

## DEPARTMENT OF HEALTH

## DEPARTEMENT VAN GESONDHEID

EXCLUSION OF CERTAIN MEDICINES FROM THE OPERATION OF CERTAIN PROVISIONS OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT 101 OF 1965)

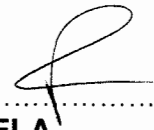
UITSLUITING VAN SEKERE MEDISYNE VAN DIE TOEPASSING VAN SEKERE BEPALINGS VAN DIE WET OP DIE BEHEER VAN MEDISYNE EN VERWANTE STOWWE, 1965 (WET 101 VAN 1965)

I, **Mandisa Hela, Registrar of Medicines**, acting by virtue of a delegation in terms of section 34A of the Medicines and Related Substances Act, 1965 (Act 101 of 1965), hereby exclude in terms of Section 36 of Act 101 of 1965, on the unanimous recommendation of the members present at a meeting of the Medicines Control Council held on 5 **October 2007** the medicines listed in the schedule hereto from the operation of the therein listed provisions of the regulations promulgated by Government Notice No. R.510 of 10 April 2003.

Ek, **Mandisa Hela, Registrateur van Medisyne**, handelend kragtens 'n delegasie ingevolge artikel 34A van die Wet op Medisyne en Verwante Stowwe, 1965 (Wet 101 van 1965), en op eenparige aanbeveling van die lede van die Medisynebeheerraad teenwoordig in 'n vergadering gehou op 5 **Oktober 2007**, sluit hierby uit, kragtens Artikel 36 van Wet 101 van 1965, die medisyne in die Bylae hiervan vermeld van die toepassing van die daarinvermelde bepalinge van die regulasies afgekondig by Goewermentskennisgewing Nr. R.510 van 10 April 2003, onderworpe aan die voorwaardes ingelys in the Bylae vermeld.



MANDISA HELA  
REGISTRAR OF MEDICINES



MANDISA HELA  
REGISTRATEUR VAN MEDISYNE

| REGISTRAT<br>ION NO/<br>REGISTRAS<br>IE NR                                                                                                                                       | NAME OF MEDICINE/<br>NAAM VAN MEDISYNE                                                                                                                                                                                                                                                                                                                                                                                                                                  | FORM OF<br>PREPARATION/<br>BEREIDINGS-<br>VORM | PROVISIONS<br>FROM WHICH<br>EXCLUDED/<br>BEPALINGS<br>WAARVAN<br>UITGESLUIT                                                                   | CONDITIONS OF<br>EXCLUSION/<br>VOORWAARDES<br>VIR<br>UITSLUITING                                              | APPLICANT<br>/<br>APPLIKANT     |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------|---------------------------------|
| C/15.4/391<br>E/15.1/223<br>C/15.4/49<br>35/15.4/0049<br>T/15.4/86<br>L/15.4/369<br>C/15.4/44<br>D/15.4/22<br>C/15.4/54<br>P/15.2/212<br>35/15.4/0088<br>C/15.4/47<br>N/15.4.123 | MINIMS ATROPINE SULPHATE 1 %<br>MINIMS CHLORAMPHENICOL 0.5 %<br>MINIMS CYCLOPENTOLATE HCL 1 %<br>MINIMS DEXAMETHASONE SODIUM PHOSPHATE 0.1 %<br>MINIMS FLUORESCEIN SODIUM 2 %<br>MINIMS LIDOCAINE HCL & FLUORESCEIN SODIUM<br>MINIMS OXYBUPROCAINE HCL 0.4 %<br>MINIMS PHENYLEPHRINE HCL 10 %<br>MINIMS PILOCARPINE NITRATE 2 %<br>MINIMS PREDNISOLONE SODIUM PHOSPHATE 0.5 %<br>MINIMS PROXYMETACAINE HCL 0.5 %<br>MINIMS TETRACAINE HCL 1 %<br>MINIMS TROPICAMIDE 1 % |                                                | <i>Regulation of<br/>the immediate<br/>container label<br/>8(1) Bilingualism</i>                                                              |                                                                                                               | Soflens (Pty)<br>Ltd            |
| 36/26/0422                                                                                                                                                                       | Fludara Oral                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Tablet                                         | <i>Regulation 8(1)<br/>Bilingualism of<br/>the immediate<br/>container label<br/>Regulation 8(2)<br/>Bilingualism of<br/>the outer carton</i> |                                                                                                               | Bayer<br>Healthcare             |
| 37/8.4/0078                                                                                                                                                                      | Rescueflow                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Tablet                                         | <i>Regulation 8 (1):<br/>Bilingualism of<br/>the immediate<br/>container label</i>                                                            | <b>Authorization<br/>only applicable<br/>to 360 units<br/>of batch<br/>07124, expire<br/>date: 30/09/2009</b> | Alliance<br>Pharma (Pty)<br>Ltd |
| Not Registered<br>Not Registered                                                                                                                                                 | Anastase 1<br>Sandos Anastrozole 1                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                | <i>Section 15(1)<br/>submission of a<br/>sample with the<br/>application</i>                                                                  | <b>A sample<br/>be submitted to<br/>the Registrar<br/>prior to the<br/>product being<br/>marketed.</b>        | SandozSA<br>(Pty) Ltd           |