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Determination

Pfizer, Inc and Hospira, Inc [2015] NZCC 19

The Commission:	Dr Mark Berry Anna Rawlings Dr Jill Walker
Summary of application:	An application from Pfizer, Inc seeking clearance to acquire all outstanding shares in Hospira, Inc.
Determination:	Under s 66(3)(a) of the Commerce Act 1986, the Commerce Commission determines to give clearance to the proposed acquisition.
Date of determination:	16 July 2015

Confidential material in this report has been removed. Its location in the document is denoted by [ ].

Contents

The proposed acquisition

1. Pfizer, Inc (Pfizer) is proposing to acquire all outstanding shares of Hospira, Inc (Hospira). The acquisition is a global merger. On 28 April 2015, the Commerce Commission received an application from Pfizer seeking clearance for the New Zealand aspects of the acquisition.[1]

The decision – clearance given

2. The Commission gives clearance to the proposed merger, as it is satisfied that the acquisition will not have, or would not be likely to have, the effect of substantially lessening competition in a market in New Zealand.

Our framework

3. Our approach to analysing the competition effects of the proposed acquisition is based on the principles set out in our Mergers and Acquisitions Guidelines.[2]

The substantial lessening of competition test

4. As required by the Commerce Act 1986, we assess mergers using the substantial lessening of competition test.

5. We determine whether a merger is likely to substantially lessen competition in a market by comparing the likely state of competition if the merger proceeds (the scenario with the merger, often referred to as the factual), with the likely state of competition if the merger does not proceed (the scenario without the merger, often referred to as the counterfactual).[3]

6. We make a pragmatic and commercial assessment of what is likely to occur in the future with and without the acquisition based on the information we obtain through our investigation and taking into account factors including market growth and technological changes.

7. A lessening of competition is generally the same as an increase in market power. Market power is the ability to raise price above the price that would exist in a competitive market (the 'competitive price'),[4] or reduce non-price factors such as quality or service below competitive levels.

8. Determining the scope of the relevant market or markets can be an important tool in determining whether a substantial lessening of competition is likely.

9. We define markets in the way that we consider best isolates the key competition issues that arise from the merger. In many cases this may not require us to precisely

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1 Merger filings have been or will be made in Australia, Canada, EU, USA, [ ].

2 Commerce Commission, *Mergers and Acquisitions Guidelines*, July 2013. Available on our website at www.comcom.govt.nz

3 *Commerce Commission v Woolworths Limited* (2008) 12 TCLR 194 (CA) at [63].

4 Or below competitive levels in a merger between buyers.

define the boundaries of a market. A relevant market is ultimately determined, in the words of the Act, as a matter of fact and commercial common sense.[5]

When a lessening of competition is substantial

10. Only a lessening of competition that is substantial is prohibited. A lessening of competition will be substantial if it is real, of substance, or more than nominal.[6] Some courts have used the word 'material' to describe a lessening of competition that is substantial.[7]

11. There is no bright line that separates a lessening of competition that is substantial from one that is not. What is substantial is a matter of judgement and depends on the facts of each case. Ultimately, we assess whether competition will be substantially lessened by asking whether consumers in the relevant market(s) are likely to be adversely affected in a material way.

When a substantial lessening of competition is likely

12. A substantial lessening of competition is 'likely' if there is a real and substantial risk, or a real chance, that it will occur. This requires that a substantial lessening of competition is more than a possibility, but does not mean that the effect needs to be more likely than not to occur.[8]

The clearance test

13. We must clear a merger if we are satisfied that the merger would not be likely to substantially lessen competition in any market.[9] If we are not satisfied – including if we are left in doubt – we must decline to clear the merger.[10]

Key Parties

Pfizer

14. Pfizer is a global research-based biomedical and pharmaceutical company active in discovering, developing, manufacturing, marketing and selling medicines for humans. Pfizer's products are sold in over 150 countries, including New Zealand. Pfizer has no manufacturing operations in New Zealand.

15. Pfizer has a particular focus on the research and development of new pharmaceuticals, across a broad range of hospital and consumer medications.

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5 Section 3(1A). See also *Brambles v Commerce Commission* (2003) 10 TCLR 868 at [81].

6 *Woolworths & Ors v Commerce Commission* (2008) 8 NZBLC 102,128 (HC) at [127].

7 Ibid at [129].

8 Ibid at [111].

9 Commerce Act 1986, section 66(1).

10 In *Commerce Commission v Woolworths Limited* (CA), above n 2 at [98], the Court held that "the existence of a 'doubt' corresponds to a failure to exclude a real chance of a substantial lessening of competition". However, the Court also indicated at [97] that we should make factual assessments using the balance of probabilities.

Hospira

16. Hospira is primarily a global provider of injectable pharmaceutical drugs and infusion technologies that it develops, manufactures and distributes worldwide. Hospira's products are sold in more than 70 countries, including New Zealand. Hospira has no manufacturing operations in New Zealand.

17. Hospira has a particular focus on injectable pharmaceuticals, which are generally administered in a hospital setting. Unlike Pfizer's focus on innovator pharmaceuticals,[11] Hospira specialises to a greater extent in generic and biosimilar products.[12]

Other relevant parties

18. In addition to Pfizer and Hospira, there are a number of other relevant suppliers of hospital medicines in New Zealand, including:

    18.1 Actavis New Zealand Limited (Actavis);

    18.2 Novartis New Zealand Limited (Novartis);

    18.3 Mylan New Zealand Limited (Mylan); and

    18.4 Rex Medical Limited (Rex Medical).

19. Another relevant pharmaceutical entity, for the purposes of this clearance application, is Celltrion Inc (Celltrion). Celltrion is based in South Korea, with no presence in New Zealand. Celltrion entered into an agreement with Hospira in 2009 that allows Hospira to market and distribute eight biosimilar medicines under development by Celltrion, including in New Zealand.[13]

Industry background

Pharmaceutical products – hospital medicines

20. This merger concerns prescription pharmaceuticals given to patients in hospital (hospital medicines) or prescribed to hospital patients for self-administration at home (community medicines). For ease of analysis, we have considered hospital and community medicines together in this decision, including presentations and galenic forms which are used in both settings. In this document, when we refer to 'hospital medicines' we mean both hospital and community medicines.

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11 Pfizer defined innovator medicines as medicines "that meet the criteria for intellectual property protection (that is, they are new, inventive, and useful), will be protected for a fixed term by patent law. During this fixed term period, no other competing company is permitted to commercialise a drug that infringes on the intellectual property-holder's patent." See Clearance Application from Pfizer (24 April 2015) at [7.7].

12 Generic and biosimilar products are respectively defined at paragraphs 24 and 30 below.

13 Hospira, Press Release, *Hospira, Celltrion, Enter Business Cooperation Agreement to Develop and Market Biogeneric Drugs*, 8 October 2009 http://phx.corporate-ir.net/phoenix.zhtml?c=175550&p=irol-newsArticle&ID=1340168&highlight=biosimilars. The relevance of Celltrion to the proposed acquisition is further discussed at paragraphs 127 to 130 below.

21. Hospital medicines can be further classified according to their form. In this case, the two relevant forms of hospital medicines are small molecule medicines and biologic (or large molecule) medicines.

Small molecule medicines

22. Small molecule medicines are comprised of chemicals formulated to a standard chemical recipe. The active ingredient in a small molecule medicine has a chemical structure that is simple and small. The majority of all medicines available are small molecule medicines.

23. When an innovator small molecule medicine is launched, it enjoys a period of patent exclusivity. During this period, the exclusivity allows the innovator company to charge higher prices for the product.

Generic small molecule medicines (generics)

24. Generic medicines can only enter the market after the expiration of the patent for the innovator small molecule medicine. Generics are manufactured to the same international quality standards and Good Manufacturing Practice requirements as those required for innovators.[14]

25. Since clinical trial data on the safety and efficacy of the active ingredient is already available from the innovator, additional clinical trials and studies are not generally required for generics to be approved by regulators.[15] Instead, simpler and cheaper bioequivalence studies, performed to internationally agreed standards, are accepted by regulatory authorities worldwide, including in New Zealand.

26. Typically, there are a number of manufacturers developing generic medicines in anticipation of the expiry of the patent on the innovator medicine. Due to this competition, generic medicines are typically cheaper than the original innovator medicine.

Biologic medicines (biologics)

27. Biologic medicines are produced from living organisms, such as a yeast, bacteria or animal cells, rather than through a chemical process. Biologic medicines have more complex structures, are less stable than small molecule medicines and are more sensitive to environmental changes.

28. Most biologic medicines are produced through genetic engineering. The manufacturing process is much more complex and expensive than that required for the production of small molecule medicines. Given the high costs involved with developing and manufacturing biologic medicines, biologics are often very expensive for purchasers while they are on-patent.

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[14] New Zealand Medicines and Medical Devices Safety Authority "Prescriber Update, Vol. 34 No.1" (2013), at 8. http://www.medsafe.govt.nz/profs/PUArticles/Mar2013GenericMedBioqueivalence.htm.

[15] Ibid.

29. In 2012, Medicines Australia stated that "[o]ver 250 innovative human-use biologics have been approved since 1990 and more than 900 are currently under development globally."[16]

Biosimilar biologic medicines (biosimilars)

30. Biologic medicines are also genericised by manufacturers when they are about to come off-patent. Genericised biologic medicines are known as biosimilars. Biosimilars are versions of the original patented biologic medicine, and must be proven to have an equivalent therapeutic mechanisms and clinical attributes. Proving this equivalence requires satisfying regulators that there are no clinically meaningful differences in terms of safety, purity, and potency from the reference biologic.

31. Unlike generic small molecule medicines, the inherent variability involved in living cells means that a biosimilar is only a "highly similar, comparable version of an approved biologic medicine,"[17] rather than an exact copy of a chemical recipe.

Hospital medicines – varying dosages and routes of administration

32. Hospital medicines (both small molecule and biologics) are manufactured in various dosages (eg 10mg/ml, 100mg/ml), with various routes of administration (eg tablets, injections) that are used for different conditions. A particular combination of dosage and route of administration is referred to as the 'galenic form' of a medicine.

33. Ensuring that the correct galenic form of the correct medication is used to treat a condition is a paramount consideration for medical practitioners. The medical side effects of using the wrong medicine or galenic form can be severe.

34. This is particularly true for Pfizer and Hospira's products, as their hospital medicines are used to treat serious illnesses, including cancer, inflammation, infection, blood clots and epilepsy, as well as chronic pain relief.

Regulatory framework in New Zealand

New Zealand Medicines and Medical Devices Safety Authority (Medsafe)

35. Before any medicines can be supplied in New Zealand, they must be approved by the New Zealand Medicines and Medical Devices Safety Authority (Medsafe). Medsafe's role is to ensure that the medicines and medical devices supplied in New Zealand have acceptable efficacy, quality and safety.[18]

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16 Medicines Australia "Biologics: A new frontier in treating disease" (2012), https://medicinesaustralia.com.au/media-release/biologics-a-new-frontier-in-treating-disease/.

17 Medicines Australia, above n17, at [1].

18 New Zealand Medicines and Medical Devices Safety Authority "Safety Information - Medsafe's Evaluation and Approval Process" (2012), http://www.medsafe.govt.nz/consumers/Safety-of-Medicines/Medsafe-Evaluation-Process.asp.

36. When bringing a new hospital medicine to market in New Zealand, a New Medicine Application (NMA) must be made to Medsafe, under either a full or abbreviated process.[19]

37. The full process includes a standard application, in which the applicant prepares the required dossier (which demonstrates the safety, efficacy and quality of the product, and which may comprise thousands of pages) from raw base data.

38. An abbreviated process allows the applicant to use an existing dossier from an approved jurisdiction. In New Zealand's case, the most commonly used dossiers come from Australia or the European Union. The internal cost and time required to prepare an abbreviated application is still significant, but much reduced as compared to a full application.

39. Medsafe has a long history of assessing small molecule and originator biologic medicines in New Zealand. Medsafe has released public guidance on its evaluation process for both generic medicines[20] and biosimilar medicines.[21]

40. Biosimilar medicines can be approved by Medsafe through non-clinical and comparative human clinical studies. Medsafe has indicated that it will take "an approach based on the comparability of the products i.e. a demonstration of similarity".[22] The reference product for those studies must be the innovator biological medicine that has consent for distribution in New Zealand.[23]

41. Given the risks involved with the variability of biologic medicines, biosimilar approvals require careful scrutiny by Medsafe. The timeframes required to obtain regulatory approval for biosimilars in New Zealand are relatively uncertain, as compared to generic small molecule medicines.[24]

Pharmaceutical Management Agency (PHARMAC)

42. PHARMAC decides, on behalf of District Health Boards, which medicines and related products are publically subsidised for use in New Zealand.[25] In this way, PHARMAC manages the funding that District Health Boards set aside for hospital medicines. While PHARMAC's involvement in the pharmaceutical industry parallels, in many

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19 New Zealand Medicines and Medical Devices Safety Authority "Guide to completing a New Medicine Application – Prescription Medicine". Available at http://www.medsafe.govt.nz/regulatory/forms.asp

20 New Zealand Medicines and Medical Devices Safety Authority "Prescriber Update 34(1)" (2013) at 8-9. http://www.medsafe.govt.nz/profs/PUArticles/Mar2013GenericMedBioqueivalence.htm

21 New Zealand Medicines and Medical Devices Safety Authority, Fact sheet, "Medsafe position on biosimilar medicines" (2014) http://www.medsafe.govt.nz/profs/RIss/Medsafe%20position%20on%20biosimilars.pdf

22 Ibid.

23 For generics, the reference product must be the New Zealand Reference Product, which is often the innovator small molecule medicine, but can also be another product for which Medsafe holds the clinical trial and pharmacology data.

24 Hospira submitted that
[ ]

25 Pharmaceutical Management Agency "Introduction to PHARMAC" (2011), http://www.pharmac.govt.nz/2011/09/16/01INTRO.pdf.

ways, that of a purchaser, PHARMAC does not actually order, purchase, or stock medicines.

43. Because New Zealand has a fixed medicines budget, PHARMAC effectively manages a limited pool of money with which to purchase medicines. Once PHARMAC has decided to subsidise a medicine, it will typically select a preferred supplier for that medicine. PHARMAC has a number of strategies it uses to promote competition and manage its budget, including:[26]

43.1 Tendering – PHARMAC runs tenders as exclusive sole-subsidised supply contracts for a fixed term (typically three years). In the case of hospital medicines, the tender process is generally specified down to the galenic form of a particular medicine. Product bundling is not permitted for exclusive tenders. If bids are unsatisfactory, PHARMAC is not bound to award a sole supply contract. PHARMAC also has discretion over when to run tenders. If it is not satisfied with a tender process, PHARMAC can instead roll over existing supply arrangements until a new supplier registers in New Zealand. PHARMAC also issues invitations to tender, or to seek feedback from all interested parties on proposed approaches and product lists.

43.2 Alternative Commercial Proposals (ACPs) – if PHARMAC considers that it is able to negotiate a better deal with a supplier outside of the tender process, it may accept an ACP. This may occur, for example, when PHARMAC is considering entering into agreements for the supply of multiple products from a single supplier. PHARMAC generally invites suppliers to submit ACPs when they provide feedback on draft tender invitations. PHARMAC may accept a bundled ACP offer, where it allows PHARMAC to make available new medicines which would not otherwise be affordable.
[ ]

43.3 Requests for Proposals (RFPs) – PHARMAC can invite suppliers to submit a proposal to supply a specific medicine or medicines, known as RFPs. This is generally done where tendering is not appropriate or where PHARMAC actively seeks a particular medicine.

43.4 Negotiation – PHARMAC will typically negotiate with the patent holder for supply of their patented medicines. PHARMAC is able to constrain prices by leveraging the fact that it only has a limited budget. If a medicine's price is too high, PHARMAC will not to contract for the medicine at all.

43.5 Section 29 of the Medicines Act 1981 – in some circumstances, PHARMAC may wish to temporarily fund a medicine that has not been approved for supply in New Zealand by Medsafe. This can occur during temporary supply disruptions, or for highly niche medicines where a small volume is only

[26] Pharmaceutical Management Agency "Information sheet, Purchasing medicines information sheet" http://www.pharmac.health.nz/assets/purchasing-medicines-information-sheet.pdf

required for a temporary period. In such situations, section 29 provides an avenue for PHARMAC to fund unapproved medicines.[27]

The emerging presence of biosimilars in the pharmaceutical industry

44. Biosimilars are growing in popularity in a number of jurisdictions worldwide, as biologic medicines continue to come off-patent.

45. Pharmaceutical regulators across the world are, to differing degrees, improving their understanding and familiarity with biosimilars. They are therefore giving an increasing level of guidance and certainty to manufacturers regarding approval requirements. This is leading to an increasing number of biosimilars being approved worldwide.

46. Confidence among the medical community is also growing, as medical practitioners become more familiar with administering biosimilars themselves. Biosimilar manufacturers are increasingly able to demonstrate to the medical community that they can rely on the safety and effectiveness of biosimilars.

Europe

47. Globally, Europe was the first market to adopt biosimilars. The European Medicines Agency (EMA) has had a pathway for approving biosimilar medicines since 2003.[28]

United States of America

48. In contrast to the EMA, the US Food and Drug Administration (FDA) has had relatively limited experience assessing and approving biosimilars.

49. The FDA's pathway was brought about through the *Biologics Price Competition and Innovation Act 2009*. The FDA only issued draft guidance on how they would approach biosimilars in 2012, with the finalised guidance documents released in April 2015.[29] In addition, there remains uncertainty over how the new and relatively untested legislation will operate in practice, including how patent disputes will play out and their impact on the approval process.[30] [31]

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27 Pfizer submitted [ ] see Clearance Application at 13.41. [ ]

28 European Medicines Agency "Scientific Guidelines – Multidisciplinary – Biosimilar", http://www.ema.europa.eu/ema/index.jsp%3Fcurl=pages/regulation/general/general_content_000408.jsp.

29 U.S. Food and Drug Administration "Guidances (Drugs) – Biosimilars", http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm290967.htm.

30 A firm introducing a generic medicine must wait until the ingredient patent (and sometime the process patent) has expired before bringing that generic to market. In contrast, a firm seeking to introduce a biosimilar must wait out or challenge a wider variety of patents (such as multiple process patents) covering the more complex manufacture of these medicines.

31 Biologics Blog, Zhiqiang Liu, Irena Royzman "Biosimilar makers turn to IPRs before litigation under the PCIA" (2015) http://www.biologicsblog.com/blog/biosimilar-makers-turn-to-iprs-before-litigation-under-bpcia/

New Zealand

50. PHARMAC has stated that "in New Zealand, biosimilars offer considerable potential for PHARMAC to increase competition, reduce costs and improve access for patients to these, and other, medicines".[32] Because biosimilars offer such a reduction in costs, PHARMAC is highly incentivised to fund biosimilars wherever possible. PHARMAC has also stated that "[c]urrently approximately US$170 billion is spent on biologics worldwide, and this is forecast to grow to approximately US$220 billion by 2017".[33]

With and without scenarios

51. To assess whether competition is likely to be substantially lessened in any market, we compare the likely state of competition with the acquisition to the likely state of competition without the acquisition.[34]

With the acquisition

52. With the acquisition, Pfizer would acquire all of the shares in Hospira and Hospira would operate as a wholly-owned subsidiary of Pfizer.

Without the acquisition

53. Without the acquisition, Pfizer and Hospira would continue to operate independently from one another. We have no evidence to suggest that any other market dynamic is likely to arise without the acquisition.

Market definition

Introduction

54. Market definition is a tool that provides a framework to help identify and assess the close competitive constraints the merged firm would likely face.[35] It encompasses actual and potential transactions between sellers and buyers, and seeks to capture the factors that directly shape and constrain rivalry between sellers.[36]

55. A market is defined in the Commerce Act as a market in New Zealand for goods and services as well as other goods and services that are substitutable for them as a matter of "fact and commercial common sense".[37] In general, the more closely substitutable two products are, the closer the competition and the greater the competitive constraint between the products.

56. We define markets in a way that best isolates the key competition issues that arise from the merger. In many cases this may not require us to precisely define the boundaries of a market.

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32 Pharmaceutical Management Agency "Fact sheet: Biologics and biosimilars" (2014) at [2].

33 Ibid.

34 Mergers and Acquisitions Guidelines above n 1 at [2.29]; *Commerce Commission v Woolworths Limited* (2008) 12 TCLR 194 (CA) at [63].

35 *Commerce Commission v New Zealand Bus Limited* (2006) 11 TCLR 679 (HC) at [123]. *Brambles New Zealand Ltd v Commerce Commission* (2003) TCLR 868 (HC) at [137].

36 *Commerce Commission v Air New Zealand Ltd et al* (2011) 9 NZBLC 103,318 (HC) at [124].

37 Commerce Act 1986, section 3(1A).

57. To help us establish whether customers would switch sufficient purchases to alternative products, we use the hypothetical monopolist test as a conceptual tool. This test asks whether a hypothetical sole supplier of a set of products (or locations) would profitably increase prices for at least one of the merging firms' products (or locations) by at least a small, but significant, amount.[38] This small, but significant, amount is often referred to as a SSNIP – a small, but significant, non-transitory increase in price.

58. In general, the smallest set of products (or locations) in which the SSNIP above the competitive price can be profitably sustained is defined as the relevant product (geographic) market.

The applicant's view of the relevant markets

59. The applicant submits that Pfizer and Hospira have largely complementary businesses, due to the businesses' different foci. Therefore, the applicant argues that there is limited overlap between the parties. As stated above, Pfizer focuses primarily on new medicines for humans and Hospira focuses on generic and biosimilar medicines, primarily injectables.

60. Pfizer submitted that the proposed acquisition would only result in actual or potential overlap in New Zealand in the supply of the ten genericised molecules listed below.[39]

Table 1: Actual and potential molecule overlaps

Therapeutic area	Molecule
[ ]	• [ ]
Anti-coagulant	• Heparin
Anti-infective	• Gentamicin • Piperacillin + tazobactam
Central nervous system (epilepsy)	• Phenytoin
Narcotic	• Morphine
Oncology/chemotherapy	• Cytarabine • Doxorubicin

38 The test assumes that all other prices are held at current levels.

39 When we refer to molecules we refer to the base ingredient of a medicine. Both small molecule medicines and biologics contain molecules, and we therefore use the term to refer to both kinds of medicines. In this instance, all of the overlap molecules are small molecules.

Therapeutic area	Molecule
	• Epirubicin • Methotrexate

61. The applicant submitted that, as a starting point, the relevant product markets should be defined no wider than the molecule level for all of the molecules identified. However, the applicant submitted that the most appropriate market definition for most molecules is likely to be narrower, at the level of clinical indication[40] or galenic form.

62. As both Pfizer and Hospira supply all of these products on a national basis, Pfizer submitted that the relevant geographic dimension is national.

The Commission's view of the relevant markets

63. For the purposes of this acquisition, we consider that the most appropriate way in which to define the relevant markets is to begin at the molecule level, but to further differentiate markets on the basis of route of administration and galenic form to reflect the granularity of PHARMAC's demand. The galenic form is generally the level at which hospitals consider these medicines, and also how PHARMAC generally runs its tendering process and negotiations with suppliers.

64. Not all suppliers of the different molecules supply or are capable of supplying these molecules in the galenic forms required by PHARMAC. As such, we have considered this clearance based on market definitions at the level of galenic form.

65. We agree with the applicant that national geographic markets are appropriate in this instance.

Demand side substitution – lack of clinical substitutability

66. PHARMAC invites tenders for the relevant molecules according to galenic form. PHARMAC does not generally tender at the molecule level for hospital medicines, as it seeks to secure supply of the specific medicines required by clinicians at hospitals.

67. The willingness and ability of medical practitioners to substitute across different galenic forms of the relevant medicines is very limited and highly context-specific.

68. Patients require particular, precise routes of administration (and in some cases doses) of medicines. These are either the most effective medicines for their treatment or those least likely to lead to severe side effects.[41] The ability of a patient

[40] Clinical indication refers to the conditions which the medicine is suitable to treat.

[41] The particular dosage of a hospital medicine that is required for a particular patient can also differ according to safety considerations, such as what other medicines the patient has been exposed to previously or the patient's weight.

to receive an alternative galenic form, or a different molecule entirely, varies depending on the patient's condition and situation.

69. Hospitals themselves also often have different protocols and preferences for particular concentrations of medicines. For example, medical practitioners are often reluctant to alter the dosage of hospital medicines through dilution, due to the risk of human error. These factors further reduce the extent of substitution that may occur in the event of a price rise.

70. For these reasons, hospitals may require the supply of a variety of available galenic forms, for any given molecule.

71. For the majority of the relevant products, there is limited or no overlap at the galenic form level between the offerings of the merging parties. The parties supply products with different galenic forms, even though the molecule may be the same.

Supply side – lack of manufacturing or regulatory substitutability

72. We consider a group of products to be in the same relevant market if firms would easily, profitably and quickly (generally within one year) switch production to the products or locations in question without significant cost. We call these firms 'near competitors'.

73. Different medicines are often not supply-side substitutable, even as between different dosages, due to costly registration and manufacturing requirements that arise when switching production to different products.

74. In addition, we understand that it is not often possible for suppliers to switch from producing a molecule in one route of administration, such as an injection, to another route of administration, such as a tablet, without significant cost and input requirements.

75. In order to supply a particular galenic form of a medicine, a specific Medsafe registration is required. However, as with generics, where a manufacturer has regulatory approval in a comparable jurisdiction (for example, Australia), they can utilise a faster registration process that takes into account the information provided to the overseas regulator.

76. New Zealand is a relatively small market for pharmaceuticals. Consequently, in the event of a price change in New Zealand, it is not likely that a supplier will be prepared to switch its production to an alternative galenic form if it is not already producing that product for overseas customers.

Conclusion on market definition

77. The Commission has assessed the competition effects of the proposed acquisition with reference to how competition occurs in these specific markets. In this case, this is through the lens of PHARMAC tender processes run at the level of galenic form.

78. Where both Pfizer and Hospira have been (or could be) competing for the same galenic form for a molecule, there is potential overlap. Defining markets in this way isolates those product markets wherein the merging parties act as competitive constraints on each other; constraints that would be lost with the acquisition.

79. However, the Commission recognises that some firms will be closer potential competitors in these markets than others. The Commission's competition analysis also considered the impact of the proposed acquisition in removing potential competitors.

80. The Commission identified four markets where Pfizer and Hospira are existing competitors [ ]. These are the national markets for the wholesale supply of:

    80.1 Methotrexate tablets, 2.5mg;

    80.2 Cytarabine injection, 1g;

    80.3 Cytarabine injection, 2g; and

    80.4 Piperacillin/Tazobactam, 4mg/500g.

81. Hospira also has active Medsafe registration for the 100mg/ml dosage of injectable Cytarabine – which Pfizer currently supplies – and Hospira could therefore be considered a potential competitor in this market.

82. The Commission has identified two additional markets wherein the acquisition could remove a potential competitor to Pfizer, being the markets for the supply of:

    82.1 Clindamycin injection; and

    82.2 Voriconazole injection.

83. Finally, the Commission has identified three markets wherein Pfizer and/or Hospira are at phase three clinical trials for pipeline biosimilars, and are consequently potential competitors:

    83.1 Infliximab;

    83.2 Rituximab; and

    83.3 Trastuzumab.

84. The merging parties also overlap in a number of pipeline products at earlier stages of clinical trials. However, due to the very high degree of uncertainty involved in developing pharmaceutical products and the lengthy time horizons, we do not

consider that products in these earlier stages of development can be considered likely and timely entrants. [42]

85. Both Pfizer and Hospira supply the anticoagulant Heparin in New Zealand, although the presentations that they supply do not overlap. Both parties also supply Heparin in Australia. The Commission has considered whether either Pfizer or Hospira could expand their Heparin product range and therefore compete with the other party. In order for this to be the case, either Hospira or Pfizer would need to be supplying a presentation of Heparin in Australia that they do not supply in New Zealand, and therefore be a potential competitor. However, the presentations of Heparin supplied in Australia by both parties are the same as they supply in New Zealand and they are therefore no more likely than any other party to enter.

How the acquisition could substantially lessen competition

86. When a firm merges with a competitor that would otherwise provide a competitive constraint, the loss of that constraint may give the merged entity the market power to substantially increase prices or decrease quality, range, innovation efforts or service levels to the purchasers of that product.

87. As outlined above, the prices for the vast majority of prescription medicines supplied by the two parties in New Zealand are set by PHARMAC through tendering processes. As a result of this transaction, Pfizer and Hospira would no longer compete for some tenders held by PHARMAC.

88. For this transaction to result in a substantial lessening of competition through unilateral effects, one or both of the merging parties must be (or would otherwise have been) a significant competitor in a particular market. Specifically, the merger must give the merged entity the ability to:[43]

    88.1 raise prices above the level that would prevail without the merger, or discount the quality, levels of service or terms and conditions of supply, where existing competition, potential competition, buyer power and other potential constraints would not be sufficient to make such a price rise (or decrease in quality) unprofitable; or

    88.2 not bring a pipeline[44] or unreleased[45] product to market in New Zealand, where the introduction of that product would have provided a significant impact on competition at the time it came to market.

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42 Further, other competition agencies typically limit their competitive analysis to phase three overlaps for originator pharmaceuticals due to the uncertainty involved in attempting to analyse the likely state of competition for pharmaceuticals at an earlier phases of development. See for example the discussion by the European Commission in COMP/M.5868, Teva/Ratiopharm (3 August 2010) at [426].

43 Commerce Commission, *Mergers and Acquisitions Guidelines*, July 2013, at [3.62].

44 When we refer to a pipeline medicine, we are referring to a medicine which one or both of the merging parties currently have in development.

45 When we refer to an unreleased medicine, we are referring to a product which has been released in another jurisdiction, but which has not yet been released in New Zealand.

Competition analysis – unilateral effects

89. In general, the more closely substitutable two products are, the closer the competition and the greater the competitive constraint between the products. We have assessed the extent of competition between the merging parties in the relevant markets by assessing the level of competitive constraint the parties were exerting on each other at the previous tender (or negotiation) round as well as the likely situation at the next tender (or negotiation) round.

Small molecule markets

Existing competition

90. We consider the relevant competitors to be those that tender or could tender for the PHARMAC contracts.

91. Table 2 outlines the parties that bid in the most recent tender round for each of the identified areas of overlap, and whether the merging parties are actual or potential competitors.

Table 2: Competitors present in each small molecule market

Overlap	Date of most recent tender	Parties that submitted in last tender round	Current supplier
Methotrexate tablets 2.5mg	2014/15	[ ] [ ]	Rex Medical
Cytarabine injection 1g	2012/13	[ ]	Pfizer
Cytarabine injection 2g	2012/13	[ ]	Pfizer
Piperacillin/Tazobactam 4mg/500g	2012/13	[ ]	Pfizer

92. For all of the identified overlaps above, PHARMAC considered that the proposed acquisition would not have a significant impact on competition, [ ].[46]

93. For Cytarabine, we do not consider that Hospira currently provides a strong competitive constraint on Pfizer. An alternative supplier will remain for each of the relevant Cytarabine injections (including the 100mg).[47] PHARMAC considers that these [ ].[48] [49] Further, Hospira

[46] Interview with PHARMAC, 13 May 2015.

[47] Hospira has active Medsafe registration for the 100mg/ml dosage of injectable Cytarabine and could therefore be considered a potential competitor in this market. However, [ ] both submitted bids to PHARMAC in the last tender round for this product and PHARMAC does not consider that the loss of potential competition would be detrimental to achieving current supply terms.

[48] [ ]

[ ].

94. For Piperacillin/Tazobactam, a number of parties will remain with current Medsafe registration. [ ] provide a competitive constraint on the merged entity.

95. [
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[

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96. [ ], we consider that Rex Medical (the current PHARMAC supplier) will continue to provide competitive constraint on the merged entity.

Clindamycin injection and Voriconazole injection.

97. Pfizer is currently the only party with an active Medsafe registration for these products.
[
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98. Pfizer supplies Clindamycin injections under an exclusive supply contract, which expires in 2016. Voriconazole injection is supplied on a non-exclusive basis, under a negotiated contract. Voriconazole is protected by patent until mid-2018, while the patent for clindamycin has expired.

99. Notwithstanding that Hospira does not have a Medsafe registration for either of these products, and has not made a decision to enter the New Zealand market, we have considered whether the proposed acquisition would result in a substantial lessening of competition, by removing a potential competitor to Pfizer for these products.

100. For Clindamycin, PHARMAC informed the Commission
[ ].[50] Mylan is currently mid-way through the approval process for a Clindamycin injectable product,
[ ]

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[49] The supply of cytarabine in New Zealand is worth [ ]. Despite this small value, PHARMAC was able to secure [ ]to these tenders. Further, as mentioned below, Medsafe registration fees can be waived for these small value products.

[50] [ ].

101. While no other party has current Medsafe registration for an injectable Voriconazole generic product, there are a number of parties who are currently in development.[51] In addition, Sandoz (the generics division of Novartis) currently supplies generic Voriconazole injections in the US.

102. We consider that with the acquisition, sufficient suppliers of Clindamycin and Voriconazole injection will remain to provide PHARMAC with sufficient competitive options at the next tender round. We note that [ ].

Countervailing power of PHARMAC

103. If faced with a price increase by the merged entity, it is likely that PHARMAC, as the sole funder of the relevant medicines, would have some degree of countervailing power. The precise extent of the countervailing power that PHARMAC would be able to exercise is, however, likely to depend on the particular situation of each market.

104. As outlined above at paragraphs 43.1 to 43.5 above, PHARMAC has a number of competitive strategies that it can use to constrain price increases. Suppliers are aware of these strategies. For example, PHARMAC generally [ ].

105. Pfizer submitted [ ].[52]

106. We consider that PHARMAC is in a strong position to solicit alternative supply in the event that the merged entity exited a relevant small molecule market or attempted to impose a price increase. Nonetheless, as we also consider it likely that there is sufficient competition across all of the relevant small molecule markets, a further analysis of the likelihood, extent and timeliness of such entry is not necessary.

Potential competition

107. The applicant submits that there are well-resourced firms producing the various Cytarabine injections and Methotrexate tablets globally that are able to supply New Zealand.

108. We have not considered potential entry, as we are satisfied that existing competition, along with PHARMAC's ability to seek alternative suppliers, is sufficient to constrain the merged entity.

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[51] [ ].

[52] [ ].

Conclusion on small molecule markets

109. Generally, a three to two merger is likely to be of concern. In this context, however, the market includes a single large and sophisticated purchaser, which can choose the competitive strategy most effective for a given situation. We consider that two suppliers is sufficient, in these relevant markets, to deliver outcomes that are approximately competitive.

110. We consider this same conclusion to apply for each of the relevant small molecule markets where a three to two situation may result (ie Cytarabine and Methotrexate), particularly given the existence of potential competition from other large, well-resourced competitors.

111. [

]53

112. Further, given the highly genericised nature of these medicines, we consider that competition is likely to take place predominantly on price.
[
]. The third parties competing with the merged entity in these markets are large, well-resourced players with strong international reputations.

113. For these reasons, the Commission is satisfied that it is not likely that any of the relevant small molecule markets will see the removal of a significant competitive constraint.

Biosimilars

114. If pipeline or unreleased medicines were not brought to New Zealand as a result of the merger (or were substantially delayed), and if the introduction of those medicines would have had a significant impact on competition, this could lead to a substantial lessening of competition.

115. The only pipeline medicines where the parties may overlap are biosimilars.[54] Therefore, biosimilar medicines are the only pipeline products we have considered further.

116. We consider that biosimilars are likely to compete in the same market as the original biologic medicines that the biosimilars are designed to emulate. We conducted our assessment of biosimilars at the molecule level, since the early development phase

53 [ ]

54 We were not able to identify any unreleased medicine where the parties overlapped and there was a real risk that one of the parties' product would not be introduced in New Zealand as a result of the merger.

of these products renders it infeasible to more precisely outline the relevant galenic forms that may be at issue.

Framework for the competitive assessment of biosimilars

117. Discussions with market participants during our investigation highlighted the high level of uncertainty surrounding the potential competitive impact of biosimilars, including if and when they may enter the market. Other than in Europe, the marketing and regulatory pathways of these medicines are new and uncertain. Generally the Commission considers that in order for a small molecule medicine to be considered a relevant potential market entrant, it must have reached phase three of clinical trials.

118. The success rate of phase three clinical trials for biosimilars is much more uncertain than for small molecule generics. This adds a further layer of uncertainty to the competitive analysis. If the merging parties' medicines do not pass clinical trials or cannot obtain the relevant regulatory approvals, there may not ultimately be any relevant overlap in these markets.

119. Once biosimilars conclude phase three clinical trials, they are still required to receive regulatory approval to come to market in New Zealand. In New Zealand, Medsafe is relatively inexperienced in approving biosimilars. This increases uncertainty in terms of timing and probability of coming to market.

120. [

]Obtaining regulatory approval in Australia enables a manufacturer to utilise the Australian regulatory dossier to fast-track approval in New Zealand.

121. For the purpose of our analysis, we have assessed all of the biosimilar pipelines where both parties overlapped at phase three clinical trials (or beyond). These biosimilars are identified in Table 3.[55]

[55] Phase three clinical trial for biosimilars are generally estimated by parties to take between 24 and 36 months. Given this, and given the further time that a biosimilar takes to come to market after phase three, including regulatory approval, biosimilars at phase one are too uncertain to allow us to assess the likely state of competition. See http://www.hospira.com/en/healthcare_trends/biologics/development_of_biosimilars/

Table 3: Parties at phase three clinical trials for overlapping pipeline biosimilars or beyond

Biosimilar	Parties at phase three clinical trials	Biosimilar available in the market[56]	Originator biologic
Infliximab	Pfizer, Baxter/Epirus.	Hospira/Celltrion – launched in the EU. Samsung Bioepis has finished clinical trials and has applied for marketing authorisation in the EU.	Johnson and Johnson
Rituximab	Pfizer, Hospira/Celltrion, Sandoz, Boehringer Ingelheim, Amgen/Actavis, Mabion, Dr Reddy's/Merck Serono.		Roche
Trastuzumab	Pfizer, Hospira/Celltrion, Sandoz, Samsung Bioepis, Mylan/Biocon, Amgen/Actavis.		Roche

122. For each the three biosimilar medicines identified above, there are a number of competing parties that have reached phase three trials. We have no reason to consider that the chance of success for these other products would be any different than for the merging parties.

123. Given PHARMAC's countervailing power, we consider that a potential substantial lessening of competition only exists in one of these markets if both of the merging parties succeed and all of the competing biosimilars fail. Due to the number of large, well-resourced competitors at phase three trials in each of these markets, we consider that the probability of such an occurrence is very low.[57]

124. However, even if such a situation were to occur, we consider that PHARMAC would still likely be able to leverage a competitive price, on the basis of competition between the originator and the biosimilar supplied by the merging parties.

125. Two instances of PHARMAC actively seeking cost savings when a biosimilar has been approved have already taken place in New Zealand:

[56] It should be noted that the originator supplier of the biologic which any approved biosimilars compete with is also, in our view, likely to compete vigorously on price with any biosimilar entrants to attempt to continue to secure supply for the relevant market in New Zealand.

[57] Further, most of these competitors are already active in New Zealand and therefore are unlikely to be more reluctant than the merging parties to enter New Zealand markets.

125.1 Filgrastim - After a biosimilar of the molecule filgrastim had been approved internationally in a number of countries, PHARMAC sought proposals from companies marketing original and biosimilar filgrastim brands.[58] As a result, in 2012 PHARMAC awarded a sole supply contract to Sandoz for its biosimilar brand of Filgrastim, Zarzio. In addition, Roche, the supplier of the originator biologic Pegfilgrastim, subsequently reduced its price after losing market share to the Filgrastim biosimilar.[59]

125.2 Infliximab – In late 2014, PHARMAC initiated an RFP process for Infliximab, calling for proposals from the current innovator provider, Sandoz, and parties who are developing an Infliximab biosimilar (despite the fact that no Inflizimab biosimilar had been approved by Medsafe for use in New Zealand). As a result of this process, PHARMAC was able to proactively negotiate a long term agreement (until 2020) with Sandoz and achieve a 30% price discount to the existing sole supply contract for the originator for Infliximab, Remicade.[60]

Hospira's agreement with Celltrion

126. Finally, there is also considerable uncertainty regarding the retention of rights to Hospira biosimilars by the merged entity.

127. Hospira has an agreement with Celltrion, in respect of each of the pipeline biosimilars where Pfizer and Hospira overlap. Under this agreement, Celltrion develops the biosmilars and grants Hospira the sole distribution and marketing rights for these biosimilars in eight countries (including New Zealand, Australia, USA, Canada and parts of Europe).

128. [

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129. [ ] to these biosimilars, we consider that there would likely be no material overlap, or any competitive difference between the with and without scenarios.[61]

130. [

[62]]

[58] https://www.pharmac.health.nz/about/annual-review/2014/biosimilar-filgrastim/

[59] Ibid.

[60] Pharmaceutical Management Agency, Media release, 4 December 2014, https://www.pharmac.health.nz/news/media-2014-12-04-infliximab-savings/

[61] This is contingent on Celltrion being able to secure a partnership with another marketing/distribution partner.

[62] [ ]

Conclusion on biosimilars

131. We consider that the proposed acquisition is not likely to result in a substantial lessening of competition for the supply of biosimilars in New Zealand, due to the number of parties developing competing biosimilars at late stage clinical trials and the resulting unlikelihood of only Pfizer and Hospira's phase three biosimilars coming to market.

Overall conclusion

132. Both with and without the transaction, the two parties would continue to face competition from a number of other suppliers for the relevant molecules, including future competition involving new and unreleased products.

133. In terms of small molecules, we did not identify any reason why competition for the supply of any form of a small molecule would be affected at a future tender (or other form of negotiation) held by PHARMAC. Further, if faced with a price increase, PHARMAC would likely be able to exercise a significant degree of countervailing power.

134. In terms of pipeline and unreleased biosimilar medicines, we consider that there is likely to be a number of competing suppliers in addition to the merged entity.

Determination on notice of clearance

135. The Commission is satisfied that the proposed acquisition will not have, or would not be likely to have, the effect of substantially lessening competition in a market in New Zealand.

136. Under s 66(3)(a) of the Commerce Act 1986, the Commission gives clearance to Pfizer, Inc to acquire Hospira, Inc, to the extent that the acquisition affects a market in New Zealand.

Dated this 16th day of July 2015

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Dr Mark Berry

Chairman