

The Association of Pharmaceutical Specials Manufacturers

MEMBERSHIP INFORMATION

“We are a small sector of the pharmaceuticals industry but together we have a strong voice and can really make a difference”

Sharon Griffiths, Chair

“Our company has a seat at the table for the decisions that really matter to the future of our business”

David Clough, Vice Chair

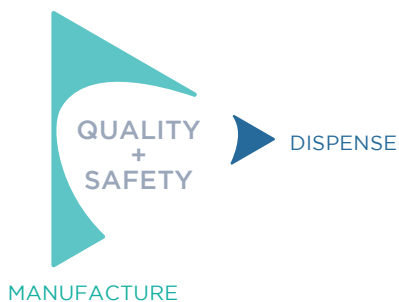


Association of Pharmaceutical
Specials Manufacturers

Join us and help to shape the future of the UK Specials sector

APSM Membership will help your company to increase success in Specials

PRESCRIBE



- **Input into policy for meetings with The Department of Health and key policy makers**
- **Input into key decisions around new legislation and Specials guidance**
- **Networking and peer group collaboration**
- **Shared PR and stakeholder engagement activities**
- **Commercial insights**
- **Technical support and consultation**
- **Issues management and reputation management**
- **Market statistics and resources**

The Association of Pharmaceutical Specials Manufacturers (APSM) is a not-for-profit trade association established to represent the interests of its members who supply Specials and unlicensed medicines in the UK.

Aims and objectives

- To promote and strengthen the UK Specials medicines industry and the use of Specials and unlicensed medicines in the UK.
- To represent the views and interests of Specials manufacturers and suppliers in particular to the UK government and the devolved administrations and health departments, regulators and other relevant third parties.
- To provide a compliant forum for the exchange of ideas and best practice and agree and maintain appropriate standards of conduct for APSM members.
- To promote a regulatory, pricing and market environment that enables the reasonable development and sustainability of Specials and unlicensed medicines markets in the interests of APSM members, patients and UK health services.

Membership criteria

1. **Manufacturers** of Specials medicines that operate under an MHRA Specials manufacturing authorisation
2. **Importers** of unlicensed medicines that operate as first supplier of these to the UK market
3. **Companies that own the rights to**, and supply Specials medicines, as the first supplier to the UK market



Get involved

Help us to shape the future of the Specials industry.

Membership of the APSM means your company can:

- Attend our APSM members meetings to provide feedback on recent work and development and feed into policy development of the APSM
- Input into relevant meetings with The Department of Health. Updated sessions on current rules are also provided to ensure members are up-to-date on current rules and procedures
- Join and take part in our Technical Group and Working Groups
- Apply for Board membership. This group applies APSM policy on a day-to-day basis and attends meetings with The Department of Health, Scottish NHS, MHRA and other relevant third parties and stakeholders

Activities and workstreams

Regulatory and market

- **Drug Tariff, pricing and reimbursement issues.** The APSM has worked with The Department of Health to develop, introduce and provide ongoing support to the Part VIII B Drug Tariff. This includes work around the arrangements and mechanism for data supply, Tariff production and ad hoc issues that arise with Part VIII B. The APSM also provides an independent point of contact that liaises with The Department of Health on relevant sensitive and confidential issues on behalf of members within a framework developed between the APSM and The Department of Health.
- Additional projects include the development of the Tariff to possible new areas and also dealing with market, communication and regulatory issues that cut across the pricing and reimbursement environment.
- **Working with NHS Scotland** to raise and discuss issues around the pricing and reimbursement of products under the Scottish Part 7S Drug Tariff.
- **Working with key stakeholders** including the Pharmaceutical Services Negotiating Committee (PSNC) and the Community Pharmacy Scotland (CPS) where necessary and to promote the aims and objectives of the APSM.
- **Promoting standards and the optimum regulatory environment, including work with the MHRA.** The APSM monitors and inputs into regulatory and legislative changes. These have included the development of UK guidance and medicines legislation impacting on the industry generally, advertising and promotional rules and medicines and pharmacy legislation and standards. There is also continuing input into guidance and rules on the manufacture and supply of Specials and unlicensed medicines including the Review of Unlicensed Medicines.
- Providing a compliant and structured **forum for the development of industry policy** and sharing of best practice and policy via regular members' meetings and operation of sub-groups. All policy development is carried out by the membership and applied by the APSM Board and Communications and Technical groups. Other interest groups are formed and operate as needed and recently this has included work around imported products and pricing and reimbursement proposals relating to this.

Activities and workstreams

Press Office and Communications

The APSM press office is concerned with **building and protecting the reputation of Specials** manufacturers and the Specials market. As well as providing a positive flow of messages to trade and professional media, the press office has an important issues management function and provides an immediate response to potentially negative PR, in consultation with members. The Communications Group meets regularly and implements an agreed plan of activity.

Examples of recent activities include:

- *How Specials Deliver Value to the NHS – a White Paper*
- *The Specials Roundtable in conjunction with Primary Care Today*
- *Stakeholder Engagement with key Patient Groups*



Members can directly input into the briefs provided to the Communications Group as well as receiving advice and guidance either individually or during members' meetings. The Communications Group also meets regularly and members are welcome to join and contribute to this group.

Technical and quality

The Technical Group comprises representatives from client quality and technical departments and provides analysis and response on a broad range **of issues that may impact on the production of Specials**. Recent workstreams include:

- Consultations with the MHRA and European legislators involving changes to the way unlicensed medicines can be manufactured and supplied in the UK
- Consultative Committee meetings at the MHRA concerning GMP, GDP and GLP
- Encouraging contribution to the BP monographs for unlicensed medicines
- Ongoing work and monitoring into areas covered in the MHRA Review of Unlicensed Medicines.

Join the APSM



We welcome applications for membership to join us.

To find out more, or talk to one of our members, please contact the APSM Membership Director, Brian Fisher via email: brian.fisher@quantumpharma.co.uk

www.apsm-uk.com

Advice and Support

Our independent advisors are not affiliated to individual member companies and are retained to represent the interests of the APSM as a whole.

APSM advisor Adrian Spooner is a qualified practising solicitor, pharmacist, a member of the Royal Pharmaceutical Society and registered with the General Pharmaceutical Council. Adrian provides advice to the APSM on various matters including internal and external compliance issues, pricing and reimbursement matters, pharmaceutical and HCP regulation and general commercial matters.

APSM press officer, Lyn Cruickshank, is an experienced PR and communications professional and member of the Chartered Institute of Public Relations. Lyn implements an annual communications programme on behalf of the APSM and also provides issues management services including 24/7 response to national press enquiries to protect the interests and reputation of the APSM and Specials sector.

Market data and research

The APSM provides detailed analysis of prescribing and dispensing data and creates quarterly reports which are available on the member sites.

The APSM also commissions a bi-annual pharmacy and GP Attitude Survey.

Website member area

Our comprehensive website is an essential resource for Specials in the UK. Members also have access to a dedicated member login area, which includes a wide range of useful materials including slide templates, data from our regular Specials Surveys, market data analysis, meeting minutes and a full list of members. Within this section you will also find information from our working groups, including plans, current issues, position papers and meeting minutes.

www.apsm-uk.com



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Join us and help us to shape the future of the Specials industry.

To find out more, or talk to one of our members, please contact the APSM Membership Director, Brian Fisher via email: brian.fisher@quantumpharma.co.uk

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