Job Description

Job title: **Senior Regulatory Executive**

Issued: January 2021

Overall Responsibilities:

Supports the Regulatory Affairs Management (RAM) on all matters relating to products in scope of PAGB. Supports the development and roll out of agreed PAGB strategies, including responsibilities for ad hoc projects. Attends meeting with relevant stakeholders and forges and maintains relationships with PAGB members, government organisations and other trade associations. Develops specialisation in either OTC medicines or Self Care Medical Devices, to help provide expert support to members. Manages relevant PAGB's working group and subgroups. Supports provision and maintenance of PAGB professional learning programme.

Key Areas of Responsibility:

1. **Regulatory and Technical**

- Support the provision of regulatory advice, information and analysis on UK and international issues, current and forthcoming EU and UK regulations and guidelines affecting all products within scope of PAGB membership.
- Specialise in key product area to become key point of contact for member companies in that area.
- Support the RAM in monitoring live issues and potential issues for the OTC sector and assist in the delivery of resulting PAGB work programmes.
- Manage agreed PAGB working groups.
- As required, provide technical input on behalf of PAGB on ingredient challenges and safety issues relating to all products in scope of PAGB membership.
- Manage, monitor, analyse and respond to consultations and proposals on regulatory matters in appropriate area of specialisation to ensure that the views of PAGB members are promoted.
- Support provision of advice and guidance on the PAGB Pack Design Code to assist members with the development of compliant packaging.
- Provide advice to PAGB membership team on admissibility of products to membership as appropriate.
- Provide advice to members relating to New Product Development initiatives, including but not limited to reclassification, product classification, compliance to regulations, borderline issues.
- Provide technical input to codes and guidelines as they are reviewed.
- Manage the development of position papers on relevant topics as required.

- Liaise as appropriate with other trade associations, including European Self Care Industry association AESGP, attending relevant working group meetings as required.
- Support both the development and roll out of agreed PAGB strategies.
- Help develop and maintain information in PAGB professional learning programme.
- Responsibility for ad hoc projects as required.
- Learn and gain an understanding in regulatory affairs arena via on the job projects and experiences, as well as mentorship.
- Gain a general understanding and keep abreast of ongoing work and issues within the PAGB regulatory team in all the product areas.
- Deputise for other members of the Regulatory affairs team as appropriate.
- Monitor relevant regulatory inbox as per agreed schedule.

2. <u>Advertising Services</u>

- Provide support to the PAGB's Advertising Department on the substantiation of claims as required.

3. <u>Training</u>

- Input into the content of the PAGB Professional Learning Programme liaising with other PAGB staff as agreed with the RAM.
- Develop regulatory training modules as required.
- Support the development of PAGB training events and seminars.
- Conduct training modules as appropriate as appropriate.

4. <u>Public Affairs and Policy</u>

- Support the provision of technical support, including the preparation of briefing documents for MPs, and Government organisations or officials.

5. <u>Media, Communications and External Relations</u>

- Organise the collation of data from members for submission to MHRA and other stakeholders.
- Support the provision of technical input into media statements, press releases and research papers.
- Monitor and report on regulatory and marketing issues and update members via mailings, presentations and PAGB publications e.g. Regulatory Intelligence, This Week and Spotlight.
- Attend external meetings as appropriate to support the Regulatory department.
- Represent PAGB at government agency meetings as required e.g. FSA, MHRA Industry Group.
- Develop and maintain relationships and trust with external contacts and members.

6. <u>PAGB Working Groups and Planning</u>

- Manage the appropriate PAGB working group and subgroup, including developing and overseeing strategy and yearly objectives.
- Manage the papers and Minutes of Working Groups as required.

7. Other

- Promote PAGB's services to existing members through company visits and to be an advocate of PAGB to potential new members.
- Support the maintenance of the systems and processes within the regulatory department, including optimising processes and updating SOPs/Guidelines as appropriate.
- Support RAM in the reporting of ongoing work to wider audience e.g. monthly report or statistics.

Qualifications and Experience

- Life sciences, chemistry, or pharmacy graduate to honours level or equivalent.
- Experience of assessing evidence.
- At least 2 years experience of working within healthcare, the pharmaceutical industry or in Regulatory Affairs

Profile and Skills

- Able to work as part of a team as well as autonomously.
- Keen interest in the regulatory and pharmaceutical environment.
- Strong research skills with experience of technical scientific documents
- Good organisation, planning, able to prioritise
- Can work under pressure to achieve deadlines
- Effective writing and minute taking skills
- Excellent presenter
- Strong Word, Excel, Adobe and PowerPoint skill