Submission to the Therapeutics Good Administration on the regulatory framework for complementary medicines: Assessment pathways

Introduction

Arthritis Australia welcomes the opportunity to provide feedback on the TGA's proposed regulatory framework for complementary medicines.

People with arthritis and musculoskeletal conditions are major users of complementary medicines with around 60% of people trying a range of products in an effort to gain relief from the chronic pain and disability associated with their condition.[1] Unfortunately a UK review of complementary compounds taken for arthritis found that there was no or little evidence of effectiveness for more than half of the compounds reviewed. In addition, one in four of the compounds for which evidence from randomised controlled trials was available was associated with common adverse effects (both minor and serious).[2]

For these reasons, Arthritis Australia has previously proposed that more rigorous evidence relating to safety and efficacy be required by the TGA to support the listing of complementary medicines. We welcome the current proposals as a major step in the right direction.

Proposed new assessment pathway

Arthritis Australia welcomes the proposal to establish a new assessment pathway for complementary medicines which would include TGA assessment of the evidence supporting the efficacy of products claiming 'intermediate' level indications.

We also welcome the enhanced evidence requirements that would be set for products to be assessed under the new assessment pathway.

These proposals will help to improve the evidentiary base for complementary medicines and help to provide consumers with much-needed information about which products have evidence of effectiveness and which do not. Provided it is accompanied by a consumer education campaign, the proposal will help consumers to make better informed decisions about their use of complementary medicines.

However, we are disappointed that the new pathway will still rely on sponsor self-assessment and certification of the safety and quality of the product. As highlighted above, safety issues with complementary products taken for arthritis are reasonably common. Many consumers have a false perception that complementary medicines are safer than conventional medicines because they are natural. While this may be true in many cases, consumers are often unaware that some complementary medicines may carry the risk of side-effects, adverse reactions such as allergies, or interactions with conventional medications. Nor do they discuss their complementary medicines use with their doctors.[3]

We recommend that the TGA includes an independent assessment of the evidence relating to the safety of products assessed under the new assessment pathway as well as effectiveness.

List of permitted indications

Arthritis Australia fully supports the proposal to establish a list of permitted indications for listed medicines in the ARTG and the proposed criteria for inclusion of an indication on the permitted indications list. We favour option 2 under which applicants could draw permitted indications from core permitted indications which can be modified with pre-approved qualifiers.

Claiming evidence of efficacy

We support the proposal to allow sponsors to claim that products assessed via the new pathway have been independently assessed for efficacy for the approved indication(s), providing the use and presentation of the claimer is approved by the TGA.

Allowing these claims will be critical to highlight to consumers those complementary medicines that have proven efficacy and have undergone the more rigorous independent assessment required under the new pathway. Ideally the claimer should also include a visual identifier that is standardised and easily recognised and understood by the consumer.

Consumer education and information

A consumer education campaign should be a central component of the implementation plan for the proposed new regulatory arrangements. The education campaign should explain the regulator's role in approving complementary medicines and the different evidence and assessment requirements for each of the three assessment pathways. The campaign should also highlight the claimer statements and explain any visual identifier that is adopted to identify those complementary medicines that have undergone independent assessment for efficacy (and, as we propose, safety) by the regulator.

Post market monitoring

Arthritis Australia has previously expressed its concerns about the high rates of non-compliance with evidence requirements uncovered by TGA in its post-listing compliance reviews for products listed on the ARTG. We welcome the statement that the TGA will increase its post-market compliance monitoring for these products.

In addition to greater levels of post-listing monitoring, it is important that real and meaningful sanctions and penalties for non- compliance are implemented, to underpin confidence in the regulatory system and enhance compliance.

Penalties need to far outweigh any potential benefit. Civil penalties and enforceable undertakings, such as corrective advertising, should apply for breaches. The TGA website should also provide information about products which have been subject to compliance reviews and the outcome of those reviews, including any sanctions or penalties incurred. These requirements will act as an effective deterrent against transgressions as well as providing consumers, health professionals and pharmacists with important information regarding the integrity of the manufacturing company.

About Arthritis Australia

Arthritis Australia is the peak arthritis consumer organisation in Australia and is supported by affiliate offices in the ACT, New South Wales, Northern Territory, Queensland, South Australia, Tasmania and Western Australia.

Arthritis Australia provides support and information to people with arthritis as well as their family and friends. It promotes awareness of the challenges facing people with arthritis

across the community, and advocates on behalf of consumers to leaders in business, industry and government.

In addition, Arthritis Australia funds research into potential causes and possible cures as well as better ways to live with the disease.

Further information

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[3] Williamson M, Tudball J, Toms M, Garden F, Grunseit A. Information Use and Needs of Complementary Medicines User. National Prescribing Service, Sydney. December 2008