PUBLIC CONSULTATION Report

Your Feedback: The Medicines Authority 2016-2020 Strategy

Objectives and scope

The Medicines Authority presented the draft 2016-2020 Strategy which is based on five key strategic goals:

- Optimised regulatory systems
- Better informed users
- Access to medicinal products
- Supporting innovation
- Organisational development

Following a number of workshops carried out with a diverse array of stakeholders, the Medicines Authority engaged in a proactive exercise to listen to stakeholders' feedback so as to:

- Assess its performance as perceived by different stakeholders;
- Measure satisfaction with the services provided;
- Understand better stakeholder needs and expectations to add value to public health and the pharmaceutical operations;
- Act on relevant opportunities for improvement in line with the objectives, priorities and resources of the Medicines Authority;
- Gather feedback on the proposed 2016-2020 Strategy.

Process used to seek stakeholder views and summary of responses

Submissions were received through the following channels: online form on the public consultations portal, the Medicines Authority Stakeholders' Satisfaction Survey, and via email; between 4 October and 1 November 2016.

Total number of feedback received:

from wholesale dealers	10
from healthcare professional	1
from manufacturers	1
from others	3
through the online form	1
through email	1
through the survey	13

Detailed overview of responses

The Medicines Authority acknowledges the views and constructive comments put forward by the diverse stakeholders. The Strategy document was described as pleasing, structured, proactive, reasonable and achievable. The overall level of satisfaction in relation to the Medicines Authority was largely affirmative, particularly with respect to showing integrity, preventing and solving problems, and the approach and attitude to stakeholders (92% fully satisfied/satisfied). 85% of respondents were fully satisfied or satisfied with the equity of service, responsiveness, and providing an effective yet supportive regulatory environment. All respondents were fully satisfied or satisfied with the quality of service of the agency and knowledge and experience of staff. The Medicines Authority's core operations, such as inspections, implementation of legislation, authorisation of medicinal products, information provision, scientific advice, accessibility, correspondence and crisis management were rated as very effective or effective by the great majority of respondents.

Positive feedback pointed towards the improvement in the services offered by the Authority, which was perceived by stakeholders over the past years. The traineeship programme was well received as an opportunity of significant exposure to regulatory science during postgraduate studies. The workforce was described as competent and workshops/training sessions organised by the Authority were encouraged. Communication was rated as a strong point for the Authority which could be further enhanced by an online chat portal. It is evident that stakeholders appreciate the Authority's efforts to limit administrative burdens through its numerous simplification initiatives. The Medicines Authority annual reports were described as informative and the growing financial stability encouraging.

Suggestions for improvement included the requirement of more active market surveillance in attempt of addressing market failure concerns, further guidance with respect to advertising, sustained development of the increasing online resources, and development of guidance documents to industry. There is ongoing active consideration of these areas by the respective directorates/units. This exercise also stimulated discussions on the management of expired medicines between the Authority and concerned entities.

Implementation

Stakeholder feedback	Way Forward	Accountability and Governance
Further thought should be given to the implementation of the Falsified Medicines Directive.	Co-ordinate visit by the European Commission to address stakeholders' feedback and concerns.	End 2016 – EU Affairs.
Enhance public awareness with respect to pharmacovigilance activities.	Launch information campaign on safety of medicines.	End 2016 – Strategy, Operations and Regulatory Affairs and Post-Licensing Directorates.
Improve monitoring of drug use through more effective online reporting systems and ensure quality standards and safe practices at clinical level.	Disseminate online form and launch information campaign on safety of medicines.	End 2016 – Post-Licensing Directorate.
Be more involved in the formation of students at University, in particular the need to report ADRs for all healthcare professional and sustain focus on regulatory science though placements.	Relaunch and rebrand the Medicines Authority International Traineeship Programme.	End 2017 – Strategy, Operations and Regulatory Affairs Directorate.
Training courses would be beneficial to all pharmacists, whether in community, industry, manufacturing or wholesale dealing.	Establish RTDI Unit; organise training, disseminate established guidelines.	End 2018 – All Directors; RTDI Unit.
Organise information sessions on new legislation and workshops on PV, RA, etc.	Establish RTDI Unit; organise training, disseminate established guidelines.	End 2018 – All Directors; RTDI Unit.
Provide guidance documents, including the areas of advertising, process for online submissions, and guidebook for QPs.	Establish RTDI Unit; organise training, disseminate established guidelines.	End 2018 – All Directors; RTDI Unit.
Develop a list of who is responsible for each sector, for example who to contact with queries re: parallel trade, pharmacovigilance, etc.	List is available internally and generic e-mails in place to ensure business continuity.	Completed.

Consider market surveillance and market failure concerns.	Market surveillance programme in place.	Completed.
Strengthen regulatory compliance; look into quality standards of licensed healthcare institutions.	Licensed healthcare institutions not within the remit of MA.	Licensed healthcare institutions not within the remit of MA.
Taking the necessary actions when required so as to ensure compliance by all suppliers.	Consultation on the Special Procedure (Penalties in respect of the Medicines Act) (Amendment) Regulations.	Post-consultation analysis underway - Strategy, Operations and Regulatory Affairs and Inspectorate and Enforcement Directorates.
Consider spot-checks on retailers that sell health products to consumers.	Outlets, other than pharmacies, are outside the remit of MA. Strengthen monitoring of pharmacy services by introducing self-assessment and risk-based pharmacy inspections including spot-checks when required.	End 2018 - Inspectorate and Enforcement Directorate.
Develop apps.	Website to be changed to responsive website.	End 2017 – Strategy, Operations and Regulatory Affairs Directorate and Information and Communication Technology.
Update and improve user-friendliness of website, introduce instant messaging service.	Website to be changed to responsive website.	End 2017 – Strategy, Operations and Regulatory Affairs Directorate and Information and Communication Technology.
Streamline online services, use online forms and applications.	Introducing online forms.	End 2019 - All Directors and Information and Communication Technology.
Enhance networking, make better use of social media, publish a newsletter or have regular spot in a magazine to promote MMA achievements and public health initiatives.	Include agreed communication initiatives in Key Tasks and Performance Targets for 2017.	End 2018 – All Directors.

Conclusion

Continuous feedback with all stakeholders is pivotal for an effective communication approach in the efficient implementation of the strategy. The Medicines Authority welcomes the comments received and in line with the strategy, will continue to engage stakeholders and review responses through the annual planning process, while adapting to changes accordingly.