# Cobalt in Orthopaedic Implants

## Joint Statement of EFORT and MedTech Europe's Orthopaedic Sector Group

**14 August 2018**

Under the new Medical Devices Regulation[1], orthopaedic implants containing Cobalt (usually in alloy form) will most likely have to bear a label communicating the presence of Cobalt in the device. This may happen if the European Commission will adopt the proposal to classify Cobalt as a carcinogenic substance. The new labelling requirements aim at informing the user that a given medical device (such as an implant) contains a CMR (carcinogenic, mutagenic or reprotoxic) substance, but should also be understood as confirmation that the manufacturer has managed any risks posed by that substance. Therefore, the label should not give rise to concerns regarding the safety of orthopaedic implants.

EFORT and MedTech Europe are nevertheless concerned that this labelling requirement may cause unnecessary alarm among patients and healthcare professionals, especially with regard to orthopaedic implants that have a long history of safe clinical use.

The indication, via the product label, that an orthopaedic implant contains a CMR substance is a new regulatory requirement of the Medical Devices Regulation. The labelling of a medical device is a 'final step' taken by the manufacturer after conducting a risk assessment of the potentially hazardous substances contained in the device, and concluding that the benefits outweigh the risks.

While a substance may be classified as a CMR based on its intrinsic toxicological properties, for some routes of exposure (e.g. inhalation) or in a specific chemical form, it may not have the same hazard profile as when present in a mixture, such as an alloy. However, the labelling requirements under the Medical Devices Regulation do not take this into account and apply irrespective of whether a CMR substance would pose any risk, potentially misleading the users and the medical community as to the safety of the device. Where a medical device's label communicates the presence of a CMR, it should be clear that only the substance *itself* is classified as hazardous, but any risks resulting from its presence in the device have been duly assessed, minimised and managed.

[1] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices

Data from MedTech Europe's Orthopaedic Sector Group confirm that the amount of Cobalt released from Cobalt Chrome alloys in orthopaedic implants correspond to merely 1/25 of the exposure which is necessary to detect any systemic effect in patients. In a small subgroup of special implants for hip reconstruction with metal-on-metal (MoM) bearing surfaces there may be an elevated metal ion release, but similar effects have not been shown for Cobalt Chrome or Stainless Steel implants with non-MoM bearings. Detailed analyses of the published long-term, large patient group epidemiological and meta-analysis studies of over 60 years of clinical use in orthopaedics demonstrate no causal relationship between Cobalt Chrome or Stainless Steel implants and carcinogenic effects.

The new legal requirement to label orthopaedic implants containing Cobalt does not change this. Demonstration of the implants' safety is an intrinsic prerequisite for obtaining regulatory approval and placing those implants on the EU market.

*The **European Federation of National Associations of Orthopaedics and Traumatology (EFORT)** is the platform organisation linking Europe's national orthopaedic associations. Its aims reflect the will of all the participating associations to promote the exchange of scientific knowledge and experience in the field of prevention and both the conservative and surgical treatment of diseases and injuries concerning the musculo-skeletal system. To this end, particular emphasis is placed upon activities focusing on education and research.*

***MedTech Europe** is the European trade association representing the medical technology industries, from diagnosis to cure. Its members are multinational companies and national medical technology associations operating in Europe and worldwide. There are more than 500,000 products, services and solutions currently made available by the medical technology industry. These range from bandages, blood tests and hearing aids to cancer screening tests, pacemakers and glucose monitors. The sector employs more than 675,000 people. There are more than 27,000 medical technology companies in Europe, of which 95% are small and medium-sized enterprises (SMEs).*