



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Business pipeline

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Business pipeline activity is about anticipating in a timely manner the quantitative and qualitative impact of pharmaceutical pipelines on the operations of the Agency.

Business pipeline

The European pharmaceutical market remains a highly complex and dynamic area as a result of research and development trends, failures, market dynamics and regulatory changes.

Accurately estimating potential applications and new scientific and technical issues to be addressed is challenging.

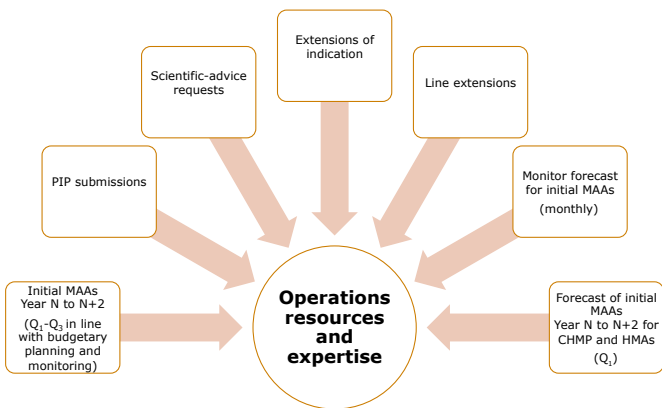
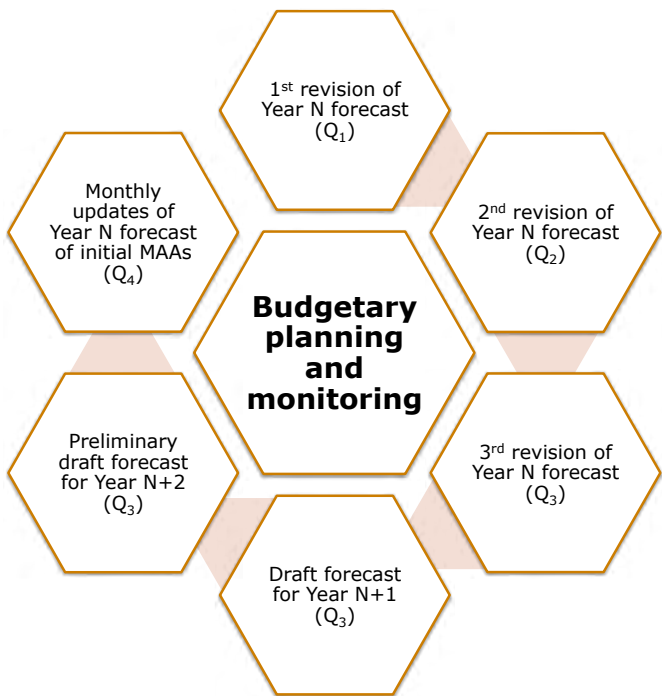
The business pipeline activity is a tool for accurate budgeting and identification of the most appropriate resources and scientific expertise.

Direct and dedicated dialogue with drug-development and portfolio managers is key.

Confidentiality

As with all communication of commercially sensitive data, the Agency manages this activity in a strictly confidential environment.

Budget, operations and environment



Environmental analyses

Business environmental analysis

- Business pipeline meetings
- Pipeline e-updates

Ad hoc scientific and technical analyses

Business pipeline meetings at the Agency

Business pipeline meetings are instrumental in contributing to the Agency's preparedness.

A unique opportunity to establish a confidential and mutually beneficial discussion on your products' regulatory pipeline, e.g. marketing-authorisation application (MAA), paediatric investigation plan (PIP), scientific advice, orphan designation and extensions.

The primary goal is to identify at an early stage any issues impacting the progress of your product portfolio, and to effectively anticipate scientific expertise needed, guideline discussion, changes in technology and drug development.

The focus is on general aspects of the product portfolio, while specific scientific or regulatory issues can be discussed at the scientific-advice stage, or in the pre-submission meetings for the marketing authorisation, paediatric investigation plan and orphan designation.

Business pipeline

Forecasting allows the European Medicines Agency to budget reliably, manage workload effectively and identify in a timely manner the best expertise to ensure highest-quality scientific opinions.

- Anticipates the necessary operational needs to keep high standards for submissions evaluation.
- Provides a unique forum for an open and mutually beneficial discussion on your pipeline.
- Key for the early identification of the most appropriate resources, scientific expertise and guidelines.
- Provides horizon-scanning analysis to the Agency's scientific committees.
- Supports the planning and implementation of the Agency's work programme.



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Related documents

- SOP/H/3387: Operation of the business pipeline activity for medicines for human use
- WIN/H/3388: Organisation and coordination of business pipeline meetings with pharmaceutical companies
- WIN/H/3389: Data acquisition, control and maintenance of business pipeline database
- WIN/H/3174: CHMP rapporteur/co-rapporteur, forthcoming applications for information to HMA-H

Further information

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