Job Description

Job title: **Senior Manager / Associate Director Regulatory Affairs**
Location: Holborn, London
Direct reports (3): Senior Regulatory Executive (x2), Regulatory Executive (x1)
Updated: March 2020

Overall Accountability:

- Lead the Regulatory department to develop and deliver PAGB's strategy for medicines, medical devices and food supplements
- Support CEO in managing the PAGB response to regulatory and scientific issues affecting member products
- Manage the regulatory affairs team in the coordination of day to day member support relating to medicines, medical devices and food supplements
- Manage relevant PAGB working groups and subgroups, including ad hoc projects as they arise
- Attend meetings, develop and maintain relationships with relevant external stakeholders in pursuit of PAGB policy objectives such as, government organisations, regulators, trade associations in the UK and, where appropriate, Europe ensuring that the PAGB position represented
- Manage relationships and external advisors on work relating to the regulatory department (Regulatory Affairs, Medical Affairs etc.)
- Manage regulatory affairs department within agreed budget
- Sign off on expenditure up to the limit of £5,000, provided it is within the approved budget.

Key Areas of Responsibility:

1 Strategy and Governance

- As member of the PAGB management team, contribute to and support the management team in the development of PAGB's overall objectives, strategy and organisation.
- Within the agreed strategy, to lead and ensure delivery regulatory activities.
- Within the agreed strategy, to support colleagues to continually improve awareness/knowledge/management of regulatory policy/issues.
- Implement the agreed work programme and report on progress to the Board.

2. Regulatory and Technical

- Coordinate the monitoring of legislative regulatory and scientific issues and identify those which affect PAGB and with management team develop and implement plans to manage these issues.
- Manage the coordination of responses to MHRA requests for information as required
- Ensure the delivery of reports and updates for member companies to inform them of issues which impact their business.
- Report to the Board regarding the RAG, AWG, FSF and other relevant groups
- Present PAGB views to regulatory bodies

- Oversee the provision of
    - regulatory advice, information and analysis on UK and international issues, current and forthcoming EU and UK regulations and guidelines affecting OTC medicines, traditional herbal medicines, food supplements and self care medical devices.
    - Monitoring of live issues and identify potential issues for the OTC sector. Identify areas where co-ordinated action by PAGB would be of assistance to PAGB member companies or regulatory agencies and assist in the development and delivery of resulting work programmes.
    - Provide technical input to codes and guidelines as they are reviewed particularly Medical Devices and Packaging
- Support members on reclassification projects with the help from the CEO
- Liaise with consultants in relation to discreet issues such as Pharmaceuticals in the Environment (PiE), Medicines Manufacturing Industry Partnership and Child Resistant Packaging standards.
- Monitor, analyse and respond to consultations and proposals on regulatory matters to ensure that the views of PAGB members are promoted.

3 Policy

- Organise the development and implementation of PAGB policy positions on regulatory issues which impact members.
- Draft and/or contribute to the development of consultation responses and submissions to Government and other stakeholders as required.
- PAGB lead on regulatory policy development. Organise PAGB representation in discussions with relevant government departments, regulators, self-regulatory bodies and trade associations at UK and EU level as part of a stakeholder engagement programme.
- Represent PAGB on AESGP's Committees and GCSF working groups as required.
- Represent PAGB in discussions with other AESGP associations to collaborate on regulatory issues of common concern

4. Training

- Develop regulatory training modules as required
- Support the development of PAGB training events and seminars
- Conduct training modules as appropriate as appropriate

5. Media, Communications and External Relations

- Develop and maintain links with government and competent authorities such as the MHRA, FSA, DHSC, DEFRA.
- Collation of data from members for submission to MHRA and other stakeholders.
- Develop and maintain links with other trade associations (e.g. AESGP) in the medicines and medical devices sectors including representing the PAGB at meetings with external stakeholders – both national and international.
- Provide technical input into media statements, press releases and research papers.
- Oversee the monitoring and reporting on regulatory and marketing issues and update members via mailings, presentations and PAGB publications e.g. Regulatory Intelligence, This Week and Spotlight.

6. **General**

- Ensure team members are trained on internal policies and procedures ensuring that they are understood and implemented correctly

- Direct, develop and motivate the regulatory affairs team
- Ensure annual objectives and development plans are established for each direct report
- Conduct performance reviews for each direct report.
- Manage PAGB's regulatory programmes within agreed budgets and report on such expenditure as required.
- Manage additional regulatory and scientific support including outside agencies.
- Promote PAGB's services to existing members and to be an advocate of PAGB to potential new members.
- Undertake any task that may be reasonably requested by the Chief Executive

Qualifications and Experience

- Educated to degree level in relevant science-based subject
- At least 7 years significant regulatory experience in the OTC industry
- Good understanding of the regulatory and pharmaceutical environment. Having commercial and strategic awareness.
- Significant industry experience in regulatory affairs, preferably in the consumer health sector for example, preparing regulatory submissions Marketing Authorisations, Reclassifications, responses to Regulatory Agency (RA) questions and other correspondence in accordance with EU regulations and guidelines, managing and maintaining Marketing Authorisations.
- Regulatory knowledge of medical device certification preferable.
- Experience of authoring and report writing.
- Project management.
- Proven successful interaction with the Regulatory Authorities.
- Experience of authoring, implementation and training of internal processes.

Profile and Skills

- Able to motivate a team and support them through change
- Able to analyse complex data to determine the key facts and to be able to communicate these at the right level for the audience.
- Problem solving skills, methodical, pragmatic, logical with technical aptitude
- Good organisation, planning, able to prioritise
- Can work under pressure to achieve deadlines
- Effective communication and report writing skills
- Proven negotiation skills
- Strong Word, Excel, Adobe and PowerPoint skills