

LESSONS FROM THE PANDEMIC: BIOMEDICAL INNOVATION, THE PHARMACEUTICAL INDUSTRY AND THE ROLE OF PUBLIC INSTITUTIONS



“Biomed Europa from the Industry point of view”

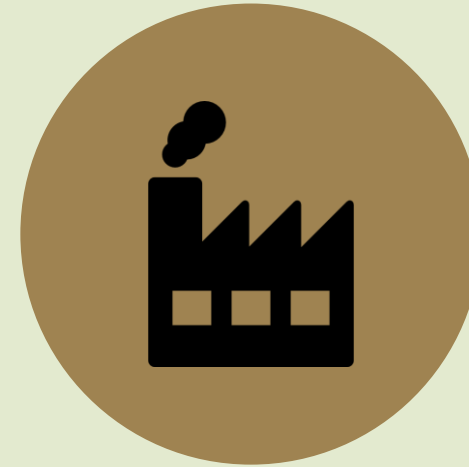
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About us



PAOLO ZANINI - PHARMACIST
FORMER PRESIDENT OF UNIFARM GROUP,
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RICCARDO CATALANO
R&D DIRECTOR @ E-PHARMA TRENTO
(A CDMO COMPANY OF UNIFARM
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Development of a new medicine

- ▶ The R&D process to develop a new medicinal product is a **huge expense** for any pharmaceutical company.
- ▶ Depending on the degree of innovation, enormous economical efforts are required for:
 - Drug discovery
 - Pharmaceutical development
 - Clinical development
 - New technologies and innovation
- ▶ For each new authorized medicine, the R&D cost is generally directly and indirectly **supported by public funds**.
- ▶ **We suppose that we all agree on that!**



Facts

- Current model of the Big-pharma companies in term of pharmaceutical research and innovation is that **profitability strategies overcome urgent needs for human well-being.**
- The result is a disconnection between **Bigpharma's R&D choices and public health priorities.**
- On the other hand, small to medium pharmaceutical companies **are not willing to face the cost** and risk of such complex studies.



Facts



- ▶ Universities and public research centers always contribute to innovation with **diffusion of open science practices in fundamental research**.
- ▶ Thus, they provide **free access to a wealth of scientific results** to private companies.
- ▶ A public R&D and delivery institution for medicines, vaccines, and related biomedical innovations **would benefit of fundamental research** to identify therapeutic priorities in the public health sector.
- ▶ But **there is a missing actor**: A company with all expertise and skills required to finalize product development.



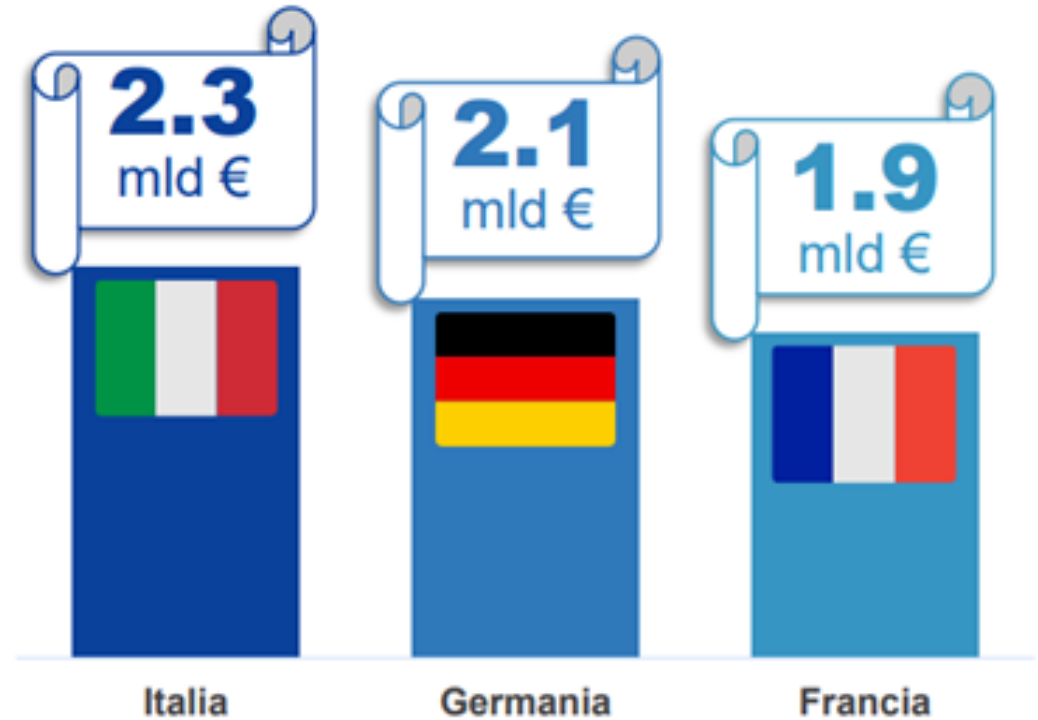
CDMO

- Contract Development and Manufacturing Organisation
- CDMOs could offer **added value, highly skilled human resources and innovation** in research and development.
- European CDMOs are consistent in the EU, with a total turnover of more than **9 billions euros** which increased of about 10% from 2018 to 2019

CDMOs in EU

- The **Italian pharmaceutical** industry plays a role of leadership in EU for development and manufacture of medicines, followed by Germany and France.
- Contract Development and Manufacturing Organizations (CDMOs), could be **the first-choice partner for Biomed Europa's project.**

I principali produttori europei per fatturato CDMO



Elaborazioni Prometeia su dati Orbis di Bureau van Dijk e varie (stime al 2019, maggio 2021)



How this cooperation can be made?

➤ The idea is drafted below:

- Public institution: to **identify the areas/medicines of interest**
- CDMO: to develop an **R&D plan** (activities/investments)
- Public institution: to **finance** all activities
- Public institution: To apply for a **patent** (if feasible).
- Public institution: To make the product available to patients at a **controlled** and **transparent** price
- CDMO: To manufacture the product



Controlled and transparent price

- Prices, particularly for new innovative/effective medicines are affected by **wide margins**.
- A price without **amortization of R&D cost** and **investor's revenues** will be significantly lower.
- A **controlled and transparent price** will ensure the supply of affordable medicines.



Biomed Europa

- Biomed Europa's goal would be **to optimize the investment with the final scope to keep the right to use the results of the research** to supply new socially useful medicines at the lowest possible price, for a collective benefit.
- In this view of cooperation with CDMOs, Biomed Europa must have **total control of the projects** based on its scientific and cultural independency.
 - Selection of projects
 - Selection of partners
 - Intellectual property rights
 - Strategic decisions on the project

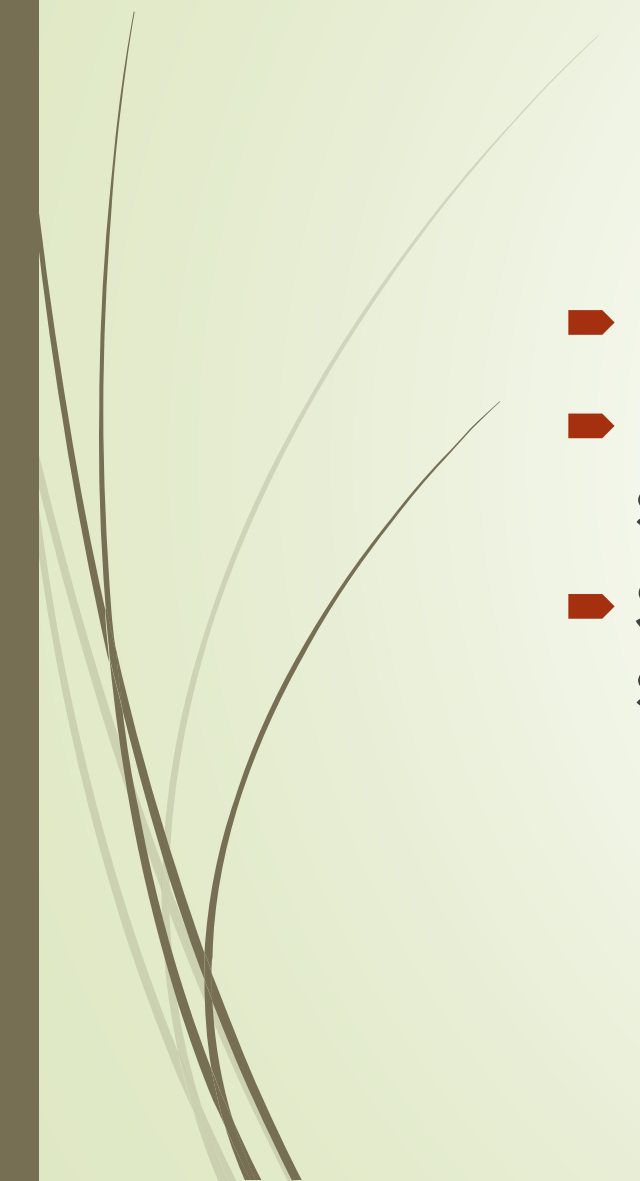


The advantage of cancelling the economical industrial risk by founding the research and development and innovation is evident.

- Encourages companies to participate to the project
- Increases knowhow maintaining it within the EU borders (vs China/USA duopoly).
- Allows to create a network of innovative companies.
- Helps to develop professional skills.
- Adds value to university research which may not be appealing for Big-Pharma companies.
- Increases companies' turnover/occupation.



And finally

- Reduces the risk of medicine shortages.
 - Increases patients access to therapies and it's sustainability
 - Significantly decreases the expense of the healthcare systems
- 



To conclude

- ▶ Is there a possible future collaboration between public funded R&D and small or medium CDMO companies?
- ▶ Recourse to public funds could be a strong incentive for Italian companies to overcome the reluctance to develop new and innovative medicines.
- ▶ BIOMED EUROPA could build a portfolio of generics or innovative drugs to be made available at a controlled price.

It's worth a try, isn't it?

**Thank you for
your
attention!**

The background features a light green gradient. On the right side, there are several thin, curved lines in a slightly darker shade of green, creating a sense of movement and depth. A thin vertical line is positioned to the right of the text.