Senate Community Affairs References Committee – Inquiry into consumer access to pharmaceutical benefits

Issues taken on notice – Australia New Zealand Bone & Mineral Society, represented by Markus Seibel MD PhD FRACP

Question by Senator FIERRAVANTI-WELLS

"Professor Seibel, should I infer from your comments that you think that the TGA definition that you referred to would be a sound definition of interchangeability? If not, what do you think should be the definition? If you do not want to elaborate today, please feel free to give us a considered written response."

Reply:

ANZBMS suggests the following definition for the term 'interchangeability':

In the broadest sense, 'interchangeability' is a condition where there are two or more items with characteristics making them equivalent in performance and effect. Applied to pharmaceuticals, interchangeability would include both bioequivalence and therapeutic equivalence, including safety. Interchangeable drugs are therefore drugs that (i) have the same quantity, quality and composition in terms of active principle, (ii) have the same pharmaceutical form and (iii) are bioequivalent unless it is evident from scientific knowledge that the medicines differ significantly as regards safety or efficacy.

The ANZBMS recommends adopting the above wording to define the term 'interchangeability" within the context of Therapeutic Groups".

2. Comments by **Senator MOORE**

The second thing is whether you could consider the doctor-patient relationship in this process. You may have heard my questions to previous witnesses about the whole role of the doctor-patient relationship being critical in the area of medication. In an inquiry last week, the issue was raised about the doctor-patient relationship and how much conversation goes on about choice with consumers and their families. Would any of you like to give some information on notice about how often and how valuable these conversations are? We have heard that this could create more confusion—the drugs being grouped and the role of the doctor. It is about talking with your doctor—what kinds of issues come into it and how is price discussed? Perhaps you could give us

something on notice about that whole process. The legislation does not say which drugs you can have but it does put the onus back on the discussion you have with the practitioner. You can take that on notice.

Reply:

The ANZBMS maintains that the doctor-patient relationship is a critical one in conditions like osteoporosis where long-term persistence and adherence to medication is necessary to prevent fractures. We recognize this as the biggest challenge we have to reduce the burden of osteoporosis. In this regard our conversations with our patients including an explanation of why a particular medication is being prescribed are vitally important. Even if the legislation does not specify what drugs the patient can take, practically speaking this often happens by the time the patient presents a prescription to their pharmacist. Grouping of drugs creates confusion in the mind of patients and makes them less likely to recall the reasons why a particular formulation was prescribed, which can include many individual patient factors the doctor considers during the patient consultation.

3. Comment by the CHAIR

I have one question which you may want to take on notice. I absolutely get the issues around interchangeability and the process, but are you saying to the committee that you do not think that the therapeutic group process is a good process at all? We heard from previous witnesses that they do not like it at all. Are you saying that you would think it would be better to get rid of that or are you saying that the process needs to be improved regarding interchangeability?

Reply:

ANZBMS cannot comment on how the process of interchangeability has worked for other medications. However, our experience in regard to the proposal for interchangeability of bisphosphonates certainly did not follow a process that involved consultation with stakeholders before the decision was made. In the past our Society has had good interaction with the PBAC with a consultative process in which our views have been sought on patient related matters. This did not occur on this occasion. Our view is that if the process of interchangeability is to remain, the excellent dialogue and consultative process that existed before needs to be reinstated. Furthermore, ANZBMS wishes to preserve choice for treating physicians without financial discrimination for the patient as doctors individualise choice appropriately given patient co-morbidities and circumstances. Therapeutic grouping will remove this choice.