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Biopharmaceutical Innovation fosters better health in Europe The Patient's Perspective

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What does biopharmaceutical innovation mean to patients?

- **First of all, it provides patients with hope for a better chance of survival, especially for those patients suffering from currently untreatable or difficult to treat diseases.**
- **Secondly, it offers more targeted medicines that are safer, more effective and with less side-effect.**

The risk of disease and response of treatment varies from person to person, due to variations in human genetic coding, interaction between our genes and the environment and our immune system. With an improved understanding of these differences we have the ability to target medical treatment much better to those people who will benefit from it.

Traditionally patients were organised into disease groups with similar symptoms and medicines were developed for them and evaluated along the benefit /risk based on the **average clinical response**. However, since we now have a better understanding of the molecular basis of disease, it has become apparent that one size treatment does not fit all. Currently there is considerable waste in the system, medicines have side effects or do not work in particular patients.

Innovative biopharmaceutical research that links medicines with biomarkers and is accompanied by diagnostic tools will bring about much more personalised treatments.

A patient's dream is to have the right medicine fit each patient at the right time. And that this remains affordable for our healthcare systems.

For some patients **speedy access** to innovative treatment can be a question between life and death, especially for those patients with rare or difficult to treat diseases with few treatment options. They depend on R& D to find new treatments.

As R & D becomes more targeted, **patient selection will become very important**. Patients who are likely to respond will have to be found and stratified into smaller groups for clinical trials.

However, I would like to raise a word of caution here: the selection process has to be accurate, otherwise there is a danger that patients are excluded who could have benefitted. This is why the research needs to include the development of drug/test solutions and reliable biomarkers.

The current regulatory process is lengthy and some patients with life threatening conditions would be willing to take more risk. Increasingly, once a biopharmaceutical medicine is centrally approved by the EMA, it is **not necessarily available to patients in all EU countries**.

Lengthy reimbursement decisions follow. Questions about the value of innovation and relative effectiveness are raised which delay the process even further.

On behalf of patients I would like to plead that it is essential that we - innovators, policy makers, regulators, and society at large - find ways to make innovative treatment available to patients and affordable by healthcare systems.

Suggestions

Given these challenges it seems obvious that patients want to and must become more involved in the R& D process. Patients see themselves no longer as a “subject” in a clinical trial but a “partner”.

We would also advocate for more patient involvement in the guideline preparation on medicines development and include in the benefit/risk assessment such factors as unmet medical need, patient's utility and values.

Conclusion

Patients want cutting edge research to take place in Europe, as some of them would like to enroll in clinical trials, especially those who have run out of treatment options. **The EU 2020 strategy** places high expectations on innovation in helping Europe to address our grand societal challenges of health, ageing, energy, climate change and to promote economic and social development. Keeping research in Europe and encouraging innovation is good for the economy, job creation, competing on world markets. It is good for patients if it brings better treatment and care.