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5 April 2012

Dear Healthcare Professionals,

Safety concerns over metal-on-metal total and hip resurfacing hip replacement systems

Your attention is drawn to the safety concerns over metal-on-metal (MoM) hip replacement implants, which have been raised by various recent publications, studies and registry reports.

One study recently published in "The Lancet" analysed data from the National Joint Registry of England and Wales for primary hip replacements undertaken between 2003 and 2011. Results indicated that (1) increased failure rate at 5 years was observed for MoM total hip replacements with larger head sizes; (2) significantly higher risk for revision was found among female patients; and (3) revisions for dislocation in men with MoM replacements were slightly lower, showing some benefit to larger head sizes. The authors suggested that patients with these implants should be carefully monitored, particularly young women implanted with large diameter heads. For the abstract of the article, please refer to the following link -

http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(12)60353-5/abstract

In fact, one of the earliest MoM hip implant systems found to be associated with a high failure rate was the ASR™ hip implant manufactured by Depuy Orthopaedics. The product was subsequently recalled from the global market in August 2010, due to a higher than expected revision rate at five years.

In late February 2012, the Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom issued advice about the management and monitoring of patients implanted with MoM hip replacements. The Agency was of the view that majority of the patients implanted with MoM hip replacements have well-functioning hips and were thought to be at a low risk of serious problems. However, a small number of them may develop progressive soft tissue reactions to the wear debris associated with the MoM articulations. The MHRA also provided management recommendations of patients with MoM hip replacements.

On 2 April 2012, the MHRA further advised orthopaedic surgeons to stop implanting MITCH TRH acetabular cups/MITCH TRH modular heads (Finsbury Orthopaedics) in combination with uncemented Accolade femoral stems (Stryker Orthopaedics) because the combination was found to have an increased revision rate (Cumulative revision rate of 10.7% at 4 years).

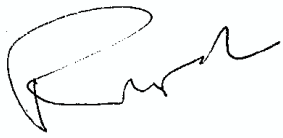
In Hong Kong, some 40 patients had received the Depuy ASR™ hip implants in both public and private hospitals. Regarding MITCH TRH acetabular cups/MITCH TRH modular heads, there was no record of the products having been distributed in Hong Kong. So far, there were no adverse incidents related to MoM hip replacements reported locally. While we shall monitor the issue closely, you are encouraged to report any adverse incidents related to MoM hip replacements to the Medical Device Control Office (MDCO) at mdco_alert@dh.gov.hk.

For more details on this issue, please refer to the information available from the MDCO's website –

http://www.mdco.gov.hk/english/recalls/recalls_20120201.html
http://www.mdco.gov.hk/english/recalls/recalls_20120229b.html
http://www.mdco.gov.hk/english/recalls/recalls_20120403.html

Thank you for your attention.

Yours faithfully,



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for Director of Health