SUBMISSION: ENQUIRY RE THE REGULATION STANDARDS FOR THE APPROVAL OF MEDICAL DEVICES

In 2008 I had the misfortune to have a Johnson & Johnson ASR left hip replacement implanted.
I have now had revisionary surgery to have this device removed. This has caused me to suffer considerable pain, great stress, and has left me with little expectation of ever completely regaining my health..
I have since learned that the device marketed by Johnson & Johnson (dePuy) had already shown signs of failing as far back as 2005, yet the surgeons continued to implant this prosthesis.
I find this very difficult to accept. I cannot understand why the implant was not totally withdrawn once problems were evident. Surely this is the province of the TGA?
I had the device in my body until the last week of January 2011. On 28th January I underwent revisionary surgery, was hospitalised for three weeks and needed care for several months post-surgery. I believe that I still have to undergo further investigative processes.
At this point in time I doubt that I will ever regain my health. I am 78 years of age and until I suffered the after-effects of the 2008 surgery I would have presumed that I would have been able to continue to lead a healthy and active life-style.
My health has deteriorated to a point where I have difficulty with walking, gardening (now non-existent), doing normal household chores, shopping and caring for my invalid husband etc.
Shortly after the first operation in 2008 I suffered what the medical profession suggested/determined was a mild stroke, and that perhaps I had another shortly afterwards.
I find it difficult to accept that the Australian trials for this device relied on data from overseas – and that there were, in actual fact, no Australian trials and investigations into the suitability of this prosthesis. Obviously the patient was the trial.
The revisionary surgery carried out on me showed an "Obvious pseudo tumour and pus coloured fluid. Sent for histology and microbiology. Capsulotomy performed. Extensive synovectomy".
Comment re Microscopic Description: "The histological features are those of chronic inflammation with fibrosis and focal pigment. Although these features raises the possibility of metalosis, the pigment appears scant"
My blood cobalt on 28/09/10 was 0.2 umol/L: On the 07/04/2011 my cobalt reading was H 39 nmol/L.
The extensive scarring to have the device removed has never healed completely, and, in fact I have developed two bursas. I suffer more pain that I did before the revisionary surgery took place.
RECOMMENDATION: I am not sure what I could recommend so that this does not happen to other Australians who would normally look forward to an increased interest in life, able to resume an active life. For a non-medical person such as I am it would not have made any sense to have been told the device was a metal on metal prosthesis, or indeed the name of the maker/distributor.
I would like to think that from this the TGA can put in place some further investigative processes which should be passed/approved by a regulatory authority.