MEDICINES CONTROL COUNCIL

DEPARTMENT OF HEALTH
Republic of South Africa

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POST CLINICAL TRIAL DRUG ACCESS

This document has been prepared to serve as a guideline to those sponsors and investigators providing investigational product to participants during clinical trials. This is to ensure that participants who derive benefit from the investigational products will be provided with the product until the products is registered and available in the public sector. This guideline represents the Medicines Control Council's current thinking on the measures to be taken to ensure that patients gain access to their treatment independently once the trial is over. It is not intended as exclusive approach. Council reserves the right to request any additional information and may make amendments in keeping with the knowledge which is current.

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1 BACKGROUND

In advance of a clinical trial, sponsors, researchers and host country governments should make provisions for post-trial access for all participants who still need an intervention identified as a beneficial in the trial. This information must also be disclosed to participants during the informed consent process.

The issue of post-trial access has become very important as many patients on clinical trials who benefit from study treatment cannot access their treatment independently once the trial is completed. This is particularly important in patients with serious illnesses requiring lifesaving therapy or treatments providing significant symptom relief which is not available from other therapies.

As participants in clinical trials have contributed significantly to the study sponsors in many ways, there is an obligation on the part of the sponsor to continue to provide study medication at no cost to all participants who are still benefiting.

2 GUIDELINES

- All patients, private and public on medication on clinical trials must be provided with post trial access of their medication without any cost to them as long as they benefit from the medication and where withdrawal is likely to lead to deterioration of the individual health status as assessed by the investigator.
- Upfront submission of a roll-over trial protocol to provide post trial access is recommended.
- Care must be taken to prevent gaps in patient treatment between the original and roll-over protocols.
- Details of post-trial access should be included in the clinical trial form 1, and informed consent document/patient information leaflet.
- Labelling of study medication accessed post trial must be in accordance with Regulation 34 of the Medicines and Related Substances Act, 1965 (Act No 101 of 1965).
- Public sector patients are not affected by Single Exit Price legislation and can receive free drugs post registration in accordance with Section 18B of Medicines and Related Substances Act, 1965.
- Private sector patients can be given an exemption from Single Exit Price legislation by National Department of Health in accordance with Section 18B of Medicines and Related Substances Act, 1965.
- Public sector patients cannot obtain many registered medicines due to cost and essential medicines list constraints making it essential for such patients to receive therapy post-trial until the medication is available to public sector patients and not just until it is commercially available.

3 REFERENCES

National Department of Health. 2003. Regulations of the Medicines and Related Substances Act, 1965 (Act 101 of 1965). Republic of South Africa

National Department of Health. 1965. Medicines and Related Substances Act, 1965 (Act 101 of 1965). Republic of South Africa.

World Medical Association Declaration of Helsinki. 2013. Ethical Principles for Medical Research Involving Human Subjects.

4 UPDATE HISTORY

Date	Reason for Update	Version & Publication
April 2016	First version for External Stakeholder comment	Version 1, May 2016
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