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Introduction

The disease

1.1 Chronic and clinically significant adhesive arachnoiditis is a painful condition caused by long term scarring of the arachnoid membrane, one of the membranes that surround and protect the nerves of the spinal cord and spinal nerves. Inflammation from medical intervention or infection can lead to the formation of scar tissue, which causes the spinal nerves to 'stick' together, hence the descriptive term 'adhesive' arachnoiditis which is used in this report. This 'tethering' of the spinal nerves can prevent them from moving freely as an individual moves, triggering pain and other symptoms.

1.2 Sufferers of adhesive arachnoiditis experience a range of symptoms, including:

- pain, particularly affecting the lower back and legs, often intense and leading to decreased mobility or in severe cases paralysis;
- bladder and bowel dysfunction; and
- impaired sexual function.

1.3 There are no reliable data on the prevalence or incidence of adhesive arachnoiditis in Australia (or apparently elsewhere) as the necessary clinical data do not exist.[1] However, it was clear to the Committee at the roundtable that the impact of adhesive arachnoiditis on the lives of sufferers and their families can be devastating.

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1 P Day, *Arachnoiditis: A brief summary of the literature,* (2001) New Zealand Health Technology Assessment, pp. 7-9.

1.4 The aetiology (i.e. clinical cause) of adhesive arachnoiditis is complex. Causes and risk factors associated with the development of adhesive arachnoiditis include:

- complications of bacterial and viral infections;
- degenerative back conditions such a disc herniation or spinal stenosis;
- trauma to the back or spine due to injury or multiple surgical procedures; and
- exposure of the spinal cord and surrounding membranes to a range of therapeutic and diagnostic agents.

1.5 Reports on the relative contribution of these factors to the development of adhesive arachnoiditis vary. It is often very difficult to establish a single causative event for individuals with adhesive arachnoiditis, as many sufferers will have experienced more than one risk factor.

1.6 For those with a diagnosis with adhesive arachnoiditis, treatment options are limited and the prognosis is poor. There is no cure for adhesive arachnoiditis and treatment is primarily pain management and assistance with functional impairment.

Context of the Committee's inquiry

1.7 Adhesive arachnoiditis was first brought to the attention of the House of Representatives Standing Committee on Health and Ageing (the Committee) by a member of the Committee in the context of constituent concerns raised by affected individuals and/or their carers.

1.8 On 19 September 2011, during the grievance debate, the Committee's deputy Chair Mr Steve Irons MP, called for the Committee to inquire into specific matters associated with adhesive arachnoiditis. A key issue raised by Mr Irons was the extent to which certain diagnostic agents, specifically the oil-based contrast media marketed as Myodil by the UK product manufacturers and Pantopaque by the USA product manufacturers[2], caused adhesive arachnoiditis. These oil-based contrast media, containing iophendylate dye as the main active ingredient, were used to help clinicians determine the causes of chronic back conditions in affected individuals. The contrast media were injected into the cerebrospinal fluid (CSF) in a process known as myelography. This allowed details of the spinal cord and spinal nerves to be visualised by X-ray.

2 In the UK Myodil was produced by Glaxo (now GlaxoSmithKline) and in the USA Pantopaque was produced by Lafayette Pharmacal.

1.9 The oil-based contrast media Myodil and Pantopaque were used in myelography from the 1950s to the 1980s in Australia and elsewhere, including the UK and USA. As a consequence, often many years post-procedure, some individuals have developed adhesive arachnoiditis.

1.10 A number of those affected have subsequently litigated seeking compensation from the product manufacturers. The basis of many of their claims for compensation is that the product manufacturers provided insufficient warnings about product safety and did not appropriately react to the evolving scientific literature. While the outcomes of litigation have varied according to individual circumstances, it is clear that some individuals in Australia and overseas have received out of court settlements from product manufacturers.[3] These out of court settlements were made by the product manufacturers without admission of guilt. The Committee comments further on litigation in Chapter 2 of the report.

1.11 Mr Irons' speech is not the first time that adhesive arachnoiditis has been debated in the House. In 2002 several Members of Parliament debated the condition, and matters relating to adhesive arachnoiditis were subject to questions on notice directed to the then Minster for Health.[4] While all speakers on the issue acknowledged the seriousness of the condition and its impact on sufferers, opinions differed on the whether a committee inquiry into adhesive arachnoiditis was warranted.[5]

Scope and conduct of the inquiry

1.12 On 22 May 2012 the Committee resolved to investigate the issue of adhesive arachnoiditis further.[6] To assist the Committee to determine the nature and scope of its investigations it initially received a private briefing on 14 August 2012 from a clinical neurologist and a representative of the Therapeutic Goods Administration. On the basis of information from that

3 Commonwealth, *Parliamentary Debates*, House of Representatives, 19 September 2011, 10707 (Steve Irons).

4 See: Commonwealth, *Parliamentary Debates*, House of Representatives, 16 September 2002, 6267 (Jennie George); Commonwealth, *Parliamentary Debates*, House of Representatives, 16 September 2002, 6270 (Mal Washer); and Commonwealth, *Parliamentary Debates*, House of Representatives, 16 September 2002, 6273 (Andrew Southcott).

5 See: Commonwealth, *Parliamentary Debates*, House of Representatives, 16 September 2002, 6267 (Jennie George); Commonwealth, *Parliamentary Debates*, House of Representatives, 16 September 2002, 6270 (Mal Washer); and Commonwealth, *Parliamentary Debates*, House of Representatives, 16 September 2002, 6273 (Andrew Southcott).

6 The Committee has a general power to inquire into the annual reports of Commonwealth agencies under Standing Order 215(c).

briefing the Committee undertook to focus on the aetiology, diagnosis, treatment and prognosis of adhesive arachnoiditis.

1.13 As noted, the Committee is aware of litigation relating to exposure to Myodil and/or Pantopaque and the development of adhesive arachnoiditis. In conducting its inquiry into adhesive arachnoiditis the Committee is of course mindful that the courts are independent of the Parliament. The Committee also emphasises that it does not have the authority to order compensation with respect to the use of Myodil or Pantopaque. Individuals who are considering such legal action should obtain their own independent medical assessment and legal advice. It is in this context that the Committee has sought to investigate issues associated with adhesive arachnoiditis with a view to assisting sufferers by raising the profile of the condition and considering practical options for support.

1.14 To progress its investigations into adhesive arachnoiditis the Committee resolved to hold a public roundtable in Canberra on 21 September 2012. The Committee invited a range of participants with experience of adhesive arachnoiditis. The roundtable opened with introductory statements by teleconference from Professor Marcus Stoodley, Professor of Neurosurgery, Macquarie University in New South Wales (NSW) and from Professor Michael Cousins, Royal Australasian College of Physicians. Other participants at the roundtable were:

- Ms Ruth Ahrens, Vice President, Australian Arachnoiditis Sufferers Association and sufferer;
- Professor Chris Baggoley, Chief Medical Officer, Department of Health and Ageing;
- Ms Bernadette Clarke, sufferer;
- Dr Tony Gill, Acting Principal Medical Adviser, Therapeutic Goods Administration;
- Mr Joern Hagemann, sufferer;
- Ms Maureen McLean, President/Secretary, Australian Arachnoiditis Sufferers Association (NSW) and sufferer;
- Professor Michael Sage, Royal Australian and New Zealand College of Radiologists;
- Mr Max Scott, sufferer (teleconference); and
- Mrs Erika Zorzit, daughter and carer of Mr Hagemann.

1.15 Following the roundtable, the Committee also took 'in-camera' evidence from representatives of GlaxoSmithKline (GSK), the product manufacturer of Myodil. On the same day as the roundtable GSK posted a press release on its website outlining its position on the use of Myodil and the

development of adhesive arachnoiditis (at Attachment A). Subsequently GSK also provided the Committee with a range of information in correspondence to the Committee, including product information sheets for Myodil from the 1970s.[7]

1.16 The Committee very much appreciates the contributions of all participants to its inquiry. The roundtable made clear to the Committee how debilitating adhesive arachnoiditis can be to sufferers. The Committee very much sympathises and hopes that the recommendations in the report will help to improve quality of life for sufferers, and their families and carers.

7 Correspondence to the Standing Committee on Health and Ageing from GlaxoSmithKline, dated 12 October 2012.