

THE EUROPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES & HEALTHCARE (EDQM)



10 YEARS OF
CO-OPERATION

Setting the Scene Let's scan the Horizon

*Keeping up with Reality and Quality: A challenge for
European Blood Establishments*

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Horizon Scanning?

HORIZON SCANNING

► Foresight science

Definition:

Horizon scanning is a technique for detecting early signs of potentially important developments through a systematic examination of potential threats and opportunities. Search for weak signals, emerging issues and interdependencies.

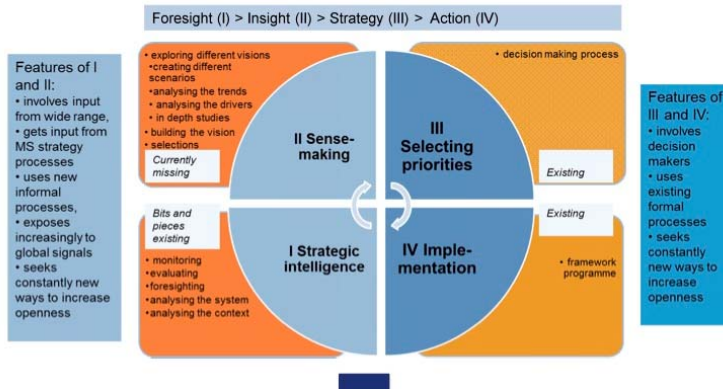
Methods:

- Observations
- Desk research, helping to develop the big picture behind the issues to be examined
- Small groups of experts meeting
- Surveys.....

► Different models/frameworks

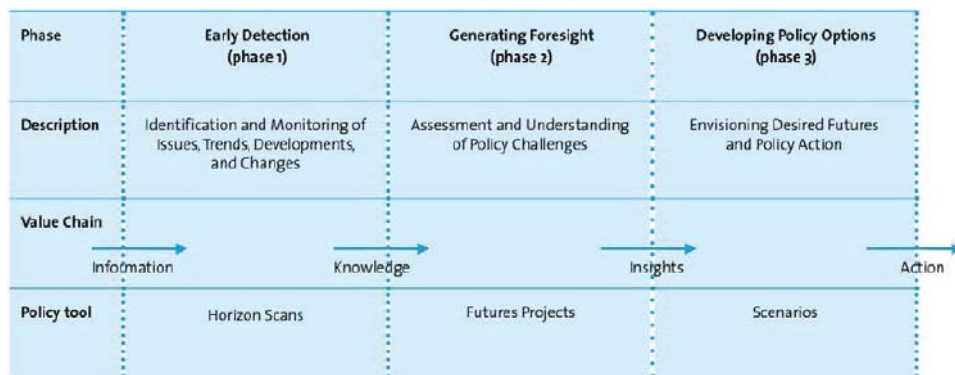


HS : CONCEPTUAL FRAMEWORK (1)



Common stages of horizon scanning from the EuroScan network. 9 This figure is licensed under the Creative Commons Attribution-NonCommercial-ShareAlike 4.0 International License (CC BY-NC-SA 4.0).

HS : CONCEPTUAL FRAMEWORK (2)



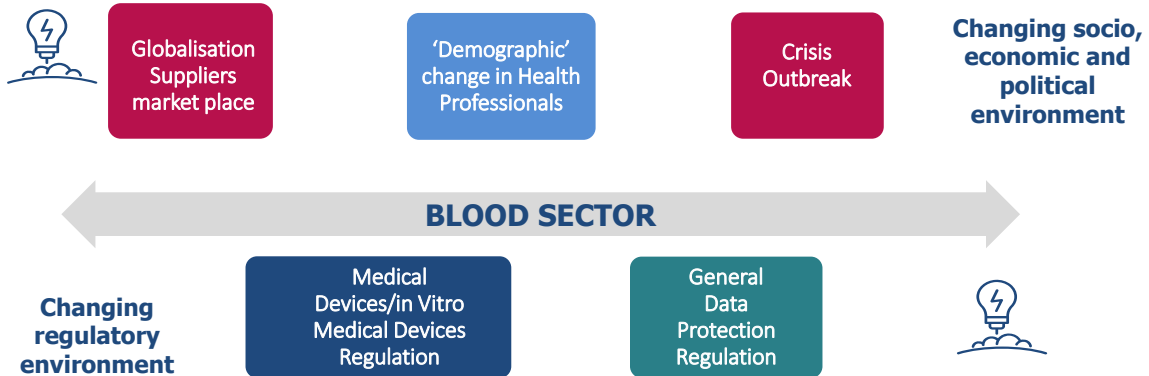
SOURCE: Illustration by Habegger, 2009, based on Schultz, 2006, and Horton, 1999.

Why scanning the Horizon in the blood sector?

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CHANGING ENVIRONMENT



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COVID-19 CRISIS

- Major disruption at all levels of healthcare services, including blood donations and supply.
 - Impact on the **continuity of blood supply**,
e.g. Decreasing number of donors, sick personnel, disruption/shortage in medical devices
 - Need to maintain **critical processes** such as collection and transportation,
 - Reliance on **Quality Management System (QMS)** during the pandemic,
 - Viewpoint of blood establishments/ regulatory/competent **authorities**,
- ▶ Experience and lessons learnt

GLOBALISATION OF THE SUPPLIER MARKETPLACE



- Current competitive environment in the field of medical device industry is creating an **impoverishment** of the suppliers market,
 - **Less** suppliers and **decreasing** diversity and the subsequent emergence of monopolies,
 - **Reliance** on medical devices/material produced outside the Europe, reliance on **third countries**,
 - BEs strive for the right balance between financial and technical specifications when preparing tenders,
 - BEs are requested to audit their critical suppliers putting additional financial burden on them,
- ▶ BEs need to **remain responsive** to this changing environment to ensure the continuity of the blood supply.

NEW REGULATORY ENVIRONMENT FOR MEDICAL DEVICES



- The **new MD and IVD** regulations carry a number of important changes, which will have an impact on both the manufacturers of Medical devices and their users,
 - **Reclassification** of certain MDs and IVDs used by BEs will imply changing the scope of their validation at BE site,
 - Requirements in MD/IVD regulation request to bring **closer scrutiny on the clinical data** provided in the technical file with expected impact on their availabilities and supplies of MD and IVD used by BEs.
- How to **secure continuity of supply** and **mitigate costs**?

HEALTH PROFESSIONALS, CHANGING SCOPE OF PRACTICE



- **Regulation of healthcare professionals** in BE such as nurses, physicians, currently fall under national and EU legislation,
 - Ongoing **demographic changes** and changes in the **availability** of certain categories of healthcare professionals, and evolving competences and needs,
 - Growing demands to re-deploy professionals in **'at risk' processes**,
- Ensuring their **efficient use** and ensuring **blood supply continuity**.

Our Approach

OUR APPROACH



IN SUM



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ACKNOWLEDGMENTS

B-QM WG Group Members & former Members

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