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Dear Dr João de Deus,

Dr Nicolino D'Autilia,

Dr Katrín Fjeldsted,

Dr Claude Schummer,

Dr Carsten Mohrhardt,

Mr Jannis Papazoglou,

Dr Enrico Reginato,

Dr Aldo Lupo,

Dr Romuald Krajewski

Subject: CEN standards for healthcare services

Thank you for your letter of 16 December regarding CEN standards for healthcare services, in particular the CEN standards for aesthetic surgery.

I am fully aware of the opposition of the medical organisations to European standardisation in the area of healthcare services and can confirm that the European Commission does not have the intention to request the European standardisation bodies to draft standards in the area of healthcare services.

As you will note in the Annual Union work programme on standardisation for 2016, the Commission is setting priorities for the standardisation for the coming year(s) directly linked to the Commission's priorities for e-health set out in the Digital Single Market Strategy and the Internal Market Strategy - but not in relation to healthcare services.

For further information,see http://ec.europa.eu/growth/single-market/european-standards/policy/index_en.htm

With regard to CEN standard for aesthetic surgery services, it is outside the Commission's competence to prevent the European Committee for Standardisation from working on European standards that have been initiated by national standardisation bodies. The Commission's competence is limited to ensuring that European standards are developed in line with the principles of the Standardisation Regulation (1025/2012) and the Commission's Communication "More standards for Europe and faster" of 2011. This means, *inter alia*, that standards are voluntary, demand-driven and developed in an inclusive process.

I would like to stress that European standards supersede any relevant national standards in the particular area but remain purely voluntary so service providers are not obliged to adopt them unless they want to. To be applicable in practice, European standards cannot contradict legislation and do not aim at replacing it where it exists. Such standards therefore would not create an obligation for doctors to comply with them.

I would be pleased to meet with the representatives of the European medical organisations to discuss more broadly your work in the area of healthcare.

Yours sincerely,