



EUROPEAN COMMISSION

Brussels, 15/07/2009
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Mr. Secretary General,

The Commission would like to thank the Italian Senate for its resolution on the proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare (COM(2008)414).

The Commission is pleased that the Senate welcomes the development of an EU framework which clarifies patients' rights and entitlements as well as Member States' obligations with regard to quality and safety of medical treatments and their financing.

The Commission welcomes the support of the Italian Senate for minimum quality standards for healthcare throughout Europe. The Commission has proposed that this be achieved through the definition of clear safety and quality standards by the national authorities but notes with interest the Italian Senate suggestion to give more attention to this issue. A stable and sustained cooperation in that field at EU level could only lead to better outcomes.

Regarding the issue of monetary compensation of patients for harm that they might suffer as a result of cross-border healthcare, the proposed Directive foresees that Member States of treatment provide patients with means of making complaints and guarantee remedies and compensation. While compensation may indeed take the form of a payment, it is up to the each Member State to establish the appropriate procedure.

The Commission is pleased that the Italian Senate welcomes the establishment of a mechanism for calculation of cross-border healthcare costs to be reimbursed to the insured person. The Commission notes the suggestion of setting up an institution to arbitrate disputes. The Commission has proposed that each individual Member State establishes a mechanism for calculating the level of reimbursement according to its own statutory social security system. The level of reimbursement will however not exceed the actual costs of healthcare received by the patient, to ensure that there will be no incentive for patients to receive healthcare in a Member State where care is cheaper, for purely financial reasons.

The Commission notes with interest the suggestion of the Italian Senate that the treatment of rare diseases be reimbursed, even when such entitlement is not provided for by the Member State of affiliation legislation. The Commission's proposal however is not affecting Member States competence to determine the catalogue of medical and drug treatments for which patients are entitled to receive reimbursement.

As far as the list of healthcare treatments defined as hospital care is concerned, the aim of a Community list is to create legal certainty for patients, doctors and health insurance funds and to have a list based on shared assessment by experts. This is fully compatible with article 152 (5) EC because this definition will only apply for the purpose of reimbursing cross-border care under the proposed directive. This will not affect Member States responsibility for the organisation and delivery of health services and medical care.

With regard to the inflow of patients, Member States must respect the principle of non-discrimination on the basis of nationality in the EU Treaty. The Commission has not proposed the introduction of a prior authorisation scheme as it would not be proportionate to the small scale of patient's mobility. In any case, recital 12 of the proposed Directive foresees that healthcare providers can refuse foreign patients if they have no capacity to offer.

Concerning the recognition of prescriptions which are issued following long-distance medical consultations, the Commission is proposing works with experts from Member States to develop tools to enable pharmacists to verify the authenticity of prescriptions. Works will also aim at supporting the interoperability of e-Prescriptions, which would facilitate their verification.

Once the Directive is adopted by both the European Parliament and the Council, the Commission in its role as the "guardian of the Treaty" will monitor its implementation and enforcement in the Member States. However, the Commission has no right to arbitrate individual disputes.

The Commission hopes that these explanations are useful for the Italian Senate and remains available to provide any further information.

While looking forward to continuing this fruitful exchange of information,

Yours sincerely

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