HPRA Response to Public Consultation on Strategic Plan 2016 - 2020

1 WHO WE ARE AND WHAT WE DO

The HPRA is the regulator of health products in Ireland. Our mission is to protect and enhance public and animal health through the regulation of medicines, medical devices and other health products. In carrying out our regulatory functions, the HPRA puts the health of people and animals at the core of everything we do. We use our scientific and clinical expertise to review and monitor health products available in Ireland or exported abroad. Our aim is to make sure that the health products we regulate are as safe as possible and do what they are intended to do.

2 PUBLIC CONSULTATION ON STRATEGIC PLAN FOR 2011 – 2015

During 2015, the HPRA began developing its next strategic plan. As part of this process, we sought the views of our stakeholders on the issues and priorities we should consider in its development. The consultation document was available on the website for public comment from 2 to 27 March 2015.

A total of eight responses were received: from other health sector agencies, healthcare professional groups, a patient association, and the retail pharmacy sector. We welcome the comments received and have summarised them below according to the key themes which emerged from the respondents' comments.

3 STAKEHOLDER VIEWS ON REGULATED AREAS

The majority of comments made related to the regulation of human medicines. A number of concerns were raised by more than one respondent, especially concerning the area of access to medicines. Medicines shortages which have occurred increasingly over the past few years were seen as a serious patient safety issue where health outcomes can be affected by lack of the appropriate medicine. Respondents appreciated that the causes of shortages were multi-factorial and not always within the remit of the HPRA. They asked that the HPRA would work closely with the HSE and Department of Health to provide information to healthcare professionals on the shortage issue and on alternative sources of suitable product for their patients.

Another priority for some respondents was the reclassification of medicines from prescription status to over-the-counter or from over-the-counter to general sale, so that patients can access medicines through pharmacies or other retail stores without the need for a prescription. Respondents acknowledged the work done by the HPRA to encourage reclassification applications from marketing authorisation holder but commented that the current system should be supplemented by a more proactive approach.

The supply of unlicensed medicines under the 'exempt medicinal products notification' scheme was seen as unsatisfactory for patients, prescribers and pharmacists though understandable given the size of the Irish market which may not support the marketing of a wide range of authorised products.

Mention was made by one respondent of the potential use of modern electronic technology to support the supply of product-related information to healthcare professionals and patients.

The appropriate designation of borderline products (i.e., classification of products as medicines, food supplements, devices, cosmetics or other) was raised by respondents who called for a more co-ordinated process and a 'health systems' approach where appropriate.

Security of the supply chain for medicines was a particular concern, with support for the HPRA to continue to focus on falsified medicines, illegal internet sales and supply chain activities.

A number of respondents expressed views about the proposals currently being debated at a European level in relation to new legislation on medical devices and veterinary medicines and the potential impact on their areas.

Respondents commented favourably on the HPRA's stakeholder communications and were welcoming of further engagement in areas in which they have particular interests.

Specific mention was made that the HPRA should have an active role in contributing to policy decision-making at national and European levels, especially in an environment where existing models of health product distribution and supply may be changing.

4 HPRA COMMENTS

Many of the areas raised by respondents in relation to medicines are ones where the HPRA has an active involvement already and where further work needs to be done over the coming years. We welcome the support of our stakeholders in furthering our aims and objectives in relation to access to medicines, appropriate regulation of health products and securing their supply chains. In our strategic plan we have reflected on the appropriate direction we should take and have addressed many of these issues, seeking to make substantial improvements over the next five years, within the context of our remit and functions.

The HPRA is contributing significantly to discussions on the new medical device and veterinary medicines EU legislation to ensure that the adopted Regulations provide enhanced protection for patients, users and animals, while providing less burdensome procedures for competent authorities and the industry sectors.

We recognise the potential value of new electronic technologies to benefit patients and their healthcare professionals and will seek to support this as appropriate at national level and at European fora.

We welcome the comments from healthcare professional regulators to continue our communications and collaboration on issues of mutual interest or concern. It is through working with other agencies and all our stakeholders that we deliver on our mission to protect public and animal health in Ireland.