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Policy Principles for a Robust Biotechnology Sector

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Policy Principles
For a Robust Biotechnology Sector

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Bio Biotechnology Industry Organization

Biotechnology

- Harnesses the power of living systems and organisms to develop new, useful, and sustainable products.
- Employs living cells to create new and more effective treatments of disease, enables plant cells to be modified more rapidly and precisely than traditional plant breeding.
- Reveals the genetic origins of diseases – such as cancer, multiple sclerosis, and diabetes – to find new methods and products to detect and treat them;
- Boosts agricultural crop yields and reduces the environmental impact of farming
- Enables manufacturing processes that reduce waste, minimize water use, prevent pollution, and curb greenhouse gas emissions.

Biotechnology in Healthcare

- Only one out of 10 biopharmaceutical discoveries is successfully developed and commercialized. Many fail after a concept is proven and before regulatory approval is obtained. ($1.2 billion and more than ten years.)
- Private sector funds 96 percent of the biotechnology R&D companies are unable to attract the investor resources necessary to fund clinical trials.
- Investors will fund capital-intensive biotech innovation only if they are confident that, if a product beats the odds and makes it to the market, they will realize a positive return on their investment.

What Can Regional Economies Do to Further Biotech

- Facilitate research cooperation among private, non-profit, and governmental organizations;
- Protect intellectual property rights to attract the private investment necessary to support biotech innovation
- Provide a transparent and predictable regulatory approval process for new biotech products that is science-based and internationally recognized; and
- maintain transparent, non-discriminatory, competitive, and commercially viable markets for biotech products

First Pillar: Research Collaboration

- Support early research through grants, funding, universities and research institutions
- Provide a legal framework for transferring research from public institutions to companies
  - Patents are the legal instruments for such transfers
- Allow the transferor (licensor) flexibility to find the appropriate partner for commercialization
  - A dozen countries have or are implementing technology transfer laws

Second Pillar: Intellectual Property

- **Patent Term:** Patent term of 20 years from filing effective-term for most inventions is approximately 17 years due to patent processing delays.
  - For biopharms only 7 to 10 years – due to the additional time required to fully develop and obtain regulatory approval for the product (Some countries restore the patent terms for biotech products to offset time lost in the regulatory review process)
- **Data Exclusivity:** Protection for test data that regulatory authorities require for approval
  - Before a biopharmaceutical company can make a product available to patients, it must conduct extensive analytical, preclinical, and clinical research tests to prove to regulators that the product is safe and effective.
  - These tests account for more than 90 percent of private sector research and development funding.

Third Pillar: Science Based and Transparent Regulatory Approval

- Preclinical
  - Establishes predictability in humans (not as easy as it sounds)
  - establishes the value of the product's therapeutic effects as compared to any harmful effects; and
  - optimizes the dosage, frequency,and means for administering the product.
- Clinical
  - Governments and biopharmaceutical companies should assure the well-being of research participants;
  - Ethical, e.g. in accordance with Declaration of Helsinki, the Good Clinical Practices through International Conference on Harmonization (ICH-GCP)
  - established industry practice and legal standards.
- Post-marketing approval
  - Phamacovigilance, post-market surveillance etc.

Fourth Pillar: Market Access

- Markets should be competitive, transparent, and non-discriminatory.
- Government purchasers then should adopt reimbursement methodologies that appropriately value the objectively demonstrated therapeutic benefit of a pharmaceutical.
- If considering cost-effectiveness, governments:
  - Should realize that a new drug might allow for the avoidance of other, more costly, health care services (e.g., hospitalizations, surgery, and nursing care);
  - Should realize that a new drug can generate economic productivity gains (healthier population)
  - Should realize that comparative effectiveness studies have limited application for certain rare or orphan diseases due to small population
  - Should realize that a new drug may offer benefits even when it is similar to an existing drug if it is more effective for some patients than the existing drug


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