Performance and Resources report quarter 4 2022 to 2023: Risk Analysis Process and Regulated Products Service

Performance and resources results for the risk analysis process and regulated products service.

Key successes in the quarter

Risk Analysis - Our public register of risk analysis issues has been added to during the quarter and contains 22 risk analysis issues, 6 more than in quarter 3. Of those issues, 16 are progressing through the risk assessment and evidence gathering phase of the process, 1 is undergoing development and agreement of a risk management approach, and 5 issues have been recorded as complete, an increase of 2 from quarter 3.

Regulated Products – We have completed 3 applications this quarter bringing our total to 34 since the service went live in January 2021. We have made steady progress with authorisations and have advised Ministers to authorise a further 15 applications, which included 8 new Genetically Modified products, 2 Novel Foods and 2 Food Additives. The Statutory Instruments legislating these authorisations were laid in each of the nations and will come into force in the next quarter.

Risk Analysis - key insights

22 issues are on the risk analysis register, with:

- 16 at risk assessment / gathering evidence
- 1 where risk management options are
- being developed
- 5 completed issues

Regulated products - key insights

There are 438 applications in the service in the following stages:

- 241 at Pre-Validation
- 162 at Risk Assessment
- 20 at Risk Management
- 15 at Authorisation
- We have completed 34 applications to date

Concerns / risks

Regulated Products - We expect that the caseload in the risk assessment stage will continue to build and that the flow of products into the system will vary from year to year. This makes

accurate forecasting challenging and it will become a risk if the caseload builds beyond acceptable levels. The risk assessment stage is where pressure may build up as this is the most resource intensive stage, and where there is greatest uncertainty, as specific issues may not become clear until detailed work on a dossier has started. We have undertaken modelling and analysis to better understand the risk of having insufficient resources to meet the expected demand.
CBD products continue to form a significant proportion of the caseload. Although the number of applications is large, these are being grouped by common characteristics or issues to efficiently assess these products.

Next steps

Regulated Products - The new Case Management System (CMS) will start receiving new applications in early June 2023. We expect the new system will help to drive significant efficiencies by reducing the number of contacts that result in non-applications. In Q4, there were 136 contacts resulting in 36 applications progressing (26%). As CMS embeds, we will be able to gather business intelligence to deliver more robust reporting and further develop our Key Performance Indicators.