



Position on the promotion of unregistered gases for therapeutic 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 promoted for therapeutic use in some instances

The regulation of gases for therapeutic 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 therapeutic use. Medicine registration is intended to ensure that only safe and efficacious products are supplied.

Position

Scope

All gases (single and mixed gases, including made-to-order mixtures) marketed for therapeutic use

Requirement

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

- only promoting gases for therapeutic 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 promote industrial or other unregistered gases for therapeutic use
- eliminate the decanting of registered gases into any cylinder for medicinal use (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 therapeutic use

If it is determined unregistered gases are being promoted for therapeutic use, members of ANZIGA are committed to promptly ceasing such activity.



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Industrial Gas Association

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