

Position on the supply of unregistered gases for medicinal use

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Foreword

This position statement represents the view of the members of ANZIGA. It is approved by the Board of Directors of ANZIGA, meaning that all members endorse and promote its contents in Australia and New Zealand.

Introduction

It has been reported that unregistered gases have been supplied for medicinal use in some instances. Other reports indicate that some doctors may have condoned the use of an "industrial" version of a registered gas to reduce monetary burden on the user.

The regulation of gases for medicinal use exists for the protection of the people these medicines are administered to. The Code of Good Manufacturing Practice (GMP) is intended to ensure that medicines are manufactured to standards appropriate for medicinal use. Medicine registration is intended to ensure that only safe and efficacious products are supplied.

Position

Scope

Any gases (single and mixed gases, including made-to-order mixtures) supplied for medicinal use.

Requirement

Members of ANZIGA, including their subsidiaries or agents are committed to:

- supplying gases for medicinal use that are either registered with the Therapeutic Goods Administration (TGA, in Australia) or MedSafe (in New Zealand), or made available under any relevant schemes administered by the TGA or MedSafe
- ensuring that they do not supply industrial or other unregistered gases for medicinal use
- eliminate the decanting of registered gases into other cylinders (decanting from a registered gas by an unlicensed manufacturer results in an unregistered gas)
- promoting to customers, their obligation under the law, to only use gases that are registered or otherwise permitted by the TGA or MedSafe for medicinal use



If it is determined unregistered gases are being supplied for medicinal use, members of ANZIGA are to commit to the prompt cessation of supply.

Yours sincerely,

The Australia New Zealand Industrial Gas Association

Approval of this position

Dieter Krupp:

Signature

Date

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