GOVERNMENT NOTICES • GOEWERMENTSKENNISGEWINGS

DEPARTMENT OF HEALTH

NO. R. 532 25 MAY 2018

SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY(SAHPRA)

Private Bag X828, PRETORIA, 0001

Tel 012 395 9475

Fax 012 395 9201

Notice: Rejection of application for registration in respect of a medicine is hereby given in the Gazette by the Chief Executive Officer of SAHPRA.

Dear Stakeholders

Notice is hereby given, in terms of the MEDICINES AND RELATED SUBSTANCES ACT, NO. 101 OF 1965 (as amended), Section 15, sub section 9, to the Applicants listed in attachment 1, who have submitted product dossiers for evaluation and product registration, of the intention to reject the application for product registration.

Reasons for rejection of the applications are as follows:

- 1. The Applicant is not licensed in terms of Section 22 C (1) (b) of the Act.
- 2. The Authority has been unable to contact the Applicant

Please use the following email address for all correspondence:

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Santhani.Chetty@health.gov.za

If no response is received within 30 days (calendar) of publication the applications referred to will be rejected.

ACTING CEO (SAHPRA)

to congruing

8/05/40/15 STAD

Attachment 1:

Table 1: List of dossier registration applications intended to be cancelled

| Applicant | Application Number(s) | | | | | | | | |
|--|-----------------------|--------|--------|--------|--------|--------|--------|--|--|
| | 300314 | 300452 | 300474 | 300486 | 320292 | 320294 | 320369 | | |
| Acupharm (Pty) Ltd | 310035 | 310088 | 310089 | 310147 | 320637 | 320633 | 320635 | | |
| | 310188 | 310189 | 310426 | 310432 | 300496 | 320288 | 310433 | | |
| | 310448 | 320270 | 320272 | 320274 | 320276 | 310148 | 320641 | | |
| | 320282 | 320284 | 320278 | 320286 | 290104 | 290218 | 300301 | | |
| | 320699 | 320700 | | | | | | | |
| Apotex SA (Pty) Ltd | 300222 | 320057 | 320074 | 320647 | 320051 | 320054 | 320055 | | |
| | 300453 | 320059 | 320075 | 320648 | 320069 | 320639 | 320280 | | |
| | 300475 | 320061 | 320077 | 340028 | 320640 | 320067 | 320065 | | |
| | 320049 | 320063 | 320079 | 340176 | 350108 | | | | |
| Arcana (Pty) Ltd | 290226 | | | | | | | | |
| Beejay Pharmaceutical Services cc | 440786 | | | | | | | | |
| Beige Pharmaceuticals (Pty) Ltd | 340393 | 300094 | 330331 | 330453 | 330320 | 340452 | | | |
| Biomox Pharmaceuticals (Pty) Ltd | 290277 | 310488 | 310489 | 310490 | | | | | |
| Brittan Health Care Group (Pty)Ltd | 410100 | 410101 | | | | | | | |
| Capricorn Biomedical (Pty) Ltd | 420092 | 420093 | | | | | | | |
| Caps Pharmaceuticals SA (Pty) Ltd | 370220 | | | | | | | | |
| Compu Pharm (Pty) Ltd | 370258 | 310398 | | | | | | | |
| Colgate-Palmolive (Pty) Ltd | 320022 | 320678 | 430882 | | | | | | |
| Crown Laboratories Ltd | 310366 | 340362 | | | | | | | |
| Crystal Pharmaceuticals (Pty) Ltd | 300296 | 330335 | 330343 | 330356 | 340025 | | | | |
| Danene Pharmaceuticals (Pty) Ltd | 340456 | 350140 | 350258 | | | | | | |
| De Bruyn Park Pharmacy | 340171 | 340172 | | | | | | | |
| Delmaak Laboratories (Pty) Ltd | 300025 | | | | | | | | |
| Detai International (Pty)Ltd (Trading As Impilo Biomed) | 350386 | | | | | | | | |
| Ess Prod Production (Pty) Ltd | 320505 | | | | | | | | |
| Eduan Stoltz | 370440 | | | | | | | | |
| Fedgas (Pty) Ltd | 290704 | 290706 | 290707 | 290708 | 290709 | 290710 | 290711 | | |
| | 290712 | | | | | | | | |
| Gen Pharm Pharmaceuticals (1993) (Pty) Ltd | 310251 | | | | | | | | |
| GR Pharmaceuticals (1967) (Pty) Ltd | 370239 | 370240 | | | | | | | |

| Health Products For Africa (Pty) Ltd | 340475 | 340477 | 340478 | | | | |
|--|------------------|------------------|------------------|---------|---------|--------|--------|
| Heel South Africa (Pty)Ltd | 360312 | | | | | | |
| Hiline Pharmaceuticals (Pty) Ltd | A380427 | A380428 | A380429 | A380702 | A380703 | | |
| Intaka Tech (Pty) Ltd | 420535 | 420536 | 450615 | | - | | |
| Isren Laboratories Cc | 300516 | | | | | | |
| Knoll Pharmaceuticals (Sa) (Pty) Ltd | 290583 | 310629 | 310630 | | | | |
| Libra Pharmaceuticals Ltd | 330527 | 320732 | | | | | |
| Lupin Laboratories S.A. (Pty) Ltd | 330071 | | | | | | |
| M Katovsky Cc | 410407 | | | | | | |
| M Millner Pharmaceuticals (Pty) Ltd | 310069 | 340338 | 340291 | | | | |
| M&B Pharma SA (Pty) Ltd | 300319 | 300320 | 300321 | 300322 | 300323 | | |
| Macmed Pharma (Pty) Ltd | 340139 | 340140 | 340220 | - | | | |
| Makeshift (Pty) Ltd | 340426 | | | | | | |
| Mates Pharmaceuticals | 310486 | 310497 | 310498 | 310499 | 310500 | 310501 | |
| Moses Marketing Ventures Cc | A400744 | | | | | | |
| MothopoPharmachem Cc | 460494 | 460495 | 460496 | 460497 | 460498 | 460499 | 460500 |
| N.G.Allen | 320392 | | | | | | |
| Natural Link Homeopathics (Pty) Ltd | 340479 | | | | | | |
| Norton Healthcare (Pty) Ltd | 280495 320364 | 280534 320365 | 280535 330052 | 280575 | 290147 | 290225 | 310697 |
| Patel BK | 330062 | | | | | | |
| Pristine Fine Chemicals (Pty) Ltd | 320668 | | | | | | |
| RCA Pharma (Pty) Ltd | 451156 | | | | | | |
| Renaissance Parenterals (Pty) Ltd | 370660 | 370661 | 370662 | 370663 | 370664 | | |
| Renalcare Services (Pty) Ltd | 360460 | 370099 | 370687 | 370688 | 370689 | | |
| Research Laboratories (SA) (Pty) Ltd | 310005 | 310263 | 310264 | 310265 | 320296 | 320297 | |
| Riker Laboratory SA (Pty) Ltd | 290078 | | | | | | |
| Roderick Narain Cc | 370537 | 380063 | | | | | |
| Scotia Pharmaceuticals (Pty) Ltd | 320546 | 330476 | 330478 | | | | |
| SCP Pharmaceuticals (Pty) Ltd | 290644 | 300298 | 300299 | | | | |
| SC Johnson Wax | 300490 | | | 1 | | | |
| Searle, Division of Monsanto SA (Pty)Ltd | 330307 | | | | | | |
| SJ Bloomer | 330342 | | | | | | |
| South African Medical Services | 320692 | 320696 | 320697 | 320698 | | | |
| Southern Cross Pharmaceuticals (Pty) Ltd | 350133 | 350134 | 360060 | 360061 | 360062 | | |
| Spectrapharm Laboratories (Pty) Ltd | 300170 | 310557 | 320261 | 320262 | | | |

| Strides SA Pharma SA (Pty) Ltd | 380257 | 410070 | 410377 | 410852 | 410925 | 411081 | 411082 |
|--|-------------|---------|--------|---------|--------|--------|--------|
| | 420022 | 420051 | 420052 | 420064 | 420112 | 420113 | 420114 |
| | 420436 | 420451 | 421106 | 430361 | 430621 | 440436 | 440437 |
| | A40039 6 | | | | | | |
| T3A Pharma (Pty) Ltd | 370684 | 370685 | 370686 | | | | |
| Tamtian Pharmaceutical (Pty) Ltd | A390294 | A390295 | | | | | |
| Tara Pharmaceuticals (Pty) Ltd | 350166 | | | | | | |
| The Premier Pharmaceutical Co Ltd | 290493 | 290494 | | | | | |
| Universal Pharmaceuticals (Pty) Ltd | 310611 | | | | | | |
| Vesta Medicines (Pty) Ltd | 320043 | 310129 | | | | | |
| Vet-Pharm Cc | 340332 | | | | | | |
| Viva Pharmaceuticals (Pty) Ltd | 310671 | 320657 | 320658 | 320659 | | | |
| Vortex Healthcare | 490223 | | | | | | |
| Xeragen Laboratories (Pty) Ltd | 310520 | 330437 | 330445 | A390223 | | | |
| Zedchem (Pty) Ltd | 320090 | | | | | | |