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Global Healthy Living Foundation Australia and CreakyJoints Australia

Submission for the Review of Medicines Australia's Code of Conduct Edition 19

To whom it may concern,

Thank you for the opportunity to provide input into the Review of Medicines Australia's Code of Conduct Edition 19. These comments are submitted by Global Healthy Living Foundation Australia (GHLF Australia) and CreakyJoints Australia on behalf of our patient communities.

About our global organisation

CreakyJoints was co-founded in the US in 1999 by arthritis patient and advocate Seth Ginsberg (diagnosed with spondyloarthropathy at age 13) and social entrepreneur Louis Tharp. In 2007, the Global Healthy Living Foundation was established as the umbrella organisation.

GHLF advocates for improved access to healthcare in many countries both locally and nationally, amplifying education and awareness efforts within its social media framework for people living with chronic conditions including inflammatory arthritis, psoriasis, osteoporosis, alopecia areata and many others.

Central to this advocacy is GHLF's commitment to educating the community about the importance of early diagnosis and intervention, optimal condition management and long-term lifestyle improvements for improved health outcomes.

About Global Healthy Living Foundation Australia and CreakyJoints Australia

Established in 2014 and incorporated in 2016, Global Healthy Living Foundation Australia (GHLF Australia) is the parent organisation of CreakyJoints Australia, and both are proud to be part of GHLF. Founded in 2015, CreakyJoints Australia is a leading source of information for Australians living with the many forms of arthritis and related conditions, along with their families.

Drawing on nearly two decades of foundational knowledge, success and the reputation of GHLF and CreakyJoints, GHLF Australia and CreakyJoints Australia aim to localise, mobilise and engage Australian health consumers and to provide education, advocacy, research and co-design opportunities for better health outcomes. (For this submission, our use of the term "health consumers" includes patients and those who care for them along with people who use health services more broadly.)

As an organisation, we participate in a range of health advocacy activities, including writing submissions for new/updated treatments to be considered by the Pharmaceutical Benefits Advisory Committee (PBAC), joining other stakeholders to promote relevant health awareness campaigns and providing input for health research projects.

We provide personalised opportunities for Australian health consumers to:

- Advocate for important state and national health care policies that directly impact their access to care via providing us with comments for submissions and sharing their stories for awareness campaigns.
- Have their voices heard through personal stories and comments published by our organisation across our media platforms and in content published by other parties such as Rheumatology Republic.
- Be directly involved in research and health policy design via opportunities we share on our platforms.

Essential to our work as a consumer organisation is our regular engagement with representatives from industry bodies (such as the Australian Rheumatology Association and Arthritis Australia) and pharmaceutical companies. This allows us to receive important information from these parties and to share our expert knowledge of our health consumer community, their needs and their opinions with these parties. We act as an essential intermediary between pharmaceutical companies and the consumer communities they serve.

About our team

GHLF prides itself on being a patient-led organisation. To us, this includes both being led by the needs and voices of our community and having people with chronic conditions in our leadership roles.

Our Australian team is led by Naomi Creek and Rosemary Ainley who both live with autoimmune arthritis. Naomi and Rosemary often participate in and co-design research projects as individual consumer representatives.

Our focus for this submission

We support Medicines Australia's aims for reviewing the Code of Conduct Edition 19 which are:

- Ensuring the Code remains relevant in light of the changing roles and practices of the wider industry and the patient and professional community.
- Continuing to align with international self-regulation and domestic policies, legislation, standards, other regulatory norms, and community expectations.
- Clarifying any requirements where experience with the Code suggests there may be ambiguity.
- Updating guidance and resources in line with these objectives.

Our submission asks the Code Review Working Group (CRWG) to consider not only the ethical and appropriate sharing of information by pharmaceutical companies with health consumers and consumer organisations but also how these cohorts can have meaningful input into the activities of pharmaceutical companies.

We believe this would reflect the increasing role of health consumers being involved in all decisions related to their care — from personal decisions about treatments to national and global health strategies.

Acknowledgement of the overarching principles of the code

The overarching principles of the code are:

1. All activities undertaken by Companies have the purpose of supporting the quality use of medicines.
2. Companies are committed to transparency in their interactions with healthcare professionals and other stakeholders, to maintain trust and confidence in the industry.
3. As the primary repository of information relating to their products, Companies are responsible for providing current, accurate, balanced, and scientifically valid information on products to support their appropriate use. The same standards apply to all other Company communications.
4. Company employees, and anyone acting on behalf of a Company, will be appropriately trained on the Code and maintain a high standard of ethical conduct and professionalism in the discharge of their duties.
5. Consistent with our ethical undertakings, nothing is offered or provided by a Company in a manner or with conditions that would have an inappropriate influence on the approval, recommendation, prescribing, and/or use of a product.
6. Companies' interactions with all stakeholders are at all times professional, consistent with all legislative requirements, and appropriate to the information needs of the respective audience.
7. Information relevant to prescribing, in particular product and safety information, are clearly communicated in all promotional materials. Promotional materials are designed by Companies to not only create awareness of Therapeutic Goods Administration (TGA) approved medicines, but to support proper assessment of their risks and benefits.
8. All promotional claims are consistent with the Australian Product Information document, including claims about competitor products, irrespective of the source on which the claim is based.
9. All events, initiated or sponsored by Companies, are reasonable and appropriate with respect to hospitality, travel and accommodation, therefore upholding the integrity and reputation of the industry.
10. All activities undertaken by Companies are clearly identified to their audience as a Company activity by the inclusion of the Company's name and city/town of the Company's Australian office.

We fully support all the overarching principles that govern the code. However, we call on the CRWG to consider either rewording the current principles or adding a new principle to cover the increasing role of consumers and consumer organisations in areas including (but not limited to):

- As sources of valuable expert information on an array of subjects including gaps in available treatments or access to treatments, feedback on current treatments and lived experiences of health issues.
- As partners in research and development planning and implementation.
- As planners of or presenters at sponsored and third-party events for various stakeholder groups.

Our comments on key topics

In the consultation paper for this review, the CRWG highlighted several topics on which it would welcome comments from members and other stakeholders.

1. New Technologies for communication with healthcare professionals
2. Informing the general public about the availability of new products and new indications
3. Scientific Exchange with healthcare professionals
4. Improving inter-company dialogue in relation to complaints
5. Engaging non-member companies in the complaints process
6. Improving Code guidance resources
7. Emerging trends from Australia and internationally

Rather than commenting on each of these topics, we have based our submission on the general themes that relate to our key focus and the above suggestions. We have not provided comments on the sections that we either endorse as they are now or that are not relevant to us.

We understand that the code is based on principles rather than specific directives, however, we have provided some examples of interactions with consumers/consumer organisations the code could be reworded to reflect.

We also understand that there are legal limitations in the types of information pharmaceutical companies can share with health consumers and how this information can be shared. Yet, these information exchanges already occur within the confines of the law. We believe there are countless more ways such exchanges can occur to the benefit of all parties.

Theme 1: Research and advocacy

It appears the code mainly considers the sharing of end-product information (such as consumer medicines information leaflets, media releases or interactions with health professionals. However, we believe engagements that occur during product development stages should also be looked at.

For example, there is a growing place for health consumers to not only participate in clinical trials but to have a say in how they are designed and implemented. Consumers are also increasingly involved in all aspects of qualitative and quantitative research with other professional researchers. Some of these projects may be connected to pharmaceutical companies.

Consumers and consumer organisation representatives also regularly participate in focus groups conducted by pharmaceutical companies. These often include consumers sharing their lived experience of certain conditions or giving their views on unbranded medical delivery devices or trials of online services.

Other examples of consumer participation in action

In its submission for the 2024 Federal Budget, the Consumers Health Forum of Australia called for a range of actions to support Australian health consumers. They stressed that our health system needs to be consumer-centred and consumers need to be more empowered to be partners in their care.

Their top four recommendations were:

1. The Commonwealth Government fund CHF $8 million over 4 years to identify, train and support 100 new health consumers to represent the consumer voice in decision making bodies relating to research, health policy, service design and delivery.

2. The Commonwealth Government fund CHF to coordinate the development of consumer training, support and resourcing to improve the engagement of the consumer voice in health research and therapeutic goods.
3. The Commonwealth Government fund CHF $600,000 across 4 years for biannual consumer healthcare conference and best practice awards.
4. The Commonwealth Government fund CHF $6 million over 4 years, to lead a multiyear cross sector collaborative which seeks to improve the working relationship and experience between consumers and practitioners.

The European Congress Of Rheumatology (EULAR) annual congress features a EULAR PARE (People with Arthritis and Rheumatism in Europe) program. This program includes dedicated representatives of consumer organisations who use their acquired knowledge to educate and influence a wide range of stakeholders about rheumatic and musculoskeletal diseases. Consumer organisations are actively encouraged to submit their abstracts and they may also receive bursaries and awards.

In Canada, patient organisations are regularly invited to virtual briefing sessions by pharmaceutical companies on how to advocate for new innovative treatments at the federal, provincial and local levels. We know there are underlying interests in sharing this information, but we believe that is mutually beneficial.

In the US, Amgen runs an "Amgen Mission Week". This is an internal event for the company that features in-person and virtual panels with primarily patients, with varying conditions who are given a platform to speak to all Amgen staff about whatever panel topic this might be. This is a way Amgen started connecting purpose to what their staff do in that could see and hear from patients how innovative treatments can change lives, amongst many other things.

We believe this is something that all pharmaceutical companies should be doing. It is a constructive way to engage consumer and consumer organisations and give them a company-wide platform to speak to the people making treatments, etc. Consumers may also be invited to tour the pharmaceutical company's head office or laboratory.

In Australia, we could look at creating a platform through which healthcare professionals, pharmacists, consumers and carers could unite to speak about consumer-centred shared-decision making. Even if such activities are not implemented here, we believe the Medicines Australia Code of Conduct needs to be future-proofed to cater for activities of this kind.

Information exchanges

The code currently states that communication with stakeholders who have a role in the research, development, registration, listing or monitoring of a therapeutic good is inherent in the National Medicines Policy and in the concept of the quality use of medicines. Companies are permitted to communicate proactively or reactively with relevant stakeholders, provided that discourse is limited to information that may assist the stakeholders in their role. We recognise that the term "stakeholders" includes health consumer organisations, advocacy groups and individuals in this context.

In addition to the comments we have made above, we ask the working group to consider two other areas of information sharing the code might be reworded to cover.

The first is the communication that occurs at trade displays, third-party scientific or medical conferences and other events that non-healthcare professionals can attend. Consumer organisation representatives

attend many such events and the representatives are often health consumers themselves. Dialogue between pharmaceutical companies and consumer organisations in these contexts often involves discussion of a product, what its pros and cons are and how a product could help a specific patient community.

The other is the product information provided by pharmaceutical companies to consumer organisations about specific medications or devices coming up for consideration by the Pharmaceutical Benefits Advisory Committee (PBAC).

Organisations like ours rely on such information to create submissions for the PBAC advocating for such products to be subsidised through the Pharmaceutical Benefits Scheme. However, it seems to us the code implies pharmaceutical companies should only provide product information to people already prescribed the product and must not be promotional. Perhaps the code review could clarify this.

Consultation arrangements, sponsorship and support for consumers and consumer organisations

The current Code of Conduct already covers these areas in many ways. We would like to see it also touch on the following areas.

Consultation remuneration

Consultation arrangements with healthcare providers are mentioned but similar arrangements with consumer experts should also be mentioned. For example, remuneration for this cohort should be appropriate and in line with the remuneration of other health experts.

Sponsorships

We know pharmaceutical companies can sponsor consumers and consumer organisations to attend various events but opportunities for this form of support are scarcer than they need to be. Is this because of concerns about potentially violating the rules against the promotion of products to the public? More clarification is needed around the circumstances that allow such events. For example, could a consumer researcher be sponsored to attend an event where their research project will be presented?

To avoid potential bias if a pharmaceutical company sponsors an individual consumer or group of consumers to attend an event, perhaps all the event sponsors could be required to contribute a fixed amount to a fund pool managed by the organising party. That party could then use the fund pool to sponsor consumers to attend the event so there is no direct link between the consumers and the contributing pharmaceutical companies.

Alternatively, perhaps pharmaceutical companies could offer some sponsorship dollars to consumer organisations which they could use to nominate appropriate staff members or other consumers to attend such events in general.

Grants for specific projects

We know pharmaceutical companies have budgeted funding that can be given to consumer organisations to use for valuable projects that serve their community and we appreciate and rely on this. At times, though, consumer organisations can feel overly restricted in how they can use such grants or pressure to use the money in areas that are not part of their main objectives. We ask the working

group to consider adapting the code or related resources to ensure subtle coercion like this can be avoided.

Interactions with the general public

Consumer medical information

Pharmaceutical companies already engage directly with the public in several ways, including via consumer medicines information leaflets and patient support programs. They may also run focus groups with consumers to gain a variety of insights on user experience. The code touches on these but there is some ambiguity around if some of the information shared this way might be considered promotional.

Also, many health consumers are both health and computer literate so they often access product information online, including via pharmaceutical company websites. The information they find may influence the products they talk to their medical team about and may end up receiving. Is that promotional?

Patient support programs

The Code of Conduct states that companies are permitted to conduct programs, with or without involvement from a health consumer organisation, that aim to increase patient compliance with, and positive patient health outcomes from, their prescribed medical treatment. These are generally excellent but we are not sure how many of these are co-designed with health consumers or consumer organisations. Should all patient support programs be co-designed with at least one consumer representative? If so, should the Code of Conduct reflect that?

While patient support programs themselves might not come under the scope of the Code of Conduct the content offered via such programs might. For example, information on program websites or in physical welcome packs offered to participants may include product information or practical tips for self-injection.

We believe some promotion of product support programs is still via printed information inserted in relevant product packaging. We would like to see more ways for such programs to be promoted via digital means, such as via dedicated program apps or QR codes on product packaging. Pharmaceutical companies could also involve consumer organisations more in creating awareness of such programs. Perhaps the working group could consider how the code relates to these forms of information sharing.

Additional feedback for the Code of Conduct working group

This suggestion might not come under the scope of this review but we believe there needs to be a better mechanism for consumers to learn about medicine shortages before they find out too late. Could there be some sort of central database consumers can opt in to that allows them to receive such notifications via SMS, for example?

Finally, if the working group considers any of our suggestions to be beyond the scope of this review, could a separate document be added to the Code Resource Toolkit to cover health consumer engagement?

Once again, we would like to thank you for allowing us to participate in this review and also for allowing us extra time to prepare this submission.

Kind regards,

Rosemary Ainley on behalf of GHLF Australia and CreakyJoints Australia