



Public Competition Assessment

13 April 2011

Aspen Pharmacare Holdings Limited – proposed acquisition of Sigma Pharmaceuticals (Australia) Pty Ltd

Introduction

1. On 16 December 2010, the Australian Competition and Consumer Commission (ACCC) announced its decision not to oppose the proposed acquisition by a subsidiary of Aspen Pharmacare Holdings Limited (**Aspen**) of Sigma Pharmaceuticals (Australia) Pty Ltd and two other entities (together **Sigma's Pharmaceutical Division** or **SPD**) from Sigma Company Limited (**Sigma**) (the **proposed acquisition**), subject to a section 87B undertaking accepted by the ACCC. The ACCC was of the view that the proposed acquisition, when considered in light of the undertaking, would be unlikely to have the effect of substantially lessening competition in any relevant market and would therefore be unlikely to contravene section 50 of the then *Trade Practices Act 1974*, now the *Competition and Consumer Act 2010* (the **Act**).
2. The ACCC formed its view on the basis of the information provided by the merger parties and information arising from its market inquiries. This Public Competition Assessment outlines the basis on which the ACCC has reached its decision on the proposed acquisition, subject to confidentiality considerations.

Public Competition Assessment

3. To provide an enhanced level of transparency and procedural fairness in its decision making process, the ACCC issues a Public Competition Assessment for all transaction proposals where:
 - a merger is opposed;
 - a merger is subject to enforceable undertakings;
 - the merger parties seek such disclosure; or
 - a merger is not opposed but raises important issues that the ACCC considers should be made public.
4. This Public Competition Assessment has been issued because the acquisition is subject to a court enforceable undertaking.
5. By issuing Public Competition Assessments, the ACCC aims to provide the public with a better understanding of the ACCC's analysis of various markets and

the associated merger and competition issues. It also alerts the public to circumstances where developments in particular markets have led, or are likely to lead, to changes in the ACCC’s assessment of competition conditions in those markets.

6. Each Public Competition Assessment is specific to the particular transaction under review by the ACCC. While some transaction proposals may involve the same or related markets, it should not be assumed that the analysis and decision outlined in one Public Competition Assessment will be conclusive of the ACCC’s view in respect of other transaction proposals, as each matter will be considered on its own merits.
7. Public Competition Assessments outline the ACCC’s principal reasons for forming views on a proposed acquisition at the time the decision was made. As such Public Competition Assessments may not definitively identify and explain all issues that the ACCC considers arise from a proposed acquisition. Further, the ACCC’s decisions generally involve consideration of both non-confidential and confidential information provided by the merger parties and market participants. In order to maintain the confidentiality of particular information, Public Competition Assessments do not contain any confidential information or disclose its sources.

The parties

Aspen

8. Aspen is listed on the Johannesburg Stock Exchange and has operations globally, including in Australia, South Africa, India, Brazil, Hong Kong, Dubai and the United Kingdom.
9. GlaxoSmithKline plc (**GSK**) holds approximately 19% of the issued shares in Aspen.
10. Aspen licenses or acquires branded drugs developed by innovator companies¹ and markets and supplies these drugs, as well as a small number of generic versions of originator drugs. Aspen does not undertake research and development intended to discover new drugs.
11. Aspen does not have any manufacturing facilities or a wholesaling business in Australia.

SPD

12. Sigma Company Limited (**Sigma**) is listed on the Australian Securities Exchange. Sigma manufactures and distributes pharmaceutical products wholesale through pharmacy and grocery channels. It also provides services to retail pharmacists.

¹ An innovator company undertakes research to develop new drugs and brings them onto the market typically under patent protection. The first brand of a new drug introduced into the market is referred to as the ‘originator drug’.

13. SPD is responsible for the manufacture, marketing and supply of all of Sigma’s prescription, generic and private label consumer pharmaceutical products. Like Aspen, SPD does not undertake research and development intended to discover new drugs and accordingly is not considered an ‘innovator company’.
14. SPD is the largest pharmaceutical manufacturer in Australia, with five manufacturing sites (three in Victoria, one in New South Wales and one in Queensland).

Other market participants

15. The largest suppliers of pharmaceutical products in Australia include subsidiaries of AstraZeneca Plc, Pfizer Inc, GSK, Sanofi Aventis and Merck & Co Inc. These are all innovator companies as they develop and sell originator drugs.
16. The largest suppliers of generic pharmaceutical products in Australia include Alphapharm Pty Ltd, SPD, Apotex Pty Ltd and Sandoz Pty Ltd, a subsidiary of Novartis AG. Approximately, one third of the prescriptions dispensed under the Pharmaceutical Benefits Scheme (**PBS**) are for generic drugs.

The transaction

17. Aspen proposed to acquire SPD from Sigma. Sigma is retaining Sigma’s Healthcare Division, which comprises Sigma’s pharmacy wholesale and retail businesses (including Australia’s two largest retail pharmacy banners, *Amcal* and *Guardian*).
18. In response to competition concerns which were identified during the ACCC’s market inquiries process, Aspen and Sigma agreed to exclude the acquisition of Sigma’s iron polymaltose product, *Ferrosig*, from the proposed acquisition.

Industry background

Overview

19. Suppliers of pharmaceutical products include manufacturers (including both manufacturers of originator drugs and manufacturers of generic versions of originator drugs) and other parties who acquire the rights to sell a pharmaceutical product in Australia and arrange for the manufacture of the drug at approved Australian or offshore facilities.
20. Typically, suppliers of pharmaceutical products use pharmaceutical wholesalers to supply and distribute their products to hospitals and pharmacies. Suppliers of pharmaceutical products are however able to supply pharmacies and hospitals directly.
21. Manufacturers/suppliers of pharmaceutical products and pharmaceutical wholesalers market their product ranges to pharmacies. Manufacturers/suppliers also market their product range to medical practitioners who can perform a key role in determining the demand for a particular brand of drug.

22. For those drugs that are listed on the PBS, the PBS provides a pricing framework which governs the supply of drugs to pharmacists from both the manufacturer/supplier and the wholesaler.

Regulatory framework

The Therapeutic Goods Administration

23. Any prescription drug intended to be supplied in Australia must be approved and registered by the Therapeutic Goods Administration (**TGA**) in accordance with the *Therapeutic Goods Act 1989* (Cth) (**TG Act**). The TG Act provides a national framework for the regulation of therapeutic goods in Australia to ensure the quality, safety and efficacy of medicines and medical devices. Following TGA approval, drug suppliers generally apply for a drug to be listed on the PBS.

The PBS

24. The PBS was implemented in 1960 and entitles Australians who hold a Medicare card to receive drugs at a government-subsidised price where those drugs are prescribed by a medical practitioner and dispensed by a pharmacist. With the exception of dextropropoxyphen hydrochloride (**DPP**) and paracetamol combinations, the relevant drugs supplied by Aspen and SPD are listed on the PBS.
25. Each drug listed on the PBS has an agreed ‘price to pharmacist’. This price (commonly referred to as ‘the PBS list price’) is negotiated by the TGA sponsor of the drug (who is typically the owner or Australian supplier of the drug), and the government. Products that produce similar health benefits are subsidised at the same level and each available brand is subsidised to the level of the lowest priced brand in the reference group. A supplier or wholesaler of a PBS-listed drug cannot increase the price at which the drug is sold to a pharmacist beyond the PBS list price.
26. The PBS dispensed price includes the PBS list price (which includes the wholesaler’s mark-up) and the pharmacist’s retail mark-ups, including dispensing fees.
27. The government subsidises the price of a drug where the price at which it is sold to a patient would be above the co-payment level (currently \$33.30 for general patients and \$5.40 for concessional patients). The pharmacist is reimbursed by the government for the difference between the co-payment paid by the patient and the PBS dispensed price.
28. The PBS does not cover the supply of drugs to public hospitals where the drugs are acquired pursuant to a tender run by a state or territory health purchasing authority. Public hospitals may, however, obtain the necessary drugs from a pharmaceutical wholesaler or hospital pharmacy, in which case the PBS list price applies.

29. State and territory health purchasing authorities are typically able to acquire drugs through a competitive tender process at prices below the applicable PBS list prices.

Price disclosure regime

30. To further reduce pressure on the PBS, in 2007 the government introduced a price disclosure regime to move the price subsidised by the government for PBS-listed drugs closer to the actual price at which those drugs are supplied in the market to pharmacists. Under section 99ADC of the *National Health Act 1953* (Cth), manufacturers/ suppliers are required to report annually on the type and value of any benefits (monetary or otherwise) provided to a pharmacist. The government may then adjust the prices in the PBS schedule so that the price the government pays for PBS-listed drugs will move closer to the actual price at which those drugs are supplied to pharmacists (reflecting any discounts and other non-price benefits). The prices of all brands of the drug subject to price disclosure will be reduced to the calculated Weighted Average Disclosed Price (**WADP**), if the difference between the current PBS and the WADP is 10% or more.
31. As of 1 December 2010, all drugs in the F2 formulary of the Pharmaceutical Benefits Schedule (which includes all of the products relevant to the ACCC’s analysis of this matter, except DPP and paracetamol) are covered by the price disclosure requirements.

Dispensing drugs

32. A medical practitioner prescribes a drug by reference to the active ingredient (e.g. prednisone) or a brand (e.g. *Panafcort* in the case of prednisone).
33. Where a medical practitioner prescribes the active ingredient rather than a brand name of a drug, the pharmacist will be able to choose which brand is dispensed. Where a brand name has been prescribed, the pharmacist will be unable to substitute an alternative brand for the prescribed brand unless an alternative brand has been registered as bioequivalent, in which case the pharmacist is able to recommend substitution of the alternative brand.
34. A pharmacist will consider many factors when determining the brand of generic medicine to stock, including the corporate and brand awareness, product quality, certainty of supply, returns policy, trading terms, product packaging and labelling, possibility of patient confusion, substitutability, price benefit to the patient, availability of complementary programs, and services provided by the supplier which support the business or professional activities of the pharmacist.
35. Wholesalers and manufacturers/suppliers compete to have products stocked and dispensed by pharmacists by offering discounts and non-price benefits. The incentives for wholesalers and manufacturers/suppliers to compete in this way depend on the extent to which a pharmacist is able to influence patient demand for the brand supplied by the wholesaler or manufacturer/supplier.
36. A pharmacist may pass on the benefits of the discounts and non-price incentives they receive from suppliers to patients in the form of reduced prescription

charges. This is more likely to occur where the PBS dispensed price is below the applicable co-payment fee.

37. To the extent that discounts and non-price benefits provided by a wholesaler or manufacturer/supplier are covered by the price disclosure regime, they may lead to a reduction in the PBS list price of the drug in the future.

ACCC review timeline

38. The following table outlines the timeline of key events in this matter.

Date	Event
6 September 2010	ACCC commenced review under the Merger Review Process Guidelines July 2006.
27 September 2010	Closing date for submissions from interested parties.
8 October 2010	ACCC requested further information from the merger parties. ACCC timeline suspended.
20 October 2010	ACCC received further information from the merger parties. ACCC timeline recommenced.
27 October 2010	ACCC published a Statement of Issues outlining preliminary competition concerns.
11 November 2010	Closing date for submissions relating to Statement of Issues.
30 November 2010	Draft section 87B undertaking proffered by Aspen. ACCC commenced market inquiries on the draft undertaking.
7 December 2010	Closing date for submission relating to draft 87B undertaking.
16 December 2010	ACCC announced it would not oppose the proposed acquisition, given the court enforceable undertaking offered by Aspen Pharmacare Holdings Limited and Aspen Asia Pacific Pty Ltd and Aspen’s decision to excise SPD’s iron polymaltose product, <i>Ferrosig</i> , from the acquisition.
16 December 2010	Section 87B undertaking accepted by ACCC.

Market inquiries

39. The ACCC conducted extensive market inquiries in relation to the proposed acquisition with a range of interested parties, including pharmaceutical companies (including both innovator companies and suppliers of generic pharmaceuticals), pharmaceutical wholesalers, state and territory health purchasing authorities, pharmacists, industry associations and regulatory bodies.

Statement of Issues

40. On 27 October 2010, the ACCC published a Statement of Issues regarding the proposed acquisition. The Statement of Issues identified one issue arising from the proposed acquisition as an issue of concern and four other issues that may raise concerns requiring further investigation prior to the ACCC forming a concluded view. Three further issues were categorised as issues unlikely to raise concerns.

41. The ACCC’s preliminary view was that the proposed acquisition was likely to raise competition concerns in the supply of iron polymaltose in Australia.
42. The ACCC’s preliminary view was that the proposed acquisition may raise competition concerns in relation to:
 - the supply of prednisone/prednisolone in Australia;
 - the supply of phenoxymethylpenicillin (**penicillin V**) in Australia;
 - the supply of betamethasone valerate in Australia; and
 - the potential for coordinated effects in those markets where the merged firm’s products would overlap with products supplied by GSK (which held 19% of the issued shares in Aspen).
43. The ACCC’s preliminary view was that the proposed acquisition was unlikely to pose competition concerns with respect to:
 - the supply of ramipril in Australia;
 - the supply of clarithromycin in Australia;
 - the supply of non-narcotic analgesics in Australia; and
 - a range of broad therapeutic areas in which both parties supplied a number of products, identified at paragraph 46 of the Statement of Issues.
44. The Statement of Issues is available on the ACCC’s website at www.accc.gov.au/statementsofissues.

Areas of overlap and market definition

45. In Australia, the operations of Aspen and SPD overlap in the supply of a number of pharmaceutical products. SPD has manufacturing operations in Australia, while Aspen imports pharmaceutical products from overseas manufacturers.
46. The operations of Aspen and SPD directly overlap in the supply of the following drugs:
 - ramipril: Aspen licenses the right to supply *Tritace*, the originator brand, and SPD supplies *Prilace*;
 - clarithromycin: Aspen licenses the right to supply *Klacid*, the originator brand, and SPD owns *Claritho*;
 - penicillin V: Aspen licenses the right to market and supply *LPV* while SPD owns the branded version of penicillin V, *Cilicaine VK* (capsule form), as well as oral and tablet versions of the drug, supplied under the brand names *Cilicaine V*, *Abocillin V* and *Abocillin VK*;
 - betamethasone valerate: Aspen supplies *Celestone* and *Antroquoril* and SPD

owns *Benovate* and *Cortival*;

- iron polymaltose: Aspen licenses the right to supply *Ferrum H* and SPD owns *Ferrosig*;
 - prednisone/prednisolone: Aspen owns the *Panafcort* and *Predsone* brands of prednisone, and the *Panafcortelone* and *Predsolone* brands of prednisolone. (*Predsone* and *Predsolone* are low dosage versions.) SPD owns the *Sone* and *Solone* generic brands of prednisone and prednisolone respectively; and
 - DPP with paracetamol combinations: Aspen owns *Di-gesic* and *Paradex* and SPD owns *Capadex*.
47. The parties’ operations also overlap in the supply of drugs falling within a number of broad therapeutic areas. These were set out at paragraph 46 of the Statement of Issues.

Market definition

48. The ACCC considered the proposed acquisition in the context of the following national markets:
- the supply of iron polymaltose;
 - the supply of prednisone and prednisolone;
 - the supply of penicillin V;
 - the supply of betamethasone valerate;
 - the supply of ramipril;
 - the supply of clarithromycin; and
 - the supply of non-narcotic analgesics².
49. The ACCC considered the impact of the proposed acquisition in the context of separate national markets for the marketing and supply of each of the drugs listed above, including to pharmaceutical wholesalers, pharmacies and state and territory health purchasing authorities. Market inquiries indicated that suppliers of pharmaceutical products compete to market and supply products nationally.
50. With the exception of the market for the supply of non-narcotic analgesics (which includes DPP and paracetamol), the ACCC identified separate product markets according to the presence of the same active ingredient or molecule.
51. While the ACCC has defined broader markets in previous matters involving the supply of pharmaceutical products, market inquiries indicated that the drugs identified above each serve a particular therapeutic purpose and a medical

² However, the ACCC considered it unnecessary to form a concluded view on market definition in relation to these products.

practitioner is unlikely to prescribe an alternative drug that does not contain the same active ingredient. Market inquiries also indicated that where state and territory health purchasing authorities conduct tenders on behalf of the public hospitals in their state or territory, the tenders are conducted for specific drugs (containing a particular active ingredient) rather than tendering for drugs capable of meeting a broad therapeutic requirement. Accordingly, it was found that there was not close demand-side substitutability between drugs containing a different active ingredient.

52. On the supply side, the ACCC considered that a supplier of one particular drug could not switch easily and without significant investment to supplying another drug with a different active ingredient. It was noted that the innovator drug in each of the above product areas is ‘off patent’ and a number of suppliers in Australia may have the skills and ability to supply a new generic version. However, market inquiries indicated that it can take up to two years before a new version of each of these drugs can be supplied in Australia. This period takes into account the time it would take to meet the requirements for registration by the TGA applicable to generic versions of previously patented medicines. Accordingly, it was found that there was not close supply-side substitutability between products with different active ingredients.
53. With respect to the supply of DPP and paracetamol combinations, market inquiries indicated that there are substitutes for DPP and paracetamol combinations including both prescription and over-the-counter non-narcotic analgesics. DPP and paracetamol combinations are only available with a prescription and, even adopting a narrower market definition limited to the supply of prescription non-narcotic analgesics, there are a significant number of substitutable products supplied by rival firms. Accordingly, the ACCC considered it unnecessary to reach a concluded view on market definition regarding the supply of DPP and paracetamol combinations.

Competition analysis

Iron polymaltose

54. The ACCC considered that the proposed acquisition was likely to substantially lessen competition in the market for the supply of iron polymaltose.
55. The acquisition would remove SPD as Aspen’s only competitor in the relevant market and as set out below, the ACCC considered that the threat of new entry or expansion in the foreseeable future was unlikely to provide a competitive constraint on the merged firm.
56. Market inquiries revealed that a reduction in competition between SPD and Aspen in relation to this market was likely to have an impact on the supply of iron polymaltose to pharmacies and also the procurement of iron polymaltose by state and territory health purchasing authorities on behalf of public hospitals.
57. Unlike drugs ingested orally, when iron polymaltose (which is injectable) is prescribed, a pharmacist is able to dispense either brand of iron polymaltose,

regardless of whether it is prescribed by a brand name (e.g. *Ferrum H*) or the active ingredient (i.e. iron polymaltose). This means that a pharmacist has significant scope to influence the sales of each brand of iron polymaltose (i.e. *Ferrosig* or *Ferrum H*). Market inquiries indicated that the merger parties competed with each other to have their own brand of iron polymaltose stocked and dispensed by pharmacists by offering discounts and non-price incentives. The ACCC considered that the proposed acquisition was likely to result in the removal of such competition and a reduction in the level of discounts and non-price incentives offered to pharmacists.

58. It was further noted that a reduction in the level of discounts and non-price incentives received by pharmacists from Aspen and SPD for sales of iron polymaltose may have impeded prospective reductions in the PBS list price for iron polymaltose in the future. As set out in paragraphs 30 to 31, under the mandatory price disclosure requirements, manufacturers/suppliers and wholesalers are required to report to the government on the type and value of any benefits provided to a pharmacist. The government may then make price adjustments to the PBS schedule so that the PBS list price will move closer to the actual price at which those drugs are supplied to pharmacists (reflecting any discounts and other non-price benefits).
59. A reduction in the level of discounts and non-price benefits provided by the merged firm to pharmacists would also impact on the pharmacist’s margins, which may result in a reduced service offering and potentially higher prices across the pharmacist’s entire product range for patients.
60. A significant proportion of iron polymaltose is supplied to public hospitals through pharmaceutical tenders run by state and territory health purchasing authorities. Market inquiries indicated that state and territory health purchasing authorities were typically able to obtain a discount on the applicable PBS list price when purchasing drugs on behalf of public hospitals via a competitive tender. The ACCC considered that the removal of competition between the only two suppliers of iron polymaltose would be likely to reduce the ability of state and territory health purchasing authorities to obtain such a discount when acquiring iron polymaltose.
61. The ACCC considered that the sunk costs and lead time required to supply a new generic version of iron polymaltose are significant relative to the small volumes of iron polymaltose supplied in Australia. In particular, the ACCC formed the view that any potential new entry or expansion is unlikely to be sufficiently timely to constrain the merged firm given the relatively long lead time of approximately two years to launch a new drug. The ACCC was also unable to identify any likely entrants into the relevant market during market inquiries.
62. Accordingly, the ACCC considered that the threat of new entry or expansion in the foreseeable future was unlikely to provide a competitive constraint on the merged firm.
63. The ACCC concluded that, in the absence of appropriate remedies addressing its competition concerns in relation to iron polymaltose, the proposed acquisition

would be likely to result in a substantial lessening of competition in the market for the supply iron polymaltose in Australia. In response to the ACCC’s preliminary concerns outlined in the Statement of Issues, Aspen and SPD agreed that SPD’s iron polymaltose product, *Ferrosig*, would no longer be included in the proposed acquisition.

Prednisone/prednisolone and penicillin V

64. The ACCC considered that, in the absence of the section 87B undertaking provided by Aspen and one of its subsidiaries, the proposed acquisition was likely to substantially lessen competition in the markets for the supply of prednisone, prednisolone and penicillin V. As the proposed acquisition gave rise to similar issues in each of these markets, they have been dealt with jointly in this section of the Public Competition Assessment.
65. The ACCC considered that the proposed acquisition would remove SPD as Aspen’s only competitor in these markets and, as set out below, the ACCC considered that the threat of new entry or expansion in the foreseeable future was unlikely to provide a competitive constraint on the merged firm.
66. As only a minimal amount of each of prednisone, prednisolone and penicillin V is supplied to public hospitals, the ACCC has focussed on the impact of the proposed acquisition on the supply of prednisone, prednisolone and penicillin V via the pharmacy channel.
67. Aspen’s and SPD’s brands of prednisone, prednisolone and penicillin V are not bio-equivalent and accordingly, a pharmacist is unable to substitute one of Aspen’s brands for one of SPD’s brands where one brand has been prescribed rather than the other. However, market inquiries following the release of the Statement of Issues indicated that these drugs, in particular prednisone and prednisolone, are commonly prescribed by active ingredient rather than brand name. Where the drugs are prescribed by active ingredient, the pharmacist is able to dispense one brand rather than another.
68. Given a pharmacist’s ability to influence customer demand for one brand of prednisone over another brand of prednisone (and the similar ability to influence customer demand for one brand of prednisolone or penicillin V over another), the ACCC considered that in the absence of the proposed acquisition there is an incentive for Aspen and SPD to offer discounts and non-price benefits to pharmacists to stock and dispense its brand of these products and that the proposed acquisition would reduce or remove such an incentive.
69. As set out above, a reduction in, or the removal of, the discounts and non-price benefits for sales of prednisone, prednisolone and penicillin V may have an impact on prospective reductions in the PBS list price for these products given the mandatory price disclosure requirements set out in paragraphs 30 to 31.
70. The ACCC also considered that a reduction in the level of discounts and non-price benefits may have an additional impact on pharmacists and their customers. The current PBS dispensed prices for prednisone, prednisolone and penicillin V are below the general co-payment level and the ACCC considered that this makes

it more likely that a pharmacist will pass on the benefit of discounts and non-price incentives in the form of reduced prescription charges. The reduction in, or removal of, these discounts and non-price benefits provided to pharmacists as a result of the proposed acquisition and the removal of competition may therefore increase the prices paid by patients for the dispensed drugs.

71. The ACCC considers that the sunk costs and lead time required to supply new generic versions of prednisone, prednisolone and penicillin V are significant relative to the small volume of sales and demand for these drugs in Australia. In particular, the ACCC formed the view that any potential new entry or expansion is unlikely to be sufficiently timely to constrain the merged firm given the relatively long lead time, of approximately 18 months to two years, required to launch a new generic version. The sunk costs are higher for prednisone, prednisolone and penicillin V than iron polymaltose because these drugs are taken orally and therefore further studies must be conducted before these drugs can be sold. The ACCC was also unable to identify any likely entrants into the relevant markets during market inquiries.
72. Accordingly, the ACCC considered that the threat of new entry in the foreseeable future was unlikely to provide a competitive constraint on the merged firm in respect of the supply of prednisone, prednisolone and penicillin V.
73. The ACCC concluded that, in the absence of appropriate remedies addressing these competition concerns, the proposed acquisition would be likely to result in a substantial lessening of competition in the markets for the supply prednisone, prednisolone and penicillin V in Australia.

Betamethasone valerate

74. The ACCC considered that the proposed acquisition was unlikely to substantially lessen competition in the supply of betamethasone valerate for the reasons outlined below.
75. While the proposed acquisition would remove SPD as Aspen’s only competitor in the supply of betamethasone valerate, there were a number of factors which the ACCC considered distinguished this market from the markets for the supply of prednisone, prednisolone and penicillin V.
76. As with Aspen’s and SPD’s brands of prednisone, prednisolone and penicillin V, the merger parties’ brands of betamethasone valerate are not bio-equivalent³. However, unlike the position with prednisone, prednisolone and penicillin V, betamethasone valerate is nearly always prescribed according to a brand name rather than the active ingredient. This practice of prescribing betamethasone valerate according to a brand name rather than the active ingredient prevents a pharmacist substituting, or recommending the substitution of, one of Aspen’s brands with one of SPD’s brands and vice versa.

³ Aspen markets and distributes the *Celestone* and *Antroquoril* brands of betamethasone valerate (*Antroquoril* is the generic version of *Celestone*) and SPD supplies the *Betnovate* and *Cortival* brands (*Cortival* is the generic version of *Betnovate*).

77. Given that a pharmacist is unable to influence patient demand for different brands of betamethasone valerate, the ACCC considered it unlikely that the proposed acquisition would impact on Aspen’s incentives to offer discounts and/or non-price benefits to pharmacists in respect of these products post-acquisition and market inquiries indicated that betamethasone valerate is not commonly discounted.
78. Nearly all betamethasone valerate is dispensed via pharmacies and only a very small proportion is supplied to public hospitals. Accordingly, the ACCC considers that the removal of SPD as Aspen’s only competitor in the supply of betamethasone valerate is unlikely to have a significant effect on the procurement of drugs by state and territory health purchasing authorities on behalf of public hospitals.
79. The ACCC also notes that Aspen does not act as the TGA sponsor of either of the betamethasone valerate brands it distributes (*Celestone* and *Antroquoril* are distributed by Aspen under an agreement with the TGA sponsor of the brands). Aspen is also not related to the TGA sponsor of *Celestone* and *Antroquoril*. This means that Aspen is unable to seek an increase in the PBS list price of these brands. Rather, any request for an increase in the PBS list price of *Celestone* and *Antroquoril* would need to be sought by their TGA sponsor.
80. For these reasons, the ACCC considered that the proposed acquisition would not result in a substantial lessening of competition in the market for the supply of betamethasone valerate.

Potential for coordinated effects

81. The ACCC considered that the proposed acquisition was unlikely to increase the likelihood of coordinated conduct or muted competition between Aspen’s 19% shareholder, GSK, and the merged firm. In reaching this view, the ACCC considered it was unlikely that GSK would be able to exercise control or a degree of material influence over Aspen. The ACCC also took into account the following factors:
 - the asymmetric nature of GSK’s 19% shareholding. Neither Aspen nor Sigma have a corresponding interest in GSK;
 - the presence of other competitors in almost all areas of overlap between GSK and SPD; and
 - the different market positions of GSK and the merged firm. GSK is an innovator company with its main competitive activities involving the development and marketing of new drugs, while Aspen and SPD primarily market and supply generic drugs. This may make it difficult for GSK to take any retaliatory action should the merged firm deviate from any consensus, for example by introducing a generic version of a drug which competes with a GSK originator drug.
82. For these reasons, and in light of evidence that Aspen actively competes with GSK, the ACCC concluded that the proposed acquisition would be unlikely to

substantially lessen competition through coordinated effects in those markets where SPD and GSK compete.

Other issues

83. With respect to the following, which were identified in the Statement of Issues as markets where the ACCC considered that competition concerns were unlikely to arise, no information was provided during the course of the ACCC’s further inquiries that contradicted the ACCC’s preliminary views:
- the national market for the supply of ramipril;
 - the national market for the supply of clarithromycin;
 - overlap in the supply of DPP and paracetamol combinations; and
 - the additional areas of overlap set out Appendix A (as also identified at paragraph 46 in the Statement of Issues).
84. With respect to the supply of the above drugs, the ACCC considered that the existence of a number of significant competitors would provide an effective competitive constraint on the merged firm post-acquisition.

Undertaking

85. On 30 November 2010, Aspen offered a court enforceable undertaking to the ACCC to remedy identified competition concerns in the national markets for the supply of prednisone, prednisolone and penicillin V. On 16 December 2010, the ACCC accepted this undertaking pursuant to section 87B of the Act.
86. The undertaking provides for Aspen to divest the following products to an approved purchaser or purchasers:
- all products containing prednisone which are currently marketed and supplied by Sigma under the *Sone* brand name;
 - all products containing prednisolone which are currently marketed and supplied by Sigma under the *Solone* brand name; and
 - all products containing penicillin V which are currently marketed and supplied by Aspen under the *LPV* brand name.
87. The objective of the undertaking is to address the ACCC’s concerns by creating a viable, effective, stand –alone, independent and long term competitor for the supply of the divested products. A copy of the undertaking is available on the *Undertakings Register (s.87B)* at <http://www.accc.gov.au>.
88. The undertaking required Aspen to divest to an ACCC approved purchaser/s the necessary assets including trademarks and other intellectual property rights relating to the manufacture and supply of the products referred to in paragraph 86 above.

89. The undertaking also required Aspen to provide the ACCC approved purchaser/s with transitional services, technical assistance, and all licences, permits and other regulatory approvals that are required for the supply of the divested products.
90. The ACCC considered that the undertaking satisfactorily addressed the ACCC's competition concerns in the markets for the supply of prednisone, prednisolone and penicillin V in that the divestiture of the products listed in paragraph 85 would replace the competitive constraint provided by SPD on Aspen.

Conclusion

91. On the basis of the above matters and analysis, including taking into account the section 87B undertaking, the ACCC formed the view that the proposed acquisition of SPD by Aspen would not be likely to result in a substantial lessening of competition in any market in contravention of section 50 of the Act.

Appendix A

(refer to paragraph 82)

- anti-ulcerants;
- anti-histamines systemic;
- alkylating agents;
- anti-depressants and mood stabilisers;
- anti-tussives;
- artificial tears;
- diuretics;
- intestinal anti-inflammatories;
- broad spectrum penicillins.
- mineral supplements;
- motility inhibitors;
- chest rubs and inhalants;
- anti-gout preparations;
- anti-tubercular products;
- macrolides;
- antacids anti-flatulents;
- laxatives;