MEDICINES CONTROL COUNCIL

DEPARTMENT OF HEALTH
Republic of South Africa

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ENOXAPARIN

APPLICATIONS FOR REGISTRATION OF MEDICINES CONTAINING ENOXAPARIN

TO ALL APPLICANTS

The Medicines Control Council considered the requirements for the registration of medicines containing **Enoxaparin** and concluded that this molecule is not an "orthodox" molecule but that it is a biological molecule.

Biological molecules may not qualify for the usual generic registration processes where bioequivalence studies alone or waivers are considered in support of the safety and efficacy of medicines containing such substances.

Having considered all the evidence and information available regarding the nature of Enoxaparin and related substances, Council resolved that for all applications for the registration of products containing Enoxaparin, clinical data shall be required to demonstrate safety and efficacy in accordance with the requirements for registration of "new chemical entities".

In pursuit of the above all applicants must submit clinical data in support of the safety and efficacy of the medicine applied for. If such information has already been submitted, this will be evaluated and the applicant will be advised accordingly.

The required clinical data must be submitted to Council within six (6) months from the date of this notification. Applicants who fail to submit this information must withdraw the relevant application(s) for registration and re-submit the application(s) only when the data/information is available. At the end of the six months period, Council will reject all applications without clinical data to support safety and efficacy.

Reference may be made to the EMEA guidelines on biosimilar products.

MS M HELA
REGISTRAR OF MEDICINES
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