approval process for a generic drug with a proven therapeutic track record may take about 6 months. Competitors whom CCS spoke to mentioned that Singapore's regulatory approval process is more efficient than in most other countries and that the barriers to entry are comparatively lower for competitors wishing to introduce a new drug into Singapore.

Countervailing buyer power

27. CCS received feedback that manufacturers dictate the prices of their pharmaceuticals (particularly for patented products), and that distributors and retailers will generally pass on any price increases, rather than resist them. However, CCS also received feedback that medical establishments and patients do have some degree of buyer power to check price increases, e.g. by switching to

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firms in the relevant market.

[13] E.g. COMP/M.4402 - *UCB / Schwarz Pharma.*

substitutes. Some of the feedback which CCS received stated that physicians and/or medical establishments can help check price increase of all four product categories (*i.e.* N3A, C1E, R6A and R1B) products, while patients and pharmacists can check price increases of pharmacy-only medicines (e.g. anti-histamines).

VII. COMPETITION ASSESSMENT

Non-coordinated effects

28. As mentioned above, the Transaction results in post-merger markets shares that exceed the CCS indicative threshold of 40% in the R6A (anti-histamines) and R1B (systemic nasal preparations) product categories.

29. As regards R6A (anti-histamines), CCS' investigations revealed that the products of GSK and UCB from this category are not new drugs, and that there are numerous generics and substitutes from other manufacturers. Pricing in this category of products is very competitive, with the Parties facing pressure from generics. Not surprisingly, the parties' market shares in the R6A product category do not, when based on volume (rather than value), cross the indicative thresholds in the CCS Guidelines (generics generally being priced at a lower value).

30. As regards R1B (systemic nasal preparations), CCS' investigations revealed that even if Actifed (produced by GSK) and Cirrus (produced by UCB) are substitutable, such that there is a pre-merger horizontal overlap in the Parties' products for the R1B category, there are still competitors like Schering Plough and Sanofi-Aventis providing generics and substitutes in Singapore post-merger.

31. Finally, the relatively low barriers to entry and the presence of countervailing buyer power, discussed above, also indicate constraints on any exercise of post-merger market power.

Coordinated effects

32. As mentioned above, the Transaction results in CR3s which (when read with the post-merger market shares of the parties) exceed the CCS indicative thresholds for all four product categories (either in volume or value or both).

33. However, any risks of coordinated behaviour are largely mitigated by the relatively low barriers to entry and the presence of countervailing buyer power, discussed above. The Parties have also claimed that large buyers such as hospitals and the National Healthcare Group's Group Purchasing Office (which the parties submit is a large buyer of generic drugs) undertake annual tenders which result in aggressive bidding amongst pharmaceutical companies, thereby leading to lower prices. CCS' investigations indicated that hospitals, particularly the public sector hospitals, do pose some constraints on price increases by suppliers. This too would also contribute to destabilizing any possible coordinated behaviour.

Ancillary Restraints

34. Under the terms of the acquisition, the Parties have also agreed that UCB and its affiliates shall not, for a period of [✂], distribute, market or sell, or enter into any arrangements with third parties for the distribution, marketing or sale of [✂]. The Parties explain that these restrictions are necessary in order for GSK to receive the full benefit of the goodwill and/or know-how of the business to be acquired. CCS is of the view that these restrictions, particularly in light of their limited duration, are directly related and necessary to the implementation of the merger, and therefore fall within paragraph 10 of the Third Schedule to the Act.

VIII. CONCLUSION

35. Based on the information available to CCS, and for the reasons stated above, CCS has assessed that the Transaction, if carried into effect, will not infringe the section 54 prohibition.

36. In accordance with section 57(7) of the Competition Act, this decision shall be valid for a period of one year from the date of this decision.

Teo Eng Cheong
Chief Executive
Competition Commission of Singapore