PM

Norwegian position on the Proposal for a Directive on the application of patients' rights in cross-border healthcare

1. Norway refers to the proposal by the European Commission for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare[1], and the European Parliament legislative resolution of 23 April 2009 on the proposal[2] (first reading). To the extent the Swedish Presidency would find it relevant, Norway would be happy to offer its assistance to contribute constructively to the Council's further work on the text of the proposal.

2. *Prior authorisation for hospital care*
   The European Parliament's amendments are a step in the right direction, but Norway believes further amendments emphasizing the Member States' need for planning and cost control should be a priority for the Council's further consideration of the proposal.

   Norway supports the European Parliament's amendment stating that the closer definition of hospital care shall be established by the Member States. A common list as proposed by the Commission is in our view not necessary or appropriate, and would be difficult to establish and keep updated.

3. *Rare diseases*
   Norway appreciates that the Directive aims at giving patients with a rare disease better healthcare through extended cooperation between the Member States. However, the European Parliament has added special rules for reimbursement of treatment for rare diseases. We do urge the European Union to consider these amendments closely. Should special rules for rare diseases apply, the wording of the proposal should be significantly clarified and modified.

   Norway fears that the amendment might be interpreted to the effect that the patient will have the right to reimbursement for costs for <u>any</u> treatment for a rare disease, irrespective of what the patient would be entitled to in the Member State of affiliation, what this Member State can offer and when. If adopting extended rights for rare diseases, they should in our view only cover situations where the Member State cannot offer adequate treatment. It would also be important to clarify that this would not in general cover treatment which is not sufficiently tried and tested by international medical science. Furthermore, the amendment to the effect that patients with rare diseases shall not be subject to prior authorisation even for hospital care should be questioned.

4. *Long term care*
   The European Parliament has decided to exclude long term care from the scope of the Directive. Norway supports such an explicit exemption. It is not clear what the rules on free movement of the EC Treaty and the EEA Agreement mean in relation to long term care.

   Long term care have integrated elements of both healthcare and (other) social services. An exemption of long term care from the Directive is necessary in order to avoid that the rules on reimbursement for cross-border healthcare are applied to the healthcare element because this would create a need for Member States to distinguish in every single case between the healthcare element and the elements of (other) social services.

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[1] COM(2008) 414 final

[2] TA/2009/0286

If the Directive is to be applied to the healthcare elements of long term care, due consideration should be given to the fact that the need for planning is significant in the field of long term care, as is the case for hospital treatment.

5. *Direct transfer of funds*
   The European Parliament has added that the Member State of affiliation should in certain cases provide for direct transfer of funds to the service provider, so that the patient does not have to pay upfront. Norway supports the idea of finding ways to lessen social inequality in cross-border healthcare.

   Norway is, however, of the opinion that the Member States should be free to set up systems for voluntary prior notification either with a guarantee for direct transfer of funds to the service provider or with a guarantee for reimbursement. Direct transfer might involve practical difficulties that could keep Member States from offering such a system, while a guarantee for reimbursement would be of significance for many patients even if they have to pay upfront.

6. *Healthcare providers*
   Norway supports limitation of the scope of the Directive to providers contracted to the public health service or health insurance or otherwise defined public system, as far as this is possible within the frame of the rules on free movement of services. In our view such a limitation would be of particular significance in relation to reimbursement of cross-border healthcare. There is a risk that reimbursement of healthcare provided by private healthcare providers might counteract national priorities within the Member States' healthcare system. National priorities will to some extent be parallel between the different Member States, whereas private providers might focus on health services with a low priority in the public healthcare system.

7. *Organ transplantation*
   The European Parliament has adopted an exemption for organ transplantation. Norway supports this exemption due to the specific nature of organ transplantation and the limited availability of human organs.

Norwegian Ministry of Health and Care Services, 6 July 2009