THALASSAEMIA INTERNATIONAL FEDERATION
In official relations with the World Health Organization

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Position Statement of the Thalassaemia International Federation on the use of DEHP plasticisers

The Thalassaemia International Federation (TIF)[1] expresses its opinion concerning the use of DEHP plasticizers, on the occasion of the publication of guidelines prepared by the European Commission's Scientific Committee on Health, Environment and Emerging Risks (SCHEER) in June 2019 and the consequent decision to phase out the use of this plasticiser from 2023[2].

BACKGROUND: *Di-(2-(ethylhexyl) phthalate (DEHP) is the most widely used plasticisers in medical devices. Among these devices are PVC intravenous fluid giving sets and blood bags. This raises the possibility that phthalates may be released directly into blood stream of a patient. For many years the danger of toxicity has been under investigation with possible reproductive toxicity, endocrine disruption, mutagenicity and carcinogenicity.*

TIF, a patient driven organisation, has for many years been concerned for possible toxicity in multi-transfused thalassaemia patients whom it represents. As these patients receive life-long blood transfusions every 2-4 weeks from infancy, their ***exposure to DEHP is both immediate, and possibly accumulative over the years***, from the early paediatric age through the endocrinologically sensitive period of adolescence to adulthood. These patients experience complications classically attributed mainly to iron toxicity, which include delayed puberty, infertility and endocrine complications. In addition, liver disease, progressing to cirrhosis and hepatocellular carcinoma are increasing in frequency as patients advance in age. These liver complications have been attributed to hepatitis viruses and iron overload, but a possible contribution from phthalates cannot be ruled out. The incidence of other malignancies is also increasing with age in thalassaemia patients and research activity in this area is significantly strengthened.

Recognising that it is difficult to separate and confirm by evidence the contribution of DEHP to organ toxicity from other possible causes (such as iron toxicity in thalassaemia patients) TIF is sharing its concern with scientists, academics, patients, industry and decision-makers on the possible damage that phthalates may cause over time to regular and direct exposure.

TIF therefore, welcomes the serious review and recent opinion expressed by SCHEER, and the possibility of phasing out its use in the near future.

TIF also strongly supports the SCHEER guidelines, which aim to test the safety of *alternative plasticisers*, which are candidates to replace DEHP in the future. The safety of regularly transfused patients, not only with thalassaemia but with other anaemias and kidney failure patients on dialysis for example, depends on careful assessment of risks as well as benefits. It is TIF's responsibility to ensure patient safety and guide its member associations on advocacy, so that the best possible patient outcomes are safeguarded.

[1] The Thalassaemia International Federation (TIF) is a patient-oriented non-profit, non-governmental umbrella federation, established in 1986 with Headquarters in Nicosia, Cyprus. Our mission is to promote access to optimal quality care for all patients with thalassaemia worldwide. To-date membership boasts 232 members from 64 countries across the globe. TIF works in official relations with the World Health Organisation (WHO) since 1996 and enjoys active consultative status with the United Nations Economic and Social Council (ECOSOC) since 2017 and the Council of Europe since 2019. Most remarkably, TIF has been awarded, in the context of the 68th World Health Assembly in May 2015, the *'Dr Lee Jong-wook Memorial Prize'* for the Federation's outstanding contribution to public health. More information about the Federation is available at www.thalassaemia.org.cy

[2] https://ec.europa.eu/health/scientific_committees/consultations/public_consultations/scheer_consultation_08_en