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Senator Rachel Siewert
Chair of Senate Community Affairs Reference Committee
P O Box 6100
Parliament House
CANBERRA ACT 2600

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Dear Senator Siewert

Arthritis Australia welcomes the opportunity to respond to the **Senate Community Affairs Reference Committee - Inquiry into Consumer Access to Pharmaceutical Benefits**. Our comments in relation to (a) and (h) of the Terms of Reference follow:

Introduction
Arthritis is an umbrella term that covers more than 100 conditions, mostly affecting the joints and causing pain, stiffness, immobility and fatigue. It can be painful, disabling and long lasting. There is no cure but with early and proper diagnosis as well as a customised management plan, it can be controlled.

One of the frustrating aspects of arthritis is that different people respond to different management plans – there is no one 'magic solution' and what works for one person, doesn't necessarily work for another. The science to predict who will respond best to which agent is still in its infancy. As a result, several drugs may have to be prescribed and trialled before success is reached.

In Australia, the most common form of arthritis is osteoarthritis, generally attributed to wear and tear, and the second most prevalent is rheumatoid arthritis (RA) a severe, autoimmune disease that attacks the body's healthy tissues causing inflammation in the joints and sometimes other organ systems. The more severe forms of arthritis are often categorised as 'inflammatory arthritis' and include RA, gout, ankylosing spondylitis (AS) and psoriatic arthritis (PsA).

Internationally-recognised clinical evidence proves that an early and proper diagnosis followed by an aggressive management regimen, including drug therapy, can prevent (but not heal) joint damage and stabilise the debilitating symptoms. This is considered best practice and is especially significant for those people battling severe inflammatory arthritis. Early and successful treatment gives those affected a fair chance to enjoy a meaningful life that may include living independently, remaining in the workforce, and reducing demands on the health system.

(a) The impact of new therapeutic groups on consumer access to existing PBS drugs, vaccines and future drugs, particularly high cost drugs.

In principle, Arthritis Australia does not object to the establishment of therapeutic groups. It does, however, object to the narrow restrictions that are associated with access to biological disease-modifying antirheumatic drugs (bDMARDs) for people living with severe forms of inflammatory arthritis – and how the criteria are determined.

bDMARDs are sometimes referred to as 'biologics'. Until recently, the main type was Tumour Necrosis Factor inhibitors (anti-TNF) which include etanercept, adalimumab and infliximab. These are available in Australia for rheumatoid arthritis, ankylosing spondylitis and psoriatic arthritis. More recently, other bDMARDs with different mechanisms (depletion of B-cells, T-cell blockade and interleukin-6 inhibition) have become available leading to much greater choice.

These drugs are expensive (around $20,000 per annum). Very few, if any, consumers can afford these medications on private prescription due to the ongoing nature of treatment – i.e. there is no cure for arthritis and in order to maintain 'remission' medication must be continued.

Currently, their subsidisation by the Pharmaceutical Benefits Scheme (PBS) is limited to those with severe and refractory, active disease, in whom major joint damage has already occurred. Before being eligible for subsidied bDMARDs, a patient must have failed to demonstrate a response to a number of traditional disease modifying anti-rheumatic drugs (DMARDs), most often methotrexate. Months or years may pass while a patient cycles through the required DMARDs to satisfy the current PBS criteria.

Worldwide clinical evidence shows that aggressive treatment of DMARDs for severe inflammatory arthritis within the first two years of onset can significantly slow the progression of joint damage. Many Australians respond to traditional DMARDs and others, who fail to benefit from this treatment regimen, have reasonable access to the more expensive bDMARDs. However, there are still some Australians who have past the critical mark of treatment by the time they are eligible for bDMARDs – i.e in other words, because the current PBS access criteria for bDMARDs for severe inflammatory arthritis does not reflect the evidence base or best practice, Arthritis Australia requests they be reviewed. For example:

- bDMARDs have shown to be very effective in early rheumatoid arthritis (RA) especially when taken with methotrexate (MTX). Therefore, in those with bad outlook RA (e.g. high level rheumatoid factor and/or cyclic citrullinated peptide (CCP)), it would be reasonable to prescribe them for those consumers who fail to respond quickly to methotrexate.
  Case study: *Only patients involved in clinical trials, i.e. very few, are able to access biologics in this way. Karen, a 38 year old nurse and the sole family breadwinner, presented with early, but severe RA, CCP positive. Unresponsive to MTX, she received adalimumab in a clinical trial and remains well and in full-time employment. At two years, Karen still has no joint damage.*

- To access treatment with biological agents for psoriatic arthritis, patients are required to have 20 or more joints currently showing active arthritis, i.e. 'tender and swollen joints'. In clinical practice, they rarely do. Indeed, the criterion does not consider the worldwide scientific trials where the mean active joint score is 6-8. Rather than restrict access to the most severe margins of disease, it seems more equitable to review the eligibility criteria in light of the current international evidence with consideration to reduce the active joint count to 8-10 in psoriatic arthritis.
  Case study:
  Claire is 40 years old and an experienced paralegal. She developed psoriasis at age 21 and struggled over many years to control her skin disease with creams and light therapy. Twelve years ago she developed severe psoriatic arthritis that over time affected multiple joints including her hands, one knee and one ankle. The pain and swelling were so severe that she eventually had to give up her job. She was barely able to look after herself, and struggled to care for her two toddlers then aged three and two. Claire and her family had to move in with her mother in order to try to cope. The disease was relentless. None of the then available therapies were successful for her and she became angry and depressed. Finally, through the benevolence of a teaching hospital committee, she was able to access etanercept, one of the newer biological drugs. This enabled excellent control of her arthritis and allowed Claire to do many everyday tasks that we take for granted. "I brushed my daughter's hair for the first time in her life today," Claire told her rheumatologist. Claire is now fully functional, has moved back into her own home and manages without any outside assistance.

- In ankylosing spondylitis, severe X-ray changes are necessary to qualify even though MRI scans show changes from very early in the disease. This means that only longstanding disease gets the new treatments because X-rays take 5-10 years to change. It would seem much fairer to require objective evidence of sacroiliitis on MRI, or other imaging, as proof of significant disease rather than wait until there is gross, irreversible damage.
  Case study:
  Ken, in his 30s, is married with two children and an unskilled labourer. He developed AS a few years ago. Clinically, Ken has bilateral sacroiliitis and a chronically painful swollen knee. But the X-ray is only abnormal on one side, though MRI is abnormally bilateral. He has tried all of the usual treatments including non-steroidal anti-inflammatories (which had to be stopped because of a bleeding ulcer), physio, suphasalazine and methotrexate. Ken has given up work, is on disability allowance, but does not qualify for bDMARDs because his X-ray does not show 'severe enough disease'.

- The Pharmaceutical Benefits Advisory Committee (PBAC) has recently recommended the current five year exclusion period between bDMARD cycles (after failure of three treatments) is removed and replaced with a new PBS restriction which allows consumers with RA to try a maximum of five bDMARDS within a lifetime. The potential for new and effective medications for severe inflammatory arthritis is increasing. More than 50 new medications are in the pipeline NOW. To cap consumer access to only five of these within a lifetime defies logic, is unprecedented for other medications available for Australians living with a severe chronic illness, and denies access & equity. There is no evidence to support this decision.

Case study:
Jennifer is in her early 30s and has had severe RA for some years. Jennifer has used all the bDMARDs available, has been on clinical trials for experimental agents and is doing badly. She has developed a dependency on strong narcotic analgesics. As her rheumatologist asks, "What can we do with her for the next 50 years?"

(h) Any other related matters

Arthritis Australia believes the Federal Government should make it mandatory that there be grassroots consumer consultation for all national health policy decisions including consumer representation relevant to the disease/subject matter on all advisory and clinical review subcommittees/committees.

As the peak consumer body representing the almost four million Australians living with arthritis, we are well equipped to assist in health policy decisions associated with the related conditions. While details of PBAC, Senate Inquiries and selected federal health policy matters are advertised on websites and through other media, Arthritis Australia, along with many peak consumer groups, does not have the capacity to regularly monitor their scheduling.

We strongly urge that all relevant stakeholders – including national consumer groups – are individually and formally invited, in a timely manner, to contribute to all relevant health policy reviews. In countries with similar health economies, such as in the UK and Europe, best practice for stakeholder participation is observed, including having consumer representation from disease-specific experience contributing to disease-specific health policy reviews and decisions. Only when this process is adopted in Australia will we see and experience a truly transparent approach to policy reviews and decision-making.

In conclusion
Arthritis Australia appreciates the opportunity to contribute to this Senate Inquiry and would be pleased to take part in any discussion regarding the points we have raised.

Yours sincerely

Ainslie Cahill
Chief Executive Officer

About arthritis
Nearly one in five Australians has arthritis – almost four million people.

In 2002 arthritis was made a National Health Priority. Today, its prevalence is higher than any other health priority but, generally, does not attract the serious attention it deserves.

Arthritis can have a negative impact on family and personal relationships, work and lifestyle choices and can cause financial strain. It is no longer acceptable to trivialise arthritis, to shrug off the disease as something that affects only 'old people', or to think that nothing can be done to manage pain and improve quality of life.

The total cost of arthritis to the Australian economy is estimated to be $23.9 billion annually. The main bearers of arthritis costs in Australia are the individuals living with the condition who, it is estimated, shoulder 61% of the total cost - largely as a result of being the bearer of the burden of disease. The Federal Government is the second biggest cost bearer, a consequence of funding the lion's share of the large health system expenditures on arthritis and also bearing the lost taxation revenues associated with the considerable productivity losses arising from the condition (Access Economics Report 2007).

More widespread access to appropriate cost effective interventions such as weight loss, exercise, self-management programs, total hip replacement and medicines, will reduce the costs to the healthcare system and the burden of disease.

As well, medication is part of the treatment regimen with many medications being very effective in retarding joint damage and reducing symptoms associated with arthritis.

Access issues must continue to be addressed to ensure an equitable health care system, irrespective of where you live and how much you earn. The social and economic benefits are self-evident: fewer adverse symptoms = improved quality of life = less national economic burden.