Human tissues and cells: quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution

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The Commission presents its **Second Report** on Voluntary and Unpaid Donation of Tissues and Cells in accordance withDirective 2004/23/EC. The report is based on the Members States' responses to a report template on voluntary and unpaid donation of tissues and cells. All Member States submitted a report to the Commission. In addition, Liechtenstein and Norway submitted a report (in total 29 reporting countries).

The report aims to provide an overview of the practice of voluntary and unpaid donation of tissues and cells, focusing on 1) legislative provisions, guidelines and policies; 2) compensation and incentives; 3) promotion and advertising, and 4) procurement and supply.

Compliance: the report shows that Member States overall comply with Article 12 of Directive 2004/23 /EC, requiring Member States to take the necessary measures to endeavour to ensure voluntary and unpaid donations of tissues and cells. Largely in line with the findings of the first report on voluntary and unpaid donation of tissues and cells (issued in 2006), this report shows that legislative provisions and guidelines on voluntary and unpaid donation of tissues and cells are well established across the EU. 27 out of the 29 reporting countries have such legislative provisions or guidelines in place.

Compensation: 19 of the reporting countries have some form of compensation or incentive structures for donors of tissues and cells (excluding reproductive cells), such as reimbursement of travel and medical costs. For reproductive cells, about half of the countries provide some forms of compensation or incentives, including reimbursement of travel costs, refreshments and compensation linked to loss of earnings. In addition, four countries give some form of compensation or incentives to relatives of deceased donors.

Promotion: 19 countries have undertaken some form of measures to promote voluntary and unpaid donation of tissues and cells, such as awareness raising and information campaigns. In addition, 23 countries have restrictions or prohibitions on advertising the need for, or availability of, human tissues and cells with a view to offering or seeking financial gain or comparable advantage (in line with article 12 of Directive 2004/23/EC).

Procurement and supply of tissues and cells: the report shows that the majority of the countries have public collectors/suppliers or a dual system of public and private collectors/suppliers. With regards to supply, 11 countries report having policies in place to endeavour to promote self-sufficiency of tissues and cells, and 17 countries have bilateral or other forms of agreements/collaboration structures to ensure national supply of tissues and cells. However, almost half of the countries report some form of shortages of tissues and cells, including bone marrow and gametes.

As set out in Article 12 of Directive 2004/23/EC, the Commission shall inform the European Parliament and the Council of any necessary further measures it intends to take in the field of voluntary and unpaid donation of tissues and cells. Based on the findings of this report, the Commission will now, together with the Member States, reflect on the potential need for further measures, keeping in mind that the Commission's legal mandate is limited to quality and safety of tissues and cells.