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## Comparison & analysis of advertising regulatory models

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# ASMI

Advancing consumer health  
through responsible self care

# Overview

- Advertising – facts & myths
- Regulation – aims & best practice principles
- Models & elements of advertising controls
- An approach to analysing & assessing advertising regulatory frameworks

# Key aims of advertising

- Raise & maintain awareness
  - Conditions
  - New & existing treatment options
- Create brand recognition which supports product selection
- Reinforce Quality Use of Medicines (QUM) messages
- Encourage consumers to seek further info
- Stimulate competition

# Limitations of advertising

- Awareness creation tool, not educational tool
- Volume of information is critical: “less is more”
- Purpose: attract attention, offer choices & encourage consumers to seek more information
- WSMI paper – place of advertising in consumer journey

# Objectives of regulations

- General aim: to encourage desired behaviour and/or discourage unacceptable conduct
- Key objectives:
  - Create a level playing field for competitors
  - Maintain public health and safety
- Wall Street Journal: *“The purpose of regulation is compliance, not punishment”*

# Principles of best-practice regulation

- Clarity in terms of requirements
- Targeted to address specific & legitimate concerns
- Restrictions directly linked to verifiable outcomes
- Minimum necessary to achieve the stated objectives
- Neither favour nor constrain market participants to compete
- Processes & procedures impartial & not self-serving
- Regular review to ensure effectiveness

# Criteria for assessing regulatory models

- Clarity & consistency in relation to requirements
- Consistent with the risks posed
- Effective in ensuring compliance
- Universal to ensure level playing field
- Timeliness in responding to non-compliance
- Fair & afford natural justice, e.g. appeals process
- Cost-effective – commensurate with risk
- Transparency & public awareness
- Simple, streamlined and user-friendly processes

# Models & elements of advertising controls

- Default regulatory position
- Point of regulatory intervention
- Parties involved in controls
- Media covered
- Codes & guidelines
- Complaints mechanisms
- Penalties & sanctions



# Default regulatory position

From most restrictive/least ideal to least restrictive/ideal:

- No advertising of OTCs permitted
- OTC advertising not permitted, but with some exceptions
- OTCs advertisable, but with some exceptions
- All OTCs advertisable

# Point of regulatory intervention

- Pre-market:
  - At market authorisation
  - Pre-approval of ads
- Post-market:
  - Reviews/audits: comprehensive, random, regular, ad hoc, complaints driven
- Combination of pre- & post-market compliance measures

# Parties undertaking compliance

- Government regulation
- Industry self-regulation
- Combination – co-regulation

# Media covered by controls

- All advertisements in all media: above-the-line (“mainstream”) & below-the-line advertisements
- Only high impact mainstream advertising
- Different compliance measures for different media

# Codes & Guidelines

- Industry codes of practice
  - Voluntary
  - Mandatory
- Codes underpinned in regulations
- Principles-based or detailed & prescriptive
- Guidelines: greater flexibility, less certainty

# Complaints mechanisms

- Underpinned in regulation
- Part of industry codes of practice
- Combination: different mechanisms for different media

# Penalties & sanctions

- Withdraw & don't repeat
- Retraction or corrective statements
- Criminal penalties & fines
- Suspension or cancellation of authorisation

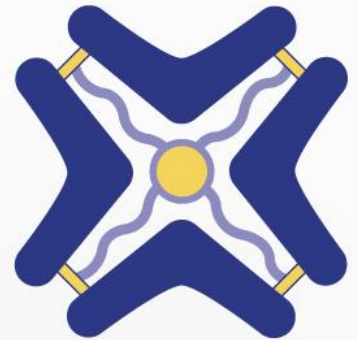
# Conclusion

- All models have strengths & weaknesses
- Global trend towards:
  - Self- & co-regulatory controls
  - Government post-market surveillance



**Thank you**

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