Proposed changes to Section 10.3 Other medicines for haemoglobinopathies

Proposal:

To give greater prominence to the recommended indications for use of the medicines listed in this section, and to address feedback received regarding more common global use and recognition of the United States Adopted Name (USAN) 'hydroxyurea' compared to the International Non-proprietary Name (INN) 'hydroxycarbamide', the EML Secretariat proposes the following changes to the listings of medicines in Section 10.3 'Other medicines for haemoglobinopathies' on the EML and EMLC:

- To create separate sub-sections for 'Medicines for sickle-cell disease' and 'Medicines for thalassaemias';
- List hydroxycarbamide (hydroxyurea) in the new sub-section for medicines for sickle-cell disease;
- Exceptionally use the United States Adopted Name (USAN) 'hydroxyurea' in preference to the International Nonproprietary Name (INN) 'hydroxycarbamide' (with the INN being reported in brackets beside the USAN);
- List deferasirox and deferoxamine in the new sub-sections for medicines for sickle-cell disease and medicines for thalassaemias.

Hydroxycarbamide (hydroxyurea) is also included on the Model Lists for use in the treatment of chronic myeloid leukaemia (CML). The same change regarding the USAN / INN is proposed for its listing for CML.

The proposed changes are shown below.

10.3 Other medicines for haemoglobinopathi	ies
10.3.1 Medicines for sickle-cell disease	
□ deferasirox Therapeutic alternatives: - deferiprone	Tablet (dispersible): 100 mg; 125 mg; 250 mg; 400 mg; 500 mg. Tablet (film-coated): 90 mg; 180 mg; 360 mg.
Complementary List	
deferoxamine	Powder for injection: 500 mg (mesilate) in vial.
hydroxycarbamide (hydroxyurea) hydroxyurea (hydroxycarbamide)	Solid oral dosage form: 100 mg [c]; 200 mg; 500 mg; 1 g.
10.3.2 Medicines for thalassaemias	
□ deferasirox Therapeutic alternatives: - deferiprone	Tablet (dispersible): 100 mg; 125 mg; 250 mg; 400 mg; 500 mg. Tablet (film-coated): 90 mg; 180 mg; 360 mg.
Complementary List	
deferoxamine	Powder for injection: 500 mg (mesilate) in vial.

8.2 Antineoplastics and supportive medicine	es
8.2.1 Cytotoxic medicines	
Complementary List	
hydroxycarbamide (hydroxyurea) hydroxyurea (hydroxycarbamide)	Solid oral dosage form: 100 mg [c]; 200 mg; 300 mg; 400 mg; 500 mg; 1 g. • Chronic myeloid leukaemia