

# FAST TRACK TO EU STRATEGIC AUTONOMY

*Speed check for digital, green and **health***

Tuesday 6<sup>th</sup> December 2022



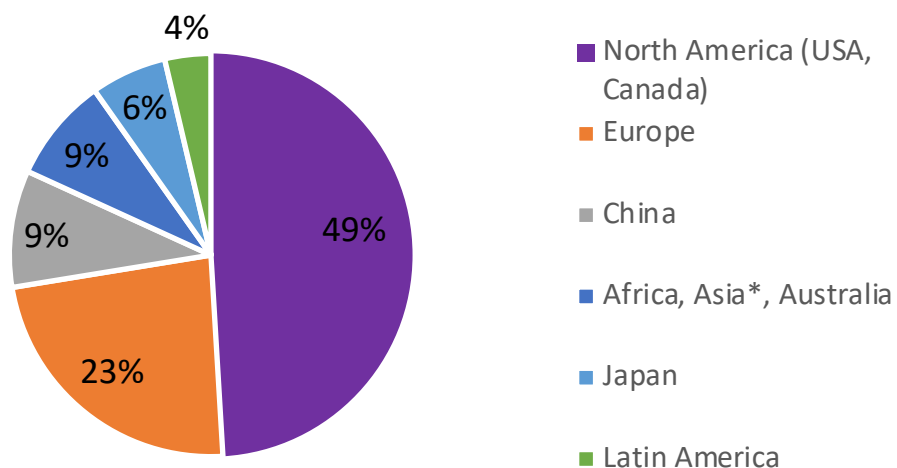
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# Long-term competitiveness in the EU: a focus on the pharmaceutical industry

The world pharmaceutical market (sales 2021, in %)

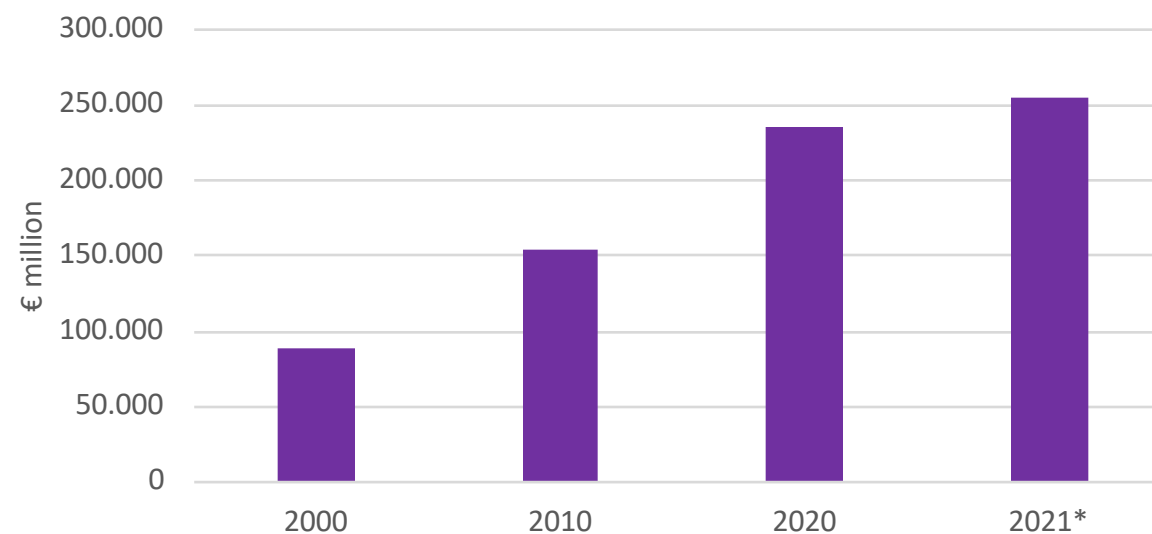


The total **European pharmaceutical market** value at ex-factory prices was estimated to have **increased to €255 billion** in 2021.

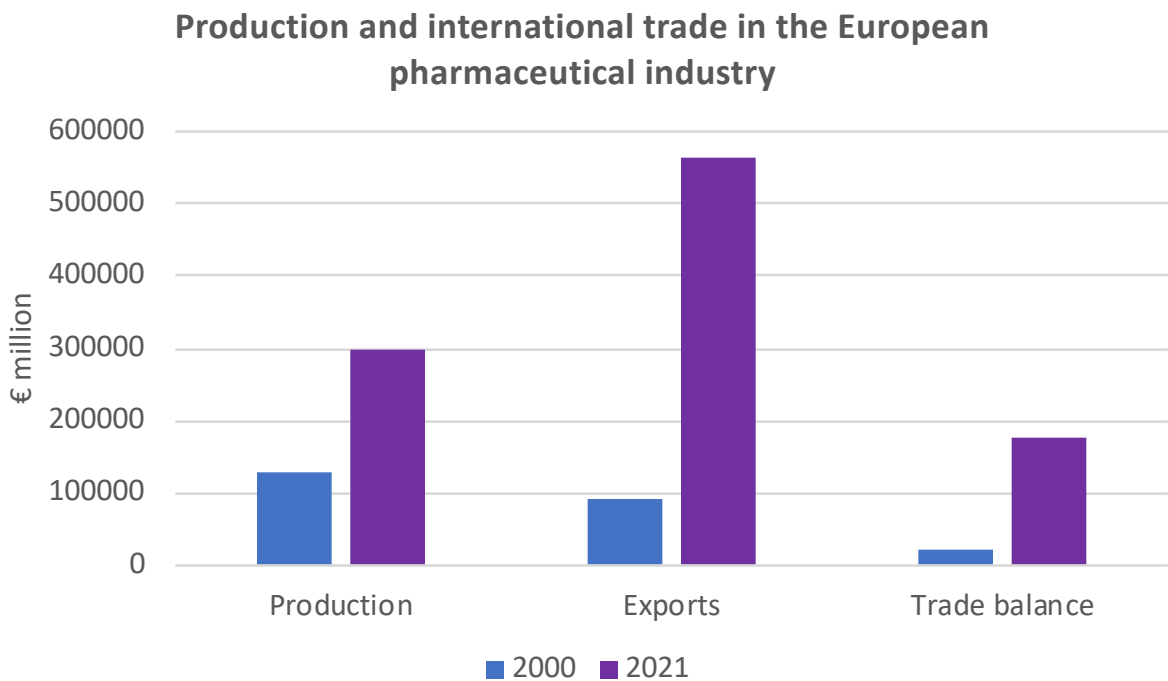
**Germany** was the top-ranking pharmaceutical market in Europe with a value of over €43 billion in 2020, followed by **France** and **Italy**.

The European pharmaceutical industry is recognised as a **highly R&D intensive industrial sector**. The **value of production** for the research-based European pharmaceutical industry **grew to €300 billion in 2021**, with **Italy** still being the main pharmaceutical producer

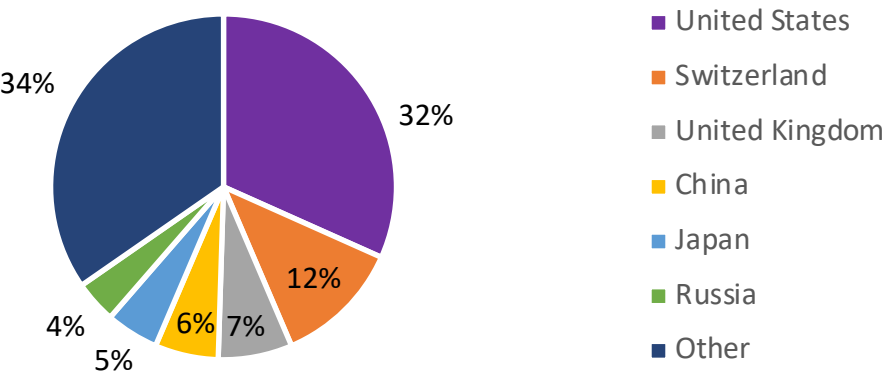
Total European pharmaceutical market value at ex-factory prices



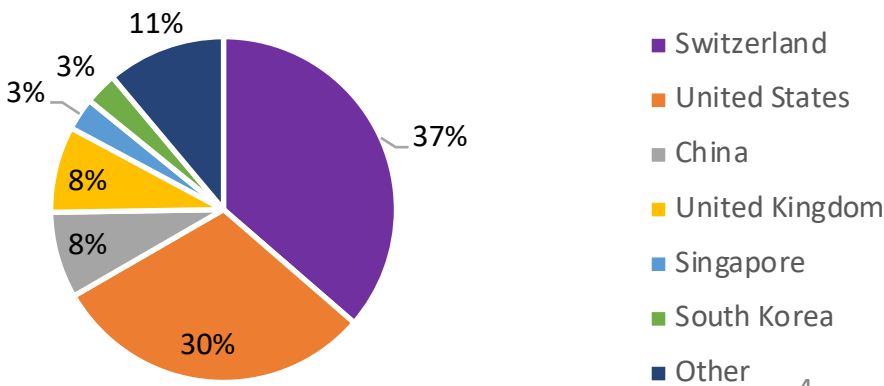
In 2021, imports accounted for €390 billion, with a **positive trade balance of €175 billion**.



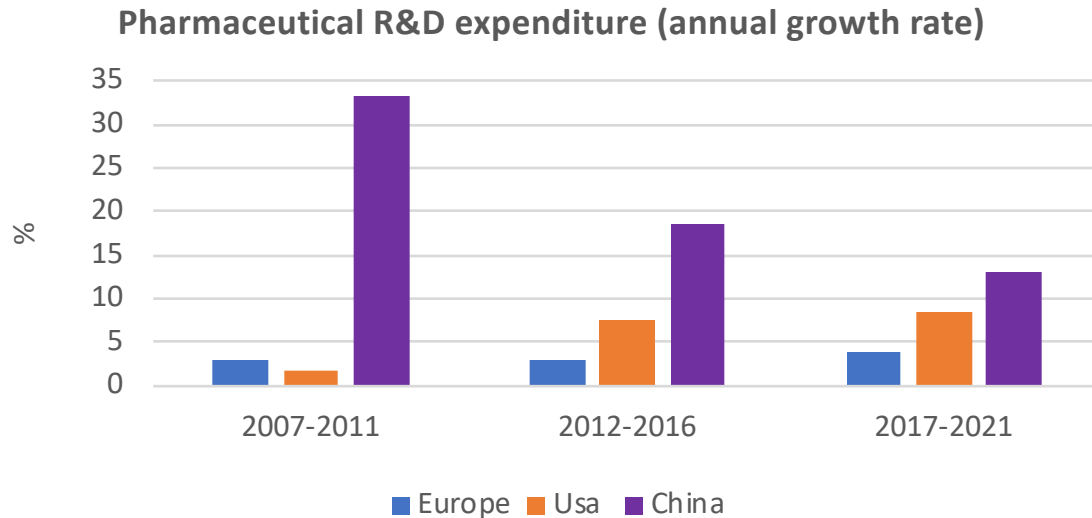
Main EU partners for export of medicinal and pharmaceutical products (2021)



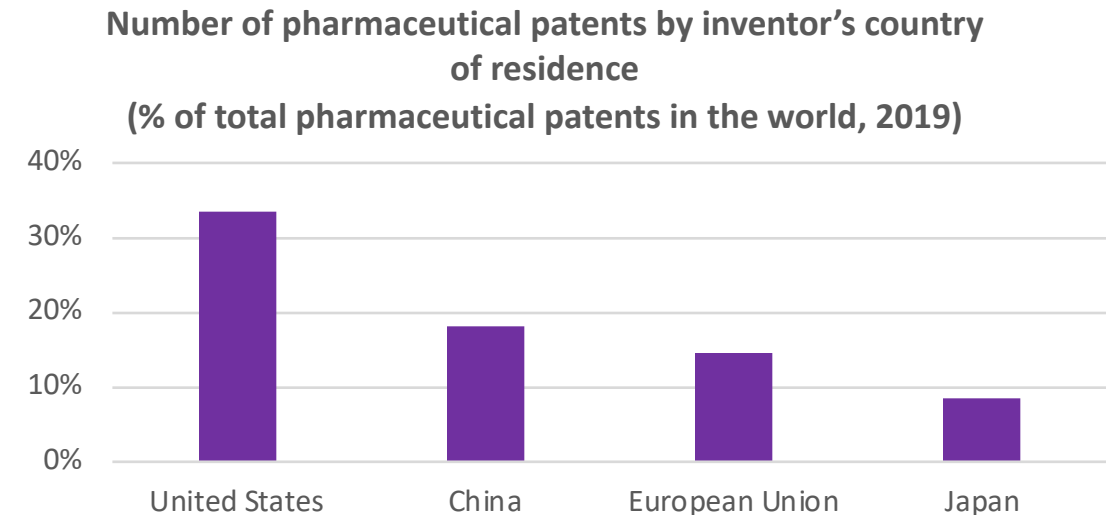
Main EU partners for import of medicinal and pharmaceutical products (2021)



**Pharmaceutical R&D expenditure in Europe has increased considerably**, growing from 1990 by about 400%. However, it is still experiencing lower growth rates than the US and China.



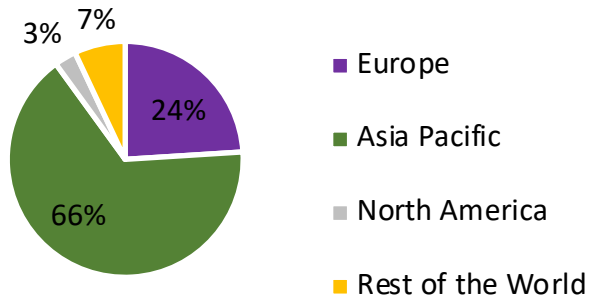
The European pharmaceutical industry is **one of the leading European sectors in terms of number of patents**.



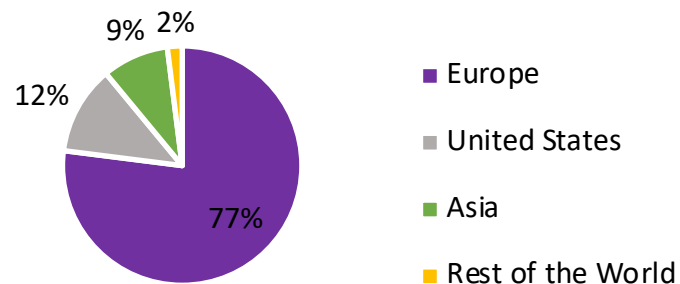
In light of the growing role of other economies in the global pharmaceutical innovation, it is crucial **to maintain and develop a predictable, robust regulatory framework**, embrace the power of **digitalisation** and **ensure innovation-supportive incentives and IP ecosystems**, as well as strengthening **raw material supply chains**.

The pandemic has revealed the **European dependence on several strategic goods and technologies.**

Shares of APIs production



Origin of APIs used for innovative medicines in the EU (2020)



## Four actions need to be taken:



Develop R&D competencies and knowledge through private-public partnerships;



Provide the capacity to turn R&D into market products;



Protect and favour the delivery of innovation through patenting and co-inventions



Retain competencies and knowledge

## Technological sovereignty and strategic autonomy

Europe should take on a **central role in promoting international cooperation in technological projects.**

Sovereignty encompasses **technologic, regulatory and economic adequacy facing the innovation challenges of a changing world.**



The report related to the Industrial Strategy identifies 137 products in **sensitive ecosystems where the EU is highly dependent on foreign sources.** These include **active pharmaceutical ingredients.**

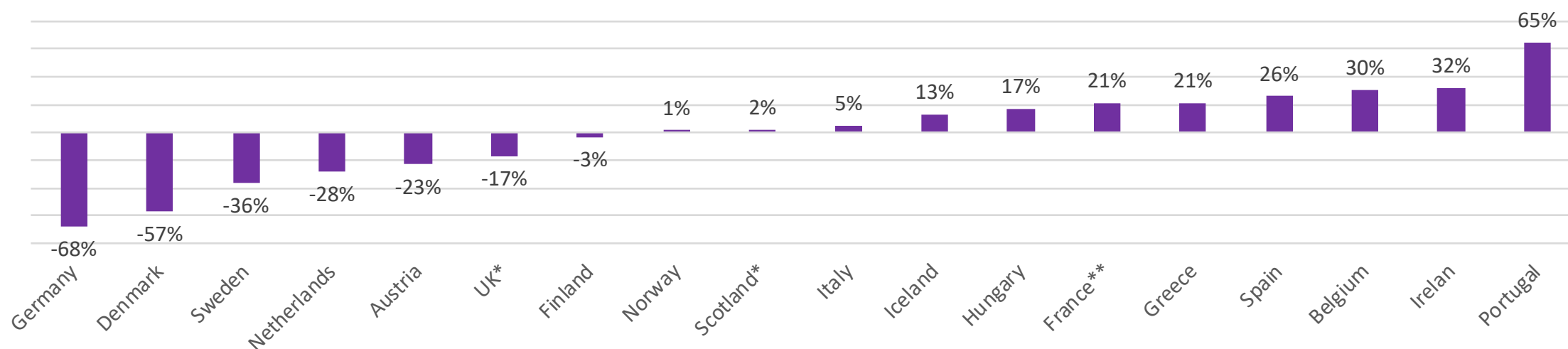
## **The Pharmaceutical Strategy for Europe (2020)**

1. ensure patients' access to **affordable medicines** and address **unmet medical** needs;
2. promote the **competitiveness, innovation capacity, and sustainability** of the EU pharmaceutical sector and the production of high-quality, safe, effective and environmentally friendly medicines;
3. strengthen **emergency preparedness** and response mechanisms and address the issue of security of supply;
4. assert EU leadership on the global stage by promoting **high standards of quality, efficacy, and safety.**

➤ *The European Commission is expected to propose an update of EU pharmaceutical legislation at the end of 2022.*

# Access to care: which role for Intellectual Property Rights?

Time elapsed between the central authorisation for placing a drug on the market and actual accessibility in the selected EU countries (deviation from the average, % values, 2017-2020)

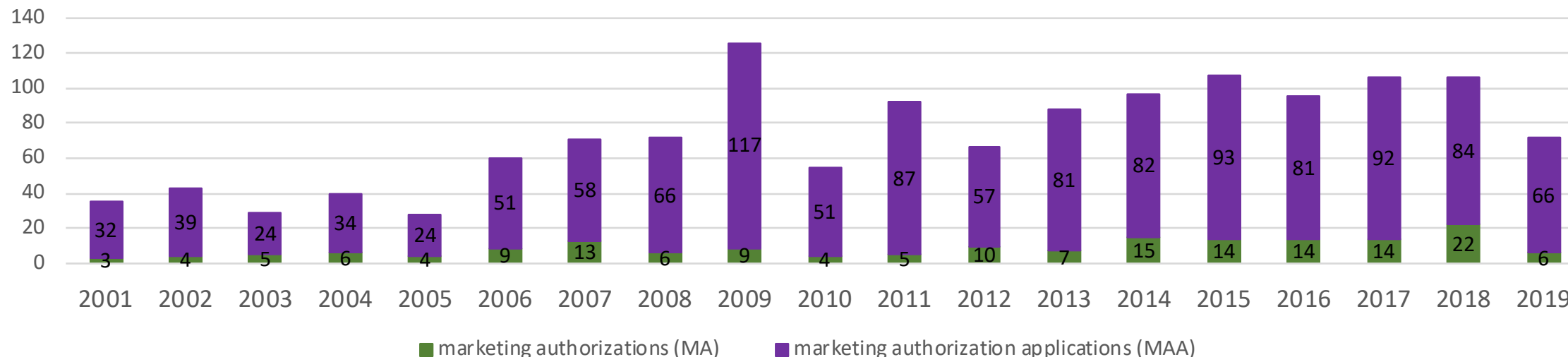


Intellectual property rights attempt to **balance long-run incentives for innovation and short-run access to innovation** and are crucial to **correct market failures in the health domain**: there is a **need for a comprehensive** UE regulation.

The **legal and policy discussions** will determine the extent to which IPRs will be confirmed and maintained as a driver for new product development and, of course, the extent to which the EU will remain attractive as a basis for R&D.



Orphan drug applications and marketing authorisations (MA) in the EU



Patients with **rare diseases experience** significant unmet health needs and lack of available therapies:

- **orphan drugs would not be developed under normal market conditions** because of their limited commercial attractiveness
- these diseases are highly complex and subject to limited scientific and clinical knowledge, resulting in the **high complexity of their research and development**.

Since 1999, EU **tax reductions, incentives and protection of exclusivity rights** have encouraged investment in the development of orphan drugs by pharmaceutical companies.

- **Technological sovereignty** in the **pharmaceutical sector** is not only a matter of competitiveness but access and equity;
- Far from proposing that the EU should be totally selfreliant and absent from global value chains, aiming at strategic autonomy within the international markets is, thus, a priority;
- So is reinforcing and building an appropriate retaining knowledge and investment in R&D activities, thank to which **Europe can take on a leading role in fields where scarce scientific and clinical knowledge can finally addressed**;
- The **EU Pharmaceutical Strategy** paves the way for the transformations to come, by confronting the most pressing challenges of our time;
- Careful consideration of ongoing health trends should translate into **proper planning and foster meaningful research and innovation efforts**;
- Best practices in answering to **unmet medical needs**, the role of IPRs and evaluation methods should be, at the same time, carefully considered.