

## **EMP welcomes the Final Appraisal Determination for REVLIMID® (lenalidomide) in the UK.**

On April 23rd, 2009 the National Institute for Health and Clinical Excellence (NICE) in the UK has issued a Final Appraisal Determination (FAD) recommending REVLIMID®, in combination with dexamethasone, for use in the National Health Service in England and Wales in patients who have received two or more prior therapies. The medicines will be reimbursed by the government for 26 cycles (approximately 2 years)

The recommendation also states that the manufacturer CELGENE will cover the drug cost of REVLIMID® for patients who remain on treatment for more than 26 cycles.

Although these reimbursement criteria are still more restrictive than the EMEA registration for the medicine<sup>i</sup>, EMP regards the decision as good news for the MM patients in the UK because initially, NICE issued a negative decision on REVLIMID®. This would have deprived many MM patients from this new medicine.

Myeloma UK, the MM patient organisation in the UK, played an important role in advocating the access to REVLIMID®. Myeloma UK also influenced recent reforms to NICE, allowing more flexibility in the appraisal for drugs for rare diseases. These reforms, together with a pricing scheme brokered by Myeloma UK, made it possible for NICE to overturn the initial negative decision on REVLIMID®.

This shows the important role Patient Organisations can play in the Healthcare Policy.

Ever since the European registration of lenalidomide, patients' access to this medicine varies in the different European Member States. After the European registration, medicines need to be approved and reimbursed by the local Healthcare Authorities in the different European countries. This situation leads to some inequalities in access to medicines in Europe.

Many European Member States take over the European registration for the local approval and reimbursement criteria in their specific country. Unfortunately, other countries impose much stricter conditions, making treatment possibilities for their citizens much more restrictive. Belgian multiple myeloma patients have a much more limited access to the medicine than their neighbours in the Netherlands or in France<sup>ii</sup>.

This is a situation which is unacceptable for EMP and its local Belgian member organisations CMP (Contactgroep Myeloom Patiënten, the Flemish MM patientgroup) and MyMu (Myélome Multiple, the French spoken patientgroup).

Both Belgian groups, who work together for the interest of the Belgian MM patient, are advocating hard for a more flexible access to this new treatment.

Hopefully with the same success as their UK colleagues...

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<sup>i</sup> On June 14th, 2007, lenalidomide obtained the European registration via the centralised procedure at the EMEA as a second line treatment for multiple myeloma, in combination with dexamethasone

<sup>ii</sup> In Belgium, lenalidomide is reimbursed under the following conditions:

-treatment in third line

-the patient must have a relapse while under treatment with bortezomib

-after 4 cycles of treatment with lenalidomide, the patient must be in PR - Partial Remission (otherwise treatment must be stopped)

-treatment is reimbursed for maximum 8 cycles

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