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Medical Devices Fairer Access Consultation

1. **Introduction**
   Thank you for the opportunity to comment on the consultation document 'Managing Fairer Access to Hospital Medical Devices'.

2. **The New Zealand Orthopaedic Association**
   The New Zealand Orthopaedic Association (NZOA) is the professional organisation representing Orthopaedic Surgeons in New Zealand. The NZOA advocates on behalf of Orthopaedic Surgeons and their patients, oversees the Orthopaedic SET Training Scheme, and issues grants for Orthopaedic research under the Wishbone Foundation. The NZ Joint Registry and the NZ Hip Fracture Registry are part of the wider group of entities supported by the NZOA.

   The following comments are specific to implant devices used in Orthopaedics.

3. **Cost Effective Purchasing**
   PHARMAC's primary focus is stated to be about reducing the cost of purchasing medical devices, and by implication that lower cost devices will lead to savings. We understand that New Zealand is one of the more expensive device markets in the world, and that other countries have achieved discounting on the prices they pay. We agree some savings can be made, but we are also mindful that New Zealand is a small market with relatively high logistics and support costs, which contribute to the higher costs that we pay.

   Orthopaedic implants are well studied and monitored by international and local Registry data. Today people in their mid-60's have more than a 90% chance of finishing their life with their primary implant. Failure of joint replacements is increasingly unlikely, however there will always be implants that fail for a variety of reasons.

As most joint implants will outlast their recipient, it is important that good choices are made at implantation. Initial cost considerations are only one factor to be taken into account. The lifetime cost of the implant, and the impact on patient outcomes and quality of life are more important considerations.

4. **Industry Technical Support**

The complex range of Orthopaedic procedures and the associated instrumentation and its inventory are challenging for everyone, in particular the nursing and hospital staff. Company representatives play an invaluable role in guiding theatre nurses through the procedure and are often required to assist the Surgeon in terms of the instrumentation. Without the company representatives, complex cases would be more difficult and more time consuming. Nurses cannot be expected to be fully conversant with all of the systems used in a department. At times, company representatives also operate assisted technology which supports the Surgeons to place implants e.g. neuro-monitoring and interoperative CT in Spine. Regular attendance of industry representatives in high volume units is customary for these reasons. Loss of that industry support would cost far more that what it would save in terms of time in the operating room and safety.

5. **Industry Educational Support**

Continuing education underpins Orthopaedics. The device industry runs educational courses for nurses, registrars and consultants. The industry also provides sponsorship for Orthopaedic Scientific meetings. Many device companies support cadaver training and direct observation of surgery leading to better Orthopaedic outcomes. Loss of this educational support would be deeply concerning to the NZOA.

6. **PHARMAC Managing 'the List'**

New Zealand Orthopaedic Surgeons have been responsible in their implant choices, and the New Zealand Joint Registry has been an important influencing factor in decision making. The comparative lack of product failures in New Zealand reflects favourably on our Trainee Selection, Training Programmes and the New Zealand personality in general. So whilst the New Zealand market has to date been open, sensible and conservative decisions have been made in the choice of implants. We welcome the ability of PHARMAC to achieve some price reductions, but consider that the Surgeon together with the patient should be the sole determiner as to the choice of implant.

7. **The Regulatory Regime**

The Therapeutic Products Regulatory Regime is soon to be introduced into New Zealand. Much of the detail of the proposed regulatory regime is unknown as it will be contained in regulations. This is a completely new approach to pre-market and post-market surveillance of implant devices, and the impact on the market is as yet unknown.

There are numerous examples of overly restrictive regulatory regimes internationally, including the US FDA and the TGA in Australia. Both regimes are known to have unduly restricted access to certain technologies which have resulted in those countries using relatively old and less successful implants.

The combination of a restrictive regulatory regime, with a centralised procurement agency may dramatically alter the New Zealand environment. Introduction of a new and unknown regulatory regime at the same time as PHARMAC moves to contract and manage a list of devices, is most unwise. Consequent changes to the market could be difficult to rectify.

8. Introduction of New Technology

Orthopaedic implant devices often undergo regular iterative improvements in safety and performance. Obtaining approval via the new Regulator to introduce these improvements to the New Zealand market, and then obtaining PHARMAC consent to purchase the improved device is likely to lead to considerable delay to market. PHARMAC has a very poor track record of introducing new pharmaceuticals into the New Zealand market, and we have no reason to expect this will be any different with devices. The combination of a restrictive regulatory regime and the ultra conservative approach by PHARMAC to purchasing will likely greatly disappoint Orthopaedic Surgeons should they find device choices to be overly limited.

9. Range of Devices in Scope

International registry data, and in particular the New Zealand Joint Registry data has already led to consolidation of Surgeon implant device choices. There is no need for PHARMAC to manage any such list of devices. This is considered to be an unnecessary and bureaucratic intervention into a market that is already performing reasonably well. When a patient requires a particular device, then that implant needs to be promptly available. For revisions, they may be implants as old as 30 years, meaning the availability of relevant and appropriate industry support will be crucial. Consolidation of the industry is already occurring. If the regulatory regime and PHARMAC's actions together result in the rapid departure of many device companies from New Zealand, then the required technical and educational support will not be readily available. This will greatly impact on patient care and outcomes.

10. Stock Management

The Orthopaedic device industry has traditionally provided hospitals with consignment stock. This produces great savings with logistics, and we would suggest it would be much more expensive to move the kits in and out of hospitals on a regular basis. Consignment stock is more likely available where there is sufficient turnover of stock sufficient for the companies to cover their costs. The set supply is part of implant provision and the costings of the instrumentation set are usually part of the overall implant cost. Kits frequently need repair or replacement and sometimes are lost. Traditionally, the device industry has supplied implants and instruments on consignment, meaning the DHB's have very little inventory costs. For example, Burwood Hospital has 13 knee and 27 hip arthroscopy instrument sets worth approximately $3.2 million. This figure doesn't include revision sets which tend to be even more expensive. A purchasing model that results in the reduction of consignment stock and instrument sets will significantly impact on productivity in hospitals.

11. Expert Medical Advice

The provision of expert advice is problematic for PHARMAC. Any expert Orthopaedic advice needs to encompass all of the Sub Specialty areas. The expert advice required in exceptional circumstances is the advice given by the specific Orthopaedic Surgeon for that particular patient.

12. Assessment of New Technology

There are successful and respected international groups that assess new Orthopaedic implants. We suggest that PHARMAC does not attempt to undertake this role, but that they leverage off the excellent work already undertaken internationally.

13. Concluding Remarks

Orthopaedic Surgeons have and will continue to modify their implant choices based on the New Zealand Joint Registry data together with other international registry results. To change a preferred implant requires the Surgeon to learn the intricacies of the new implant. This means that patients must go through the learning curve which unfortunately can include some less than perfect results. Given the number of implants now in place, there needs to be guarantee of supply for revision surgery. There is a need for a range of device companies to remain active in New Zealand because no one company has the intellectual property for all options that might be required across all Orthopaedic Sub Specialties. We urge PHARMAC to exercise caution in the interference in the New Zealand Orthopaedic device market. Cost savings to the taxpayer are always welcome but care needs to be taken to understand that the 'cost' of a device encompasses much more than the actual device and instrumentation, but includes technical and educational support and stock management.

We are very concerned that the implementation of the Therapeutic Products Regulatory Regime at the same time as PHARMAC imposes centralised purchasing for medical devices will lead to a reduced availability of implant choices, potentially leading to poorer patient outcomes and dissatisfied Orthopaedic Surgeons. We support PHARMAC collecting information on the device market and ensuring competitive contract prices. We don't consider a restrictive device list is a necessary or progressive step.

We look forward to further consultation and involvement with PHARMAC as they progress through their consultation.

Yours sincerely

Andrea Pettett
Chief Executive