



SERVICES AUSTRALIA AND NEW ZEALAND

Regulatory Affairs

- Current regulatory awareness
- Early warning of changes in relevant areas of regulation by regulatory authorities on industry
- Confidential assessment of potential safety or health risks for products
- Confidential review of advertising claims and their substantiation
- Assistance with the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) and the Australian Inventory of Chemical Substances (AICS)
- Co-ordination between industry and agencies with respect to technical, scientific or toxicological evidence
- Technical assessments for acquisitions
- Provision of information to marketing personnel as required
- The review of products for compliance to the National Trade Measurement Act and Regulations.

Cosmetics

- Confidential review of ingredients in cosmetic products to ensure they are on the AICS and not restricted by entries in the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)
- Confidential review of packaging to check country of origin, trade measurement and ingredient labelling compliance
- Advice on cosmetic versus therapeutic claims
- Advice on claims for new or competitor products
- Advice on manufacturing, marketing, import or export of cosmetic products
- Assistance with registration with NICNAS as a cosmetic or industrial chemical importer
- Interaction with NICNAS to notify or exempt new ingredients not on AICS including writing notifications and permit applications
- Advice on the safety or health risks of cosmetic or industrial chemical ingredients and products
- Advice on the writing of Safety Data Sheets (SDSs) to the Australian approved format
- Advice on compliance with NICNAS Cosmetic Guidelines and Cosmetic Standard
- Compliance with Environmental Protection Authority (EPA) New Zealand Group Standards including the Cosmetic Group Standard.



Medicines/ Medical Devices

- Product areas include OTC medicines, complementary medicines, nutritional supplements, traditional medicines, sunscreens and disinfectants
- Compilation and submission of applications and evidence for:
 - Registrations for Therapeutic Goods onto the Australian Register of Therapeutic Goods (ARTG)
 - Listings for Therapeutic Goods onto the ARTG via the Therapeutic Goods Administration's (TGA's) eBusiness Services (eBS) website
 - New excipients to be added to the ARTG via the TGA's eBS website
 - APIs and Complementary Medicines Actives to the TGA
- Confidential review and assistance with the following for Therapeutic Goods and Therapeutic Devices:
 - Advice on claims for new or competitor products
 - Ingredients, packaging and labels, potential safety or health risks
 - Importing, exporting, manufacturing and marketing
- Medicine/poisons scheduling to the Advisory Committee on Medicines Scheduling (ACMS) and Advisory Committee on Chemicals Scheduling (ACCS)
- Medical Device Inclusions for Therapeutic Goods onto the ARTG via the TGA's eBS website
- Notification of Therapeutic Devices to New Zealand Medicines and Medical Safety Authority (Medsafe) via Web Assisted Notification of Devices (WAND)
- Related Product Notifications and Registrations to Medsafe (NZ)
- Personal representation to government authorities (state and federal)
- Safety and quality issues.

Foods

- Review of formulations for conformity to the Food Standards Australia New Zealand (FSANZ) Food Standards Code
- Advice on food laws, fair trading laws, Food Safety Standards and hygiene regulations
- Confidential review and assistance with the following for foods:
 - Advice on claims for new or competitor products
 - Ingredients, packaging and labels, potential safety or health risks
 - Generating supportive data for claims
 - Importing, exporting, manufacturing and marketing
- Personal representation to government authorities
- Technical assessment and assistance with respect to Good Manufacturing Practice (and internal auditing).



Engel, Hellyer & Partners Pty Ltd

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ABOUT US

Engel, Hellyer & Partners Pty Ltd is a leading technical regulatory affairs consulting organisation for the pharmaceutical, nutritional food, complementary medicine, medical device and cosmetic toiletry industries.

Established in 1982 and located in Sydney, Australia, we have extensive experience in dealing with government, companies and industry associations in the above areas.

Our qualified personnel have contacts at senior levels of the Therapeutic Goods Administration, NICNAS, state health departments, contract manufacturers and laboratories.

OUR TEAM

Dr Graeme Haley – Director

BSc(Hons), PhD, GradDipAdmin, FRACI, CChem

Has over 25 years of international experience in the pharmaceutical and cosmetics industries as a manager and director in product development, production and supply chain.

An Industrial Chemistry graduate and Engineering postgraduate of the University of New South Wales and a Business Administration postgraduate of the University of Technology Sydney in Australia.

He was elected a Fellow of the Royal Australian Chemical Institute in 1993. He has served on a number of Standards Australia Product and Devices Committees and is currently a member of the CS-042 Sunscreen Agents Committee and the CS-108 Cosmetics-Terminology Committee.

He has been a Director and Consultant with Engel, Hellyer & Partners Pty Ltd for over 10 years.



Dr Renée Badenhop - Director BSc(Hons), PhD (Medicine), MIP (Master of Industrial Property), Registered Patent & Trade Mark Attorney

Has 13 years post graduate experience in medical sciences and 4 years consulting experience as a Registered Patent & Trade Mark Attorney.

She received a Bachelor of Science at the University of Sydney and Bachelor of Science (Honours) at Macquarie University and in 1997 she was awarded a PhD (Medicine) at the University of NSW. In 2005 she completed a Master's Degree in Industrial Property at the University of Technology and was registered as a Patent & Trade Mark Attorney.

For 6 years she was a Senior Scientist at the Garvan Institute before taking a position at a top tier Patent & Trade Mark Firm as a Patent Attorney. In 2007, she took on the role of Chief Operations Manager at a medical device company where she was responsible for Product R & D and Regulatory Affairs.

She joined Engel, Hellyer & Partners Pty Ltd as a director and consultant in 2013.

John Attard - Director

BSc, MScM, MBA, MRACI CChem

Completed his Bachelor of Science, Master of Science Management and Master of Business Administration at the University of Technology, Sydney.

A chartered chemist of 10 years standing, he started his career in the QC laboratory of a multi-national pharmaceutical company and then progressed to more senior roles dealing with quality and manufacturing.

For the last 7 years he has worked as a manager in the Compliance Programme at the National Industrial Chemicals Notification and Assessment Scheme (NICNAS). His responsibilities included chemical review, training and outreach activities, regulatory audit and compliance work.

As part of his role at NICNAS he has worked with many organisations (local and multi-national) to assist them in attaining compliance with the requirements of the scheme. He is currently undertaking a Juris Doctor (law degree) at the University of Technology, Sydney.



Dr Gloria Mao - Director BSc (Hons), MA (Molecular Biology), PhD (Toxicology)

Has over 15 years of international experience in the complementary medicine and cosmetic industries. She received her doctorate from the University of California, Los Angeles in Toxicology. She received her Masters of Arts in Molecular Biology from Harvard University and her Bachelors of Science in biochemistry from the University of Illinois.

She has consulted on formula reviews and safety and claims substantiation for health and beauty products and has experience working with regulators worldwide. From 2006 till 2017 she was a scientific advisor to the Association of South East Asian Nations (ASEAN) Scientific Committee on the harmonisation of traditional medicines and health supplements regulations where she was a lead in writing the guidelines for product quality and safety.

While based in the United States, she was the Principal Toxicologist for Amway's nutrition brands sold worldwide. In 2010 she became a Senior Regulatory Scientist at Amway of Australia where she prepared cosmetic safety assessments.

She joined Engel, Hellyer & Partners as a director and consultant in 2017.

We hold corporate membership or associate corporate membership of the following organisations:

- Accord
- Australian Self-Medication Industry
- Complementary Healthcare Council of Australia
- Cosmetic Toiletry and Fragrance Association Inc – New Zealand

The Directors are also individual members of these professional bodies:

- The Royal Australian Chemical Institute
- The Australian Society of Cosmetic Chemists
- Association of Therapeutic Goods Consultants
- The Institute of Patent and Trade Mark Attorneys of Australia

