27 October 2010

Statement of Issues — Aspen Pharmacare Holdings Limited - proposed acquisition of Sigma Pharmaceuticals Limited's Pharmaceutical Division

1. Outlined below is the Statement of Issues released by the Australian Competition and Consumer Commission (**ACCC**) in relation to the proposed acquisition of Sigma Pharmaceuticals Limited (**Sigma**)'s Pharmaceutical Division by Aspen Pharmacare Holdings Limited (**Aspen**) (the **proposed acquisition**).

2. A Statement of Issues published by the ACCC is not a final decision about a proposed acquisition, but provides the ACCC's preliminary views, drawing attention to particular issues of varying degrees of competition concern, as well as identifying the lines of further inquiry that the ACCC wishes to undertake.

3. In line with the ACCC's *Merger Review Process Guidelines* (available on the ACCC's website at www.accc.gov.au) the ACCC has established a secondary timeline for further consideration of the issues. The ACCC anticipates completing further market inquiries by 11 November 2010 and anticipates making a final decision by 25 November 2010. However, the anticipated timeline can change in line with the *Merger Review Process Guidelines*. To keep abreast of possible changes in relation to timing and to find relevant documents, market participants should visit the Mergers Register on the ACCC's website at www.accc.gov.au/mergersregister.

4. A Statement of Issues provides an opportunity for all interested parties (including customers, competitors, shareholders and other stakeholders) to ascertain and consider the primary issues identified by the ACCC. It is also intended to provide the merger parties and other interested parties with the basis for making further submissions should they consider it necessary.

Background

5. On 6 September 2010 the ACCC commenced a public review of the proposed acquisition after receiving a submission from Aspen seeking informal clearance from the ACCC.

The parties

Aspen Pharmacare Holdings Limited

6. 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.

7. GlaxoSmithKline plc (**GSK**) holds approximately 19% of the issued shares in Aspen.

8. Aspen licenses or acquires branded drugs developed by innovator companies and markets and supplies these drugs, as well as a small number of generic versions of originator drugs, to wholesalers in Australia for supply to pharmacies and hospitals. Aspen does not undertake research and development intended to discover new drugs.

9. Aspen does not have any manufacturing facilities or a wholesaling business in Australia.

10. Key products supplied by Aspen in Australia include *Ceclor*, *Keflex*, *Redipred*, *Di-Gesic*, *Tazac*, *Panafcort*, *Panafcortelone*, *Tritace*, *Cardizen*, *Andrews Tums*, *Gastrostop*, *Bio Oil*, *Murine*, *Tixylix*, *Phisohex* and *Anagraine*.

Sigma Pharmaceuticals Limited's Pharmaceutical Division

11. Sigma's Pharmaceutical Division (**SPD**) includes Sigma's pharmaceutical products' manufacturing, marketing and supply business in respect of all prescription, generic and private label consumer products.

12. SPD manufactures markets and supplies generic versions of innovator drugs as well as branded drugs developed by innovator companies. Like Aspen, SPD does not undertake research and development intended to discover new drugs.

13. SPD is the largest pharmaceutical manufacturer in Australia, with five manufacturing sites (three in Victoria, one in New South Wales and one in Queensland). It has the largest Australian-owned over-the-counter (**OTC**) portfolio with major brands such as *Herron*, *Chemists' Own*, *Ural* and *Coloxyl*, and is also the largest Australian-owned supplier of prescription pharmaceuticals.

14. Sigma is listed on the Australian Securities Exchange (**ASX**).

The transaction

15. Aspen has sought informal clearance for the proposed acquisition of SPD.

16. Sigma's Healthcare Division, which Sigma intends to retain, comprises Sigma's pharmacy wholesale and retail businesses (including Australia's two largest retail pharmacy banners, *Amcal* and *Guardian*).

17. The parties advise that the proposed acquisition is conditional upon clearance being received from the ACCC.

Other market participants

18. The largest suppliers of pharmaceutical products in Australia include subsidiaries of AstraZeneca Plc, Pfizer Inc, GSK, Sanofi Aventis and Merck & Co Inc. These suppliers are all innovator companies (i.e. developers of originator medicines).

19. 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 of generic drugs.

Industry background

Regulatory framework

The TGA

20. 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.

21. The TGA carries out a range of assessment and monitoring activities to ensure therapeutic goods available in Australia are of an acceptable standard. Following TGA approval, drug suppliers generally apply for listing on the PBS.

The PBS

22. 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.

23. The Pharmaceutical Benefits Advisory Committee (**PBAC**) considers applications to list a drug on the PBS and recommends whether those drugs should be listed and consequently subsidised by the Australian government.

24. Once a drug has been approved for listing on the PBS, the price to be paid by a pharmacist for that drug is negotiated between the government and the manufacturer or supplier of the drug through the Pharmaceutical Benefits Pricing Authority (**PBPA**). Products that, in the judgement of the PBPA, 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. The PBS dispensed price includes the manufacturer's price and wholesale and retail mark-ups (to the wholesaler and pharmacist), including dispensing fees.

25. When a PBS-listed drug is dispensed, the patient pays a co-payment to the pharmacist (currently a maximum of $33.30 for general patients and a maximum of $5.40 for concessional patients) and any delivery fee, after-hours fee, brand or therapeutic premiums, or special patient contribution that may be applicable.

Pharmacists are in turn reimbursed by the government for any difference between the patient co-payment and the reimbursement price of the drug set by the PBPA.

26. Where a manufacturer or supplier applies to list the first new generic brand of a drug already listed on the PBS, a price reduction of at least 12.5% from the negotiated price of the drug listed on the PBS must be offered by the supplier.[1] This reduction in the PBS list price flows on to all drugs in the same reference pricing group.

27. To further reduce pressure on the PBS, the government has 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. Section 99ADC of the *National Health Act 1953* (Cth) requires manufacturers/ suppliers to report annually to the Department of Health and Ageing on the type and value of any benefits (monetary or otherwise) provided in relation to the supply of a brand of a PBS listed drug which is subject to the mandatory price disclosure requirements. The ACCC notes that this information is provided to the government on a commercial-in-confidence basis. The government may then make price adjustments in the PBS schedule where the weighted average ex-manufacturer price (excluding the wholesaler mark-up) is less than the current PBS ex-manufacturer price by at least 10 per cent.

Dispensing medicines

28. A medical practitioner prescribes a drug by reference to the active ingredient (e.g. prednisone) or by reference to a brand (e.g. Panafcort in the case of prednisone).

29. Where a medical practitioner has prescribed a branded drug (e.g. Panafcort) and the medical practitioner has not indicated on the prescription that it cannot be substituted, a pharmacist is obliged under the Community Pharmacy Agreement[2] to discuss with the patient substitution of a generic brand for the prescribed branded medicine. Pharmacists provide advice about brand substitution in accordance with the Pharmaceutical Society of Australia's Guidelines on Pharmaceutical Benefits Scheme Brand Substitution.

30. A pharmacist is only, however, able to substitute one brand for another if the drugs have been registered for bio-equivalency or the doctor has written the name of the active ingredient on the prescription (e.g. prednisone rather than Panafcort).

[1] This requirement was introduced in 2007 and flows from the formulary classification of medicines. Formulary One (**F1**) contains only single brand drugs and Formulary Two (**F2**) contains only multiple brand drugs. Once a drug is on F2, it will remain in this category even if other brands are delisted. The F2 category has been split into two categories: F2A which comprises drugs where there are multiple brands but there were not high levels of discounting as at 1 October 2006 and F2T which comprises drugs where there were high levels of discounting as at 1 October 2006. Drugs within both F2 categories have also been subject to further reductions in the PBS list price. The distinctions within the F2 category will be removed on 1 January 2011.

[2] The Fifth Community Pharmacy Agreement between the Commonwealth Government and the Pharmacy Guild of Australia.

31. The ACCC understands that an individual pharmacist will typically stock the originator brand and one generic brand (if available) of most prescription drugs.

32. A pharmacist will consider many factors when determining the brand of generic medicine that is stocked, including corporate and brand awareness, the product quality, certainty of supply, the returns policy, trading terms, the product packaging and labelling, the possibility of patient confusion, substitutability, the price benefit to the patient, the availability of complementary programs, and the services provided by the supplier which support the business or professional activities of the pharmacist.

33. Wholesalers and manufacturers/suppliers compete to have products stocked by a pharmacist by offering price and non-price benefits. However, the incentives on 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 supplier's products. Where products are not registered as bioequivalent, the pharmacist is unable to recommend to a patient the substitution of an alternative brand and is therefore unable to influence patient demand unless the doctor prescribes the active ingredient.

34. A pharmacist may pass on the benefits of the discounts and non-price incentives received from suppliers to customers in the form of reduced prescription charges, for those drugs which cost less than the maximum co-payment amount (currently $33.40 or $5.40 for concessional patients).

35. Further, to the extent that discounts and non-price benefits are covered by the price disclosure regime, they may lead to a reduction in the PBS list price of the drug.

Areas of overlap

36. Aspen and SPD both supply pharmaceutical products that are prescribed and sold in community pharmacies and used in hospitals throughout Australia.

37. 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;
- phenoxymethylpenicillin (**penicillin V**): Aspen owns LPV and SPD owns Cilicaine VK;
- betamethasone valerate: Aspen supplies Celestone and Antroquoril and SPD owns Benovate and Corival;
- iron polymaltose: Aspen licenses the right to supply Ferrum H and SPD

owns Ferrosig;

- prednisone/prednisolone: Aspen owns Panafcort (containing prednisone) and Panafcortelone (containing prednisolone), both of which are the originator brands. SPD owns versions of these drugs which are marketed as Sone and Solone; and

- dextropropoxyphen hydrochloride (**DPP**) with paracetamol combinations: Aspen owns Di-gesic and Paradex and SPD owns Capadex.

38. The parties' operations also overlap in the supply of drugs falling within a number of broad therapeutic areas. These have been set out at **paragraph 46**.

With and without test

39. In assessing a merger pursuant to section 50 of the *Trade Practices Act 1974* (Cth) the ACCC must consider the effects of the transaction by comparing the likely competitive environment post-acquisition if the transaction proceeds (i.e. the "with" position) to the likely competitive environment if the transaction does not proceed (i.e. the "without" or "counterfactual" position) to determine whether the proposed acquisition is likely to substantially lessen competition in any market.

40. The ACCC's preliminary view is that the most likely counterfactual would involve Sigma retaining SPD, although the ACCC recognises that Sigma may be required to sell various assets, potentially within the SPD business and/or raise funds to reduce its debt levels.

Market definition

41. The ACCC's preliminary view is that the following markets are relevant to the proposed acquisition:

- the supply of iron polymaltose in Australia;

- the supply of prednisone and prednisolone in Australia;

- the supply of penicillin V in Australia;

- the supply of ramipril in Australia;

- the supply of clarithromycin in Australia;

- the supply of betamethasone valerate in Australia; and

- the supply of non-narcotic analgesics in Australia.

42. The ACCC proposes to take a purposive approach to market definition, recognising that market definition is a tool to identify and define the boundaries of competitive overlap between the merger parties. Accordingly, the ACCC

proposes to consider the proposed acquisition in the context of separate national markets for the marketing and supply of each of the drugs listed above, including to wholesalers, pharmacies and state and territory health purchasing authorities (where each of the merger parties compete). Market inquiries indicated that suppliers of pharmaceutical products compete to market and supply products nationally.

43. With the exception of the market for the supply of non-narcotic analgesics, the ACCC has identified product markets according to the presence of the same active ingredient or molecule. While the ACCC has defined broader markets in previous matters involving the supply of pharmaceutical products, market inquiries indicate that the drugs identified above each serve a particular therapeutic purpose and a doctor is unlikely to prescribe an alternative drug. In particular:

- *iron polymaltose* is an iron supplement indicated for iron deficiency, and is delivered via intramuscular and/or intravenous use. Iron polymaltose will be prescribed when oral iron supplements have failed or oral absorption is compromised (e.g. by illness);

- *prednisone and prednisolone* are both corticosteroids and are used to treat asthma, inflammatory skin diseases and numerous other conditions. Prednisone and prednisolone are approximately four times as potent as hydrocortisone and in terms of duration of action are an intermediate between hydrocortisone and another corticosteroid, dexamethasone;

- *penicillin V* is an orally active form of penicillin, an antibiotic used to treat mild to moderately severe infections. Penicillin V is used to treat streptococcal infections, pneumococcal infections and fusospirochetosis (Vincent gingivitis and pharyngitis). If a patient has one of the identified infections, a doctor is likely to prescribe penicillin V;

- *ramipril* is used to lower high blood pressure (i.e. hyper-tension) or congestive heart failure. Market inquiries suggest that other products indicative for hypertension (e.g. Irbesartan) are not as potent;

- *clarithromycin* is a macrolide antibiotic indicated for the treatment of certain bacterial infections, including respiratory tract infections, skin infections and peptic ulcers; and

- *betamethasone valerate* is a topical corticosteroid used to treat skin lesions, and is available in both ointments and creams of various strengths.

44. Market inquiries also indicate that state and territory health purchasing authorities conduct tenders for specific drugs (containing the same active ingredient or molecule) rather than tendering for drugs capable of meeting a broad therapeutic requirement.

45. On the supply side, the innovator drug in each of the above product areas is 'off patent' and a number of suppliers in Australia may have the skill and ability to supply a new generic version. However, market inquiries indicate that it would

take two to three years before a new version of each of these drugs could be supplied in Australia. This period takes into account the time it would take to meet the requirements for all prescription drugs (including generic versions of previously patented medicines) to be registered by the TGA. Accordingly, the ACCC is of the preliminary view that there is likely to be limited supply side substitution in relation to each of the above product areas.

46. The ACCC notes that if broader markets were adopted, there would be further areas of overlap between the merger parties' operations. In particular, if markets were adopted according to the relevant therapeutic groups, Aspen and SPD would overlap in the supply of drugs falling within the following therapeutic areas:

- anti-ulcerants;
- anti-histamines systemic;
- alkyating 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;

47. With respect to the supply of DPP and paracetamol combinations, market inquiries indicate that there are substitutes for DPP and paracetamol combinations including both prescription and OTC non-narcotic analgesics. DPP and paracetamol combinations are only available on prescription and even adopting a narrower market definition, which is limited to the supply of prescription non-narcotic analgesics, there are a significant number of substitutable products supplied by rival firms. Accordingly, the ACCC considers it unnecessary to reach a conclusive view on market definition regarding the supply of DPP and paracetamol combinations.

The ACCC invites industry participants to comment on market definition.

The ACCC welcomes any comments from market participants regarding the ACCC's preliminary views on market definition. In particular, the ACCC seeks views on whether the drugs identified in paragraph 43 above constitute distinct markets or whether they fall within broader markets incorporating different drugs.

Statement of issues

48. For the purpose of this Statement of Issues, the issues in this matter are divided into three categories, 'issues of concern', 'issues that may raise concerns' and 'issues unlikely to pose concerns'.

Issues of concern

Market for the supply of iron polymaltose

49. Post acquisition, Aspen would be the sole supplier of iron polymaltose in Australia. Aspen currently licenses the right to market and supply Ferrum H in Australia from Vifor International Inc. SPD owns Ferrosig which is indicated for intramuscular and intravenous use in doctors' surgeries and hospitals, while Ferrum H is only indicated for intramuscular use in doctors' surgeries (although market inquiries indicated that Ferrum H is still used in hospitals).

Likely limited constraint from the PBS

50. Both of Aspen's and SPD's iron polymaltose products are listed under the PBS. This means that the 'price to pharmacist' has been agreed by the supplier and the Minister of Health (which acts on the recommendation of the PBPA).

51. Suppliers of PBS listed drugs do, however, have the annual opportunity to submit a price change request to the PBPA. A range of factors are relevant to the PBPA's assessment including any increase in the costs of producing the relevant drugs and the price at which the drugs are sold in reasonably comparable overseas countries.

52. It also remains open for suppliers to offer discounts and non-price benefits to pharmacists to incentivise them to stock the supplier's brand of the drug. These discounts and non-price benefits effectively reduce the price paid by pharmacists to below the PBS list price.

53. Unlike pharmaceuticals taken orally, it is not necessary for injectable drugs such as Ferrum H and Ferrosig to be registered for bio-equivalency before the products can be substituted for each other. Accordingly, even if a particular brand (e.g. Ferrum H) is prescribed, it is open for pharmacists to recommend the substitution of Ferrosig (this being the only other brand available). This appears to provide an incentive for a supplier to offer discounts and non-price benefits to a pharmacist to influence demand for its brand.

54. Pharmaceutical purchases made by state and territory health purchasing authorities on behalf of public hospitals are not covered by the PBS. While market inquiries indicate that the price paid by the state and territory health purchasing authorities is currently closely aligned to the PBS list price for these products, the ACCC has a preliminary concern that the merged firm would be able to directly, or via wholesalers, increase the price at which iron polymaltose is purchased by state and territory health purchasing authorities. The ACCC notes that a significant proportion of iron polymaltose supplied in Australia is

purchased by state and territory health purchasing authorities for use in public hospitals.

Barriers to entry and expansion

55. Market inquiries have indicated that it would take approximately two years for a new entrant or an existing supplier of drugs in Australia to launch a competing iron polymaltose product in Australia, and that it would involve sunk costs of approximately $250,000 to $500,000. This cost estimate takes into account the cost of purchasing the dossier describing how to make the drug, testing the drug, registering it with the TGA and conducting a bio-equivalency study. The ACCC notes that the sunk costs incurred by a new entrant and an existing supplier are unlikely to differ significantly given that market entry can be affected by engaging contract manufacturers located in Australia and overseas. Market inquiries indicate that access to off-shore manufacturers capable of producing the relevant drugs is not a barrier to entry.

56. The ACCC considers that potential new entry or expansion is unlikely to be sufficiently timely to constrain the merged firm given the relatively long lead time to launch a new version of iron polymaltose.

57. The ACCC is seeking further information on whether the threat of new entry or expansion in the foreseeable future would provide a competitive constraint on the merged firm.

Preliminary conclusion

58. The ACCC's preliminary view is that the proposed acquisition is likely to result in a substantial lessening of competition in the market for the supply of iron polymaltose.

59. In particular, the ACCC has concerns that the merged firm would have the ability and an incentive to:

- obtain an increase in the PBS price of Ferrosig and Ferrum H;
- change the current level of discounts and/or non-price benefits offered to pharmacists for sales of Ferrosig and Ferrum H; and/or
- extract significantly higher prices from state and territory health purchasing authorities for Ferrosig and Ferrum H.

The ACCC invites industry participants to comment and provide information in relation to:

- the extent to which the merged firm would be able to obtain an increase in the PBS-list price for Ferrosig and/or Ferrum H;
- the extent to which the proposed acquisition would enable the merged firm to change the level of discounts and/or non-price benefits offered to pharmacists;
- the extent to which the merged firm would be able extract higher prices from state

and territory health purchasing authorities for Ferrosig and Ferrum H; and

- the likely timeframe required to launch a competing iron polymaltose product in Australia and whether the threat of new entry and expansion within that timeframe would be sufficiently timely to constrain the merged firm.

Issues that may raise concerns

Market for the supply of prednisone and prednisolone

60. Prednisolone is the active metabolite of prednisone and could be considered to be in a separate market from the supply of prednisone. However, the ACCC considers that it is not necessary to reach a view on the market definition given that the competition assessment will be unchanged regardless of whether the drugs are considered to be in separate or combined markets.

61. Aspen owns the Panafcort brand of prednisone as well as a low dosage generic version of prednisone (Predsone). SPD markets and supplies the Sone generic brand. In the case of prednisolone, Aspen owns Panafcortelone and SPD markets and supplies Solone. There are currently no other suppliers of prednisone or prednisolone in Australia.

Likely limited constraint from the PBS

62. As in the case of the supply of iron polymaltose, PBS listing prevents the supplier from increasing the current price that a pharmacist (and wholesaler) must pay to purchase prednisone and prednisolone. However, a manufacturer/ supplier may apply to the Department of Health and Aging for a price review or price premium for a PBS listed drug.

63. PBS listing also does not prevent a supplier from reducing the effective price at which pharmacists and, potentially patients, pay for the drugs.

64. Market inquiries indicate that suppliers are more likely to be incentivised to offer price and non-price benefits where a pharmacist is able to influence the patient demand for the supplier's brand. This appears likely to be the case when a supplier's brand has been registered as bioequivalent with the competing brand as this will enable a pharmacist to recommend the substitution of one brand for another. If there is no bio-equivalency, a pharmacist can only influence the brand dispensed if a doctor prescribes the active ingredient, in this case prednisone or prednisolone rather than the brand name (e.g. Panafcort or Panafcortelone).

65. Neither Aspen's and SPD's prednisone brands nor Aspen's and SPD's prednisolone brands have been registered for bio-equivalency and market inquiries suggest that prednisone and prednisolone products are currently not heavily discounted. However, the ACCC notes that a pharmacist will have some ability to influence patient demand for prednisone and prednisolone brands if a doctor prescribes the active ingredient rather than a brand name.

66. As discussed previously, the PBS does not apply to pharmaceutical purchases made by state and territory health purchasing authorities on behalf of public hospitals. However, a very small proportion of the sales of prednisone and prednisolone (less than 10%) are currently supplied outside of the PBS.

Barriers to entry and expansion

67. As prednisone and prednisolone are off patent drugs, a new entrant or any existing pharmaceutical company is able to launch a generic version. However, market inquiries indicate that it would take approximately two to three years and may require sunk costs of up to $700,000 to launch generic versions on the Australian market. This takes into account the time taken to source the active ingredient, conduct the necessary clinical trials in order to obtain registration of the medicine with the TGA and conduct a bio-equivalency study.

68. Accordingly, the ACCC considers that potential new entry or expansion into the supply of prednisone and prednisolone may not be sufficiently timely to constrain the merged firm given the relatively long lead time to launch new versions of prednisone and prednisolone. Market inquiries also indicate that the sunk costs associated with launching a competing version of prednisone and prednisolone are high relative to the margin received for the supply of these drugs. .

69. The ACCC is seeking further information on whether the threat of new entry or expansion in the foreseeable future would provide a competitive constraint on the merged firm.

Preliminary conclusion

70. The ACCC's preliminary view is that the proposed acquisition may raise competition concerns in relation to the supply of prednisone and prednisolone.

71. In particular, the ACCC has concerns that the merged firm may have the ability and an incentive to:

- obtain an increase in the PBS price of prednisone and prednisolone;
- change the current level of discounts and/or non-price benefits offered to pharmacists for sales of its prednisone and prednisolone products; and/or
- extract significantly higher prices from state and territory health purchasing authorities for its prednisone and prednisolone products.

The ACCC invites industry participants to comment on and provide information in relation to:

- the extent to which the merged firm would be able to obtain an increase in the PBS-list price for the prednisone and prednisolone products supplied;
- the extent to which the absence of bioequivalence limits the degree of substitution between the different versions of prednisone and prednisolone;
- the extent to which there are incentives for suppliers of prednisone and prednisolone to offer discounts and non-price benefits to pharmacies given the

absence of bio-equivalency;

- the extent to which the merged firm would be able to extract higher prices from state and territory health purchasing authorities for prednisone and prednisolone; and
- the likely timeframe required to launch competing prednisone and prednisolone products in Australia and whether the threat of new entry and expansion within that timeframe would be sufficient to constrain the merged firm.

Market for the supply of penicillin V

72. Aspen owns the right to market and supply LPV, which contains penicillin V, and SPD markets Cilicaine VK, the branded version of penicillin V, through a subsidiary. No other brands of penicillin V are currently supplied in Australia.

73. The ACCC's preliminary views regarding the operation of the PBS as a constraint on the merged firm reflect similar issues set out in paragraphs 62 to 66 with respect to the supply of prednisone and prednisolone. Aspen and SPD's penicillin V products are not bioequivalent and therefore a pharmacist has limited ability to substitute the brands.

Barriers to entry and expansion

74. Market inquiries have indicated that it would take approximately two years to launch a competing (generic) version of penicillin V, and would require sunk costs of $250,000 to $500,000. This cost estimate takes into account the cost of purchasing the dossier describing how to make the drug, testing the drug, registering it with the TGA and conducting a bio-equivalency study.

75. Market inquiries also indicate that penicillin V is not a strong selling drug and that it has declining levels of growth. Market inquiries also indicate that the sunk costs associated with launching a competing version of penicillin V are high relative to the margins associated with the supply of penicillin V.

76. Accordingly, the ACCC considers that potential new entry or expansion into the supply of penicillin V may be unlikely in the foreseeable future.

Preliminary conclusion

77. The ACCC's preliminary view is that the proposed acquisition may result in a substantial lessening of competition in the market for the supply of penicillin V in Australia.

78. The ACCC's preliminary view as to the effect of the proposed acquisition in this market reflect similar issues to those outlined at paragraphs 70 and 71 with respect to the market for the supply of prednisone and prednisolone in Australia.

The ACCC invites industry participants to comment on and provide information in relation to:

- the extent to which the merged firm would be able to obtain an increase in the PBS-list price for Cilicaine VK and/or LPV;
- the extent to which the absence of bioequivalence limits the degree of substitution between Cilicaine VK and LPV;
- the extent to which there are incentives on suppliers of penicillin V to offer discounts and non-price benefits to pharmacies given the absence of bio-equivalency; and
- the extent to which the merged firm would be able to extract higher prices from state and territory health purchasing authorities for penicillin V.

Market for the supply of betamethasone valerate

79. The proposed acquisition involves the aggregation of two branded and two generic versions of betamethasone valerate. Aspen has the rights to supply the Celestone (branded) and Antroquoril (generic) products, and SPD supplies the Betnovate (branded) and Cortival (generic) products.

80. Each of Aspen's betamethasone valerate products are bioequivalent and each of SPD's betamethasone valerate products are bioequivalent. However, the Aspen's and SPD's products are not bio-equivalent to each other.

81. The strength and formulation of betamethasone valerate products (creams and ointments) vary and may not be interchangeable in treating the same type and severity of condition. Aspen and SPD directly overlap with respect to one type of product, namely betamethasone valerate 0.02% cream.

82. The ACCC's preliminary views regarding the operation of the PBS as a constraint on the merged entity reflect similar issues to those set out in paragraphs 62 to 66 with respect to the supply of prednisone and prednisolone. Aspen's and SPD's betamethasone valerate products are not bioequivalent and therefore a pharmacist has limited ability to recommend brand substitution to a patient. However, the ACCC notes that Aspen is not the TGA sponsor for either the Celestone or Antroquoril products (rather Schering-Plough Pty Limited has retained sponsorship). This means that it is Schering-Plough Pty Limited, and not Aspen, that could seek any increase in the PBS price for these products.

83. The ACCC is seeking information from market participants on the barriers to entering the market for the supply of betamethasone valerate and whether the threat of new entry or expansion in the foreseeable future would provide a competitive constraint on the merged firm.

Preliminary conclusion

84. The ACCC's preliminary view is that the proposed acquisition may result in a substantial lessening of competition in the market for the supply of betamethasone valerate in Australia.

85. The ACCC's preliminary view as to the effect of the proposed acquisition on this market reflect similar issues to those outlined at paragraphs 70 and 71 with respect to the markets for the supply of prednisone and prednisolone in Australia.

The ACCC invites industry participants to comment and provide information in relation to:

- the extent to which the absence of bioequivalence limits the degree of substitution between the different versions of betamethasone valerate;
- the extent to which there are incentives for suppliers of betamethasone valerate to offer discounts and non-price benefits to pharmacies given the absence of bio-equivalency; and
- the likely timeframe required to launch a competing product in Australia and whether the threat of new entry and expansion within that timeframe would be sufficient to constrain the merged firm.

Coordinated effects on those markets where the merged firm's products would overlap with products supplied by GSK

86. Market inquiries indicate that there is currently minimal overlap between the operations of Aspen and GSK (currently a 19% shareholder in Aspen) but following the proposed acquisition of SPD, the merged firm's and GSK's operations would overlap in a number of different product areas, as identified in the **Appendix**.

87. Given GSK's 19% shareholding in Aspen, the ACCC is concerned has some concerns that coordinated effects may be facilitated by the flow of information from Aspen to GSK and that competition between the merged firm and GSK may be 'muted' in those markets where there is an overlap between products supplied by the merged firm and products supplied by GSK.

88. There appear to be a number of characteristics of pharmaceutical markets which may be conducive to coordinated conduct post-acquisition between the merged firm and GSK, including:

    - it may be easier to reach agreement on homogenous pharmaceutical products (particularly with respect to drugs which are off-patent and where bioequivalent generic versions exist);

- high barriers to entry may mean that the threat of retaliation through new entry is less likely; and

- coordination is easier to sustain in highly concentrated markets, particularly those where Aspen and GSK may be the only suppliers.

89. However, the ACCC notes that the lack of pricing transparency with respect to the supply of pharmaceutical products may act as a disincentive for suppliers to agree on prices given that it would be difficult to detect any deviations from any such implicit consensus on price.

90. The ACCC is therefore exploring further whether the proposed acquisition may increase the likelihood of coordinated effects in those markets where there is an overlap between products supplied by GSK and the merged firm.

The ACCC invites industry participants to comment on and provide information in relation to:

- the nature and extent of any impediment to an implicit consensus being reached or muted competition arising between the merged firm and GSK, including the lack of pricing transparency;

- the extent to which rival suppliers would provide a competitive constraint on the merged firm and GSK. In particular, please provide details on the identity of these suppliers and the suppliers' market positions; and

- the extent to which the proposed acquisition increases the likelihood of coordinated effects in the product areas identified in the Appendix and in the supply of drugs more widely in Australia.

Issues unlikely to pose concerns

91. The ACCC considers that the proposed acquisition is unlikely to pose competition concerns in respect of the following issues. However, the ACCC will accept submissions from industry participants on these issues and will further consider potential competition issues if it considers that such an assessment is warranted.

Market for the supply of ramipril

92. The proposed acquisition involves the aggregation of the two largest selling brands of ramipril supplied in Australia (i.e. Tritace, the innovator brand supplied by Aspen and Prilace, the highest selling generic version manufactured and supplied by SPD). While there would be eight suppliers of ramipril post acquisition, the brands supplied by the merged firm as a result of the proposed acquisition would represent over 50% of the market for the supply of ramipril.

93. The ACCC considers that the proposed acquisition is unlikely to substantially lessen competition for the supply of ramipril due to the existence of several

significant competitors that would be likely to provide an effective competitive constraint on the merged firm. The ACCC notes that post-acquisition, 17 brands of ramipril would be supplied in Australia by eight independent suppliers. Further, each brand of ramipril is bioequivalent which means a pharmacist is able to substitute any generic version of ramipril for the branded version (except where a doctor specifies that there is to be no substitution).

Market for the supply of clarithromycin

94. The ACCC considers that the proposed acquisition is unlikely to substantially lessen competition for the supply of clarithromycin due to the existence of several significant competitors that would likely provide an effective competitive constraint on the merged firm. Post-acquisition, there would be five independent suppliers of alternative brands of clarithromycin, each of which is bioequivalent and would therefore be substitutable for the merged firm's products.

Overlap in the supply of DPP and paracetamol

95. DPP and paracetamol combinations are prescription only non-narcotic analgesics which were removed from the PBS in 1988. Aspen supplies Di-gesic and Paradex, and SPD supplies Capadex. Post-acquisition, the merged firm would be the only supplier of DPP and paracetamol combinations.

96. The ACCC considers that the proposed acquisition is unlikely to substantially lessen competition for the supply of DPP and paracetamol combinations due to the existence of a large number of substitutable products that would be likely to provide an effective competitive constraint on the merged firm.

97. Market inquiries indicate there are a range of substitutes for DPP and paracetamol combinations including both prescription and OTC non-narcotic analgesics. The ACCC also notes the findings of the European Medicine's Agency Committee for Medicinal Products for Human Use and New Zealand's Medicine Adverse Reaction's Committee which found that DPP and paracetamol combinations are no more effective than other painkillers, including paracetamol alone. The ACCC is not aware of any research contradicting or supporting these findings in Australia.

98. Sales of DPP and paracetamol combinations have declined significantly over the last ten years (by approximately 33%) and this arguably suggests that customers have been substituting away from DPP and paracetamol combinations to other non-narcotic analgesics.

99. For the purposes of the competition analysis, the ACCC did not consider it necessary to form a definitive view regarding the market definition for the supply of DPP and paracetamol combinations and in particular whether DPP and paracetamol combinations fall within a broader market for the supply of non-narcotic analgesics or within a narrower market for the supply of prescription non-narcotic analgesics. On either market definition, there would be a large number of alternate products supplied and marketed by more than 20 rival suppliers.

Additional overlaps

100. The ACCC's preliminary view is that for each of the additional areas of overlap identified at paragraph 46, the proposed acquisition would be unlikely to substantially lessen competition in the relevant markets for the following reasons:

    - there would be a number of competing suppliers to the merged firm in the broad therapeutic area identified; and/or

    - the competing products supplied by Aspen and SPD do not contain the same active ingredient which means a pharmacist is unable to substitute one of Aspen's products for one of SPD's products (or vice-versa).

ACCC's future steps

101. The ACCC will finalise its view on this matter after it considers market responses invited by this Statement of Issues.

102. The ACCC now seeks submissions from market participants on each of the issues identified in this Statement of Issues and on any other issue that may be relevant to the ACCC's assessment of this matter.

103. Submissions are to be received by the ACCC no later than 11 November 2010. The ACCC will consider the submissions received from the market and the merger parties in light of the issues identified above and will, in conjunction with information and submissions already provided by the parties, come to a final view in light of the issues raised above.

104. The ACCC intends to publicly announce its final view by 25 November 2010. However the anticipated timeline may change in line with the *Merger Review Process Guidelines*. A Public Competition Assessment for the purpose of explaining the ACCC's final view may be published following the ACCC's public announcement.

Appendix

Overlap in products supplied in Australia by SPD and GSK (by molecule or active ingredient)

1. Aciclovir
2. Allopurinol
3. Amoxycillin
4. Digoxin
5. Ethinyloestradiol
6. Lamotrigine
7. Mesalazine
8. Morphine sulfate
9. Methadone
10. Nicotine (stop smoking aids)
11. Ondansetron
12. Paroxetine
13. Ranitidine
14. Ropinirole
15. Sumatriptan
16. Salbutamol
17. Thyroxine
18. Valaciclovir
19. Valeriana officinalis
20. Paracetamol and paracetamol combinations (including with codeine)
21. Ibuprofen and ibuprofen combinations (including with codeine)
22. Aspirin and aspirin combinations (including with codeine)

23. Vitamin C