

Media Release - BRISBANE DRUG COMPANY CONVICTED OF COUNTERFEITING

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Curacel International Pty Ltd today became the first Australian drug company to be convicted of manufacturing counterfeit medicines, the Federal Parliamentary Secretary for Health, Trish Worth has announced.

Curacel was today fined a total of \$84,000 at the Brisbane Magistrate's Court having been convicted of manufacturing counterfeit medicines, carrying out unlicensed steps in the manufacture of medicines and manufacturing and supplying unapproved medicines.

Curacel Company Director, Mr Karim Rouan Cham, was also fined \$12,000 for his involvement in label swapping of over the counter preparations.

The charges were laid by Australia's drug watchdog, the Therapeutic Goods Administration (TGA), following a criminal investigation by the TGA Surveillance Unit.

"In May 2000 Australia enacted new legislation to make the import, export, manufacture and supply of counterfeit medicines a specific criminal offence following the publication of new World Health Organization (WHO) guidelines to crack down on the global counterfeit drug trade," Ms Worth said.

"Concerns about Curacel first came to the attention of the TGA Surveillance Unit in June 2000.

"The Surveillance Unit Investigators executed search warrants at Curacel premises in February 2001 and subsequent investigations led to the cancellation of the company's manufacturing licence in June 2001 and the laying of these charges in May 2002.

"The company and Mr Cham pleaded "guilty" to the charges at the Brisbane Magistrate's Court earlier this year and today's sentencing is the first conviction recorded under Australia's new anti-counterfeiting legislation."

The TGA investigation showed that the Schedule 4 Poison Dimethyl Sulfoxide (DMSO) had been added to Curaclear Cura APR Cream and Curaclear Acne & Pimple Gel; and the Schedule 4 Poison Hydroquinone had been added to Curaclear Complexion Powder.

"These products were all marketed as over the counter products and the added substances are only available in Australia for human use as Prescription Only Medicines," Ms Worth said.

"The presence of these unauthorised ingredients was concealed by the company and not disclosed in the company's manufacturing records or on the product labels.

"There is an inherent public health risk associated with consumers unknowingly self medicating with prescription-only medicines without the benefit of the advice of their health care professional."

In its investigations, the TGA also found that Curacel had re-bottled and re-labelled bottles of Curacel Vitamins Minerals and Grapeseed Tablets, extending the shelf life of the tablets.

"The company sourced bottles and tamper resistant caps identical to those used on the original product and had bogus labels printed with a fictitious batch number and expiry date that extended the shelf life of the product by two years beyond their actual expiry. The company then supplied the expired tablets to consumers," Ms Worth said.

"The stability of the formulation and the period for which ingredients remain therapeutically active are among the factors taken into account when determining a products expiry date.

"To misrepresent expired medicines as being within this specification creates the risk that the product may not be therapeutically active and therefore could deny the consumer the benefit sought."

Ms Worth congratulated the TGA on its thorough investigation of Curacel, its swift action to revoke the company's manufacturing licence when unsafe practices were found, and its determination to take legal action against the company and its director.

"This sends a clear message to manufacturers of health care devices and medicines that the regulator will not tolerate illegal

and unsafe manufacturing processes that could put the health of Australians at risk," Ms Worth said.

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