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Ms Naomi Bleeser
Committee Secretary
Senate Standing Committee on Community Affairs
PO Box 6100
Parliament House
CANBERRA ACT 2600

Dear Ms Bleeser

Inquiry into Consumer Access into Pharmaceutical Benefits

At the Public Hearing in Canberra on Friday May 7, 2010 the Committee Chair and other Committee members put a number of questions on notice. Arthritis Australia provides the following additional information and comments.

Senator Fierravanti-Wells asked whether Arthritis Australia considers that there should be a full review of the PBAC decision relating to biological disease modifying anti-rheumatic drugs (bDMARDs) for people living with severe inflammatory arthritis, and how such a review should be structured. Arthritis Australia's comments follow:

- Arthritis Australia's submission and statement to this Senate Inquiry expressed concern over the Pharmaceutical Benefits Advisory Committee (PBAC) recommendation of a new restriction relating to bDMARDS. The 2010-11 Federal Budget confirms:

  "….new restrictions will apply for patients receiving bDMARDs treatment for rheumatoid arthritis. The current access restrictions will be modified to allow up to five bDMARDs treatment courses in a lifetime.

  "Both the price restriction and the restrictions changes will be consistent with the December 2009 recommendations of the Pharmaceutical Benefits Advisory Committee."

  This budget measure reinforces Arthritis Australia's view that worldwide best treatment practices and the weight of clinical evidence, including the impact on consumers, has been given a lower priority in favour of cost savings.

- The PBAC should convene as a matter of urgency a bMARDs Roundtable involving PBAC representatives, Australian Rheumatology Association, clinicians in private practice, Arthritis Australia (to represent consumers), and pharmaceutical companies that have new bMARDs or other newer treatments in clinical trial stage.

- The Roundtable should have information about the latest and best treatment standards from overseas Regulatory and Professional Colleges.

- There should be the opportunity for submissions.

- The discussions and the Roundtable outcomes should be published.

Senator Moore asked two questions about consumer involvement:

Given that there is a consumer member on the PBAC, Senator Moore asked what is the interaction with that person, and what is the value of that position on the PBAC and how can it work. Arthritis Australia's comments follow:

- Due to confidentiality restrictions placed on all PBAC members, there has never been any discussion between the PBAC consumer representative – or other committee members for that matter – about medications for arthritis and associated musculoskeletal conditions. We believe this lack of interaction applies to all other disease-specific health consumer groups throughout Australia.

- To ensure greater consumer input, while protecting the confidential nature of reviews and new listings, it should be mandatory for a consumer representative to be appointed to each of the subcommittees and working groups and any other advisory/policy mechanisms, associated with the PBAC.

- As a way to avoid 'professional' consumer representation, consumer nominees to the PBAC should be selected directly from grassroots consumer organisations, and should rotate every 12 months.

- Grassroots consumer nominees should be required to agree to strict confidentiality requirements, with legal penalties in place for breaching the agreement.

- A model worthy of consideration is that of the European Medicines Agency (EMA) – a decentralised body of the European Union with headquarters in London. Its main responsibility is the protection and promotion of public and animal health, through the evaluation and supervision of medicines for human and veterinary use. In this regard, Arthritis Australia points out the following:

    - The opportunity for input by health consumer groups into the deliberations of the EMA is evident at all levels. There is a Patient Health Protection Committee of the EMA and there are scientific committees that work with patients and consumer organisations (the Patients and Consumers Working Party – PCWP).

    - The PCWP provides recommendations to the EMA and its human scientific committees on all matters of interest to patients in relation to medicinal products.

    - The PCWP also looks at how to best implement the recommendations for improvement in areas such as transparency and dissemination of information, product information, pharmacovigilance, and interaction between the scientific committees and consumer organisations.

    - This working party also consults with patients and consumers on benefit/risk considerations.

    - The PCWP is composed of representatives from 15 health consumer organisations (subjected to eligibility criteria), representatives from the five EMA human scientific committees and representatives from the EMA secretariat.

    - Summaries of the evaluation and deliberation of the EMA's committees and the PCWP are publicly available. The PCWP also meets at least annually with the EMA's Health Care Professionals Working Group to ensure adequate coordination of issues of common interest.

The second question is about the doctor-patient relationship in the context of deciding which medication to choose; how much conversation takes place about choice with patients and their families, and how is price discussed. Arthritis Australia's comments follow:

The doctor-patient interaction is, of course, a critically important component in chronic disease management. This will vary according to a number of issues including personalities, level of education of the patient, time spent etc. Many issues compete for discussion in such a setting. Price of treatment may well be one of those, but there are may be barriers to honest communication here – i.e. not all doctors will be aware of a patient's individual financial circumstances, and not all patients will be comfortable discussing their financial circumstances with a doctor. Usually the doctor, as the patient's advocate, will prescribe what they believe is the *best* treatment, rather than the *cheapest*. This may present a new barrier to adherence to therapy i.e. the patients may choose not to take the medication, with all the potential problems and future health costs that this can cause.

Senator Siewert, the Committee Chair asked whether the Consumer Roundtable participants are of the opinion that the therapeutic group process is a good process or would they prefer that it did not exist, or whether it should it be improved in the context of drug interchangeability. Arthritis Australia's comments follow:

- The Pharmaceutical Benefits Scheme (PBS) gives all Australian residents and eligible overseas visitors access to over 2600 brands of prescription medicines in a way that is affordable, reliable and timely. The PBS must be sustainable and, therefore, there will need to be policy adjustments from time to time.

- Considerably more work needs to be done in defining the 'interchangeability' of drugs. These deliberations must be transparent and, when finalised, must be properly communicated to both the medical professionals who write the prescriptions and to the patients who are the consumers.

- In relation to therapeutic groups, it is not the concept of therapeutic groups that is of concern to consumers, but it is the guidelines and access restrictions that government officials attach to the groups that can be unfair, discriminatory and deny chronically ill patients access to PBS subsidised drugs.

- Many people with chronic illnesses, such as severe and inflammatory forms of arthritis, are usually on fixed incomes or government benefits and cannot afford any increase in PBS co-payments, or even worse, to pay for drugs that are not PBS subsidised.

- Whatever policies relating to PBS reimbursement are put in place by governments from time to time, they must be totally transparent and be based on improved clinical outcomes for patients.

Yours sincerely

Mona Marabani
President

Ainslie Cahill
Chief Executive Officer