

School of Medical Sciences Masterclass 2018 – 23 November 2018

THERAPEUTIC GOODS REGULATION IN AUSTRALIA THE CHALLENGE OF CHANGE

Overview:

This Masterclass is addressed to non-legal executives and interested persons to explain the policy drivers, legal framework and related practices concerning the registration and listing of therapeutic goods under the Therapeutic Goods Act 1989.

Sessions will address the development of policy, the resultant law and related practice relating to therapeutic goods in every day English terms with relevant examples. The Masterclass will end with an in-depth discussion of contemporary issues impacting the therapeutics industry in Australia.

Learning Outcomes:

By the end of this Masterclass you will be able to:

- Understand the history and development of therapeutics goods regulation in Australia
- Explain the legal framework supporting the regulation of therapeutic goods in Australia
- Assess the policy environment and understand the implications of recent amendments to the regulation of therapeutic goods in Australia
- Evaluate the future regulatory environment for therapeutic goods in Australia

Lecturers:

- Dr. Orin Chisholm – Program Director and Senior Lecturer in Pharmaceutical Medicine, School of Medical Sciences, UNSW
- Allan Anforth – Lecturer in Therapeutic Goods Law, UNSW, Master of Pharmaceutical Medicine program; Adjunct Professor of Law, University of Canberra, Barrister Canberra Chambers, Canberra
- Doug Kentwell – Principal Consultant, Capital K Consultants
- Jenny Francis – Principal Legal and Policy Advisor, Health Products Regulation Group
- Elizabeth de Somer – CEO, Medicines Australia



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Time	Topic	Presenter
09.00 am	Welcome and Introduction	Dr Orin Chisholm
09.15 am	Development and evolution of therapeutic goods policy in Australia	Doug Kentwell
10.15 am	Morning tea	
10.45 am	The Therapeutic Goods Act and Regulations explained	Allan Anforth
12.15 pm	Lunch	
01.30 pm	Regulatory reform – an update from 2017/18 and a forecast for 2018/19	Jenny Francis
03.30 pm	Afternoon tea	
04.00 pm	Panel discussion: the contemporary setting	Dr Orin Chisholm Allan Anforth Doug Kentwell Elizabeth de Somer
05.00 pm	Close	

Your Investment:

Early-bird (closes 26 Oct): AUD\$995 (savings AUD\$400)

Standard registration (closes 23 November): AUD\$1395

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