Scientific Committee on Emerging and Newly Identified Health Risks

Request for a scientific opinion

on the safety of metal-on-metal joint replacements with a particular focus on hip implants

1. Background

A specific category of implants are those used for hip arthroplasty. This treatment is very successful in recovering unrestrained and pain free mobility in patients suffering from diseases such as advanced osteoarthritis, which accounts for about two thirds of all total hip replacements.

A preliminary evaluation indicates that the number of European patients implanted with metal-on-metal hip replacements is above 100.000[1]. Given the extensive use of these implants, considerable effort is put into increasing their life span. Since first-generation metal-on-metal (MoM) implants demonstrated problems with durability, alternative harder articulating surfaces were developed to decrease wear. These newer articulating surfaces are made of different materials, to which the second-generation MoM hip implants belong.

Metal-on-metal hip replacements offer the potential to decrease wear, but pose additional challenges such as the release of metal ions, including cobalt and chromium. Both metals are known to be toxic under specific circumstances. The health implications remain unclear, but concerns related to hypersensitivity reaction and subsequent osteolysis, T-cell infiltration and pseudotumor have been raised in a number of recent scientific publications. Long term effects are still not fully assessed especially in terms of carcinogenicity, genotoxicity and reproductive toxicity.

Besides their use in hip arthoplasty metal alloy implants have been used successfully in orthopaedics for years, for example in knee operations and fracture repair. All metal implants are known to release metal ions because of corrosion, but some metal-on-metal prostheses do so to a much greater extent than previously thought. In the case of total knee arthroplasty large metal surface areas are present leading to the possibility of increased release of metal ions.

[1] Based on data from FR, PT, DK, NO, NL, DE, AT, CZ, FI, CH, ES (mainly sales figures)

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2. Terms of reference

In the light of the above considerations, the Scientific Committee on Emerging and Newly Identified Health Risks is requested to provide a scientific opinion on 'The safety of metal-on-metal joint replacements with a particular focus on hip implants'.

In particular, the SCENIHR is asked:

1. To determine the short, medium and long term local and systemic health effects caused by metal particles, metal ions, metallo-organic compounds resulting from the implanted medical device and if possible to provide indications on limit values for the metals in any forms.

2. To advise on the predictive value of metal ions in body fluids, clinical strategies and other aspects needed to ensure the safety of implanted patients. Criteria that should inform the medical decision with respect to the implanted patient should be identified where possible.

3. To identify criteria regarding the safety and safe use of MoM implants used in arthroplasty, paying special attention to design and patient groups.

4. Where relevant to identify needs for further research.

3. Deadline

31 March 2013.