Question for written answer P-002868/2014
to the Commission
Rule 117
Kartika Tamara Liotard (GUE/NGL)

Subject: Unavailability of medicines for people suffering from Cushing's syndrome

On the basis of a report by the European Medicines Agency (EMA), the medicine Nizoral was withdrawn from sale in all EU Member States in 2014, as were all other oral forms of ketoconazole. Nizoral is primarily used to treat fungal infections, but is also of vital importance to people suffering from Cushing's syndrome. Sufferers from this condition take the medicine under strict supervision by an endocrinologist, which limits the risks reported by the EMA. Cushing's syndrome sufferers are far more at risk without Nizoral/ketoconazole than they are if they take it.

1. What progress has the Commission made towards a decision on the oral form of ketoconazole? Does it intend to accept the EMA's recommendations in full?

2. Is the Commission aware that Nizoral and other forms of ketoconazole for oral administration have recently been withdrawn from sale in all Member States?

3. Is the Commission aware that this is causing acute, life-threatening problems for people with Cushing's syndrome?

4. Does the Commission know that, for some of these people, no other effective medicine is available and that even an operation is not (or is no longer) possible in their case, that they cannot function normally in society and that their life expectancy is severely curtailed?

5. The majority, by far, of users of Nizoral and ketoconazole were taking the medicine against fungal infections. Is the Commission aware that it has become financially too unattractive for manufacturers to produce Nizoral and oral forms of ketoconazole, because there are too few Cushing's syndrome sufferers to make the medicine's manufacture viable?

6. Does the Commission realise that, in practice, the EMA's theoretical recommendation that Member States authorise the medicine only for the treatment of Cushing's syndrome is not feasible, because as a result of this recommendation (pending a decision by the Commission), the medicine is no longer being produced?

7. Does the Commission realise that European coordination is needed in this case because Member States themselves will no longer be able to safeguard the production of ketoconazole in tablet form?

8. What will the Commission do to ensure without delay that Nizoral, or tablets containing at least 200 mg of ketoconazole, once again become(s) available to patients with Cushing's syndrome?