

Drug Development and Technology

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Received: January 23, 2019; **Published:** April 23, 2019

The Portuguese statement in the UN Report to promote innovation and access to health technologies in the context of the 2030 Agenda, presented on March 06, 2018, stated that the process of research and development of new medicines is expensive, but it is very necessary and should be stimulated in all societies and countries.

In effect, the research and development of new medicines is a long and complex process, with great costs and with reduced possibilities of success. Thousands of molecules are identified and tested every year, but few become prescription drugs. Various scientific disciplines are involved in the process, including organic chemistry, molecular biology, toxicology, medicine, pharmacology, biochemistry, and Computer-aided chemistry.

Several studies developed by prestigious institutions coincide in specifying that, on average, it is necessary about 10 years since the discovery of a new molecule with pharmacological property until it is placed on the market as a medicine, with an average expenditure of 2,600 million US dollars.

The global pharmaceutical market was estimated at 1,11 billion dollars in 2017 and is expected to reach 1,43 billion dollars by 2020. In 2017, the top 10 global pharmaceutical companies generated sales worth 437,257 billion US dollars, approximately 40% of the world market, and the 15 leading global pharmaceutical companies made sales of 568,617 million US dollars, representing 51% of the world market share.

Several years ago, that researchers are introducing several technologies in the initial stage of drug development, to solve problems that can determine the failure of it. Thus, the compound can be modified to solve the problems detected while maintaining the therapeutic effects, or not to continue with the development of the drug, thus avoiding a later failure that implies greater economic cost.

In general, the greatest technological efforts in this field have been directed to the following aspects:

- a) Increase of the yield of the technologies of obtaining organic molecules, through chemical synthesis routes or isolation of different sources, use of biotechnological methods, combinatorial chemistry, nanotechnology, proteomics, metabolomics and 3D printing.
- b) Introduction and development of new techniques for obtaining the compounds.
- c) Improvement of the model systems for screening tests.

In addition, difficult research objectives are receiving greater attention from researchers, promoting technological innovation, which is an important contribution in the current conditions; and the prior knowledge of specific molecular targets is necessary, even its carelessness can hinder the development of the bioactive compound. The discovery of phenotypic drugs is increasingly being used due to the improved model systems and the means for their continuous evaluation, demonstrating that it is an effective method to discover first class drugs.

Many results obtained in recent years show the effort made internationally. For example, in 2018 China approved the inclusion of the first scheduled monoclonal antibody injection for programmed cell death-1 (PD-1), Tuoyi (toripalimab) for the treatment of melanoma, this biotechnological product is the first release of PD drug-(L) 1 developed locally in China in competition with the drug PD-(L) 1 world leader (pembrolizumab). In this year, in United States it was demonstrated that interleukin 17 inhibitor (IL-17) bimekizumab has the ability to significantly eliminate psoriatic plaques in moderate to severe patients treated with 320 mg of the drug.

Even, countries with less resource destined to the investigation in comparison with United States, China, European Union,

Japan, India, Canada and South Korea have achieved some interesting results. Cuba is an example in this sense. The country has a biotechnology industry with 34 companies, more than 20,000 researchers and 61 production facilities. In 2018, 101 biopharmaceutical products were in different stages of development, of which 76 are innovative products and 20 are potentially "first-in-class" products. One of the leading products of Cuban biotechnology is the Heberprot-P, a unique medicine of its kind in the world, used in the therapy of diabetic foot ulcer, which has benefited 290,000 patients in the world.

The fundamental tendency of the research and development process is the discovery of high-potency and personalized drugs, and in alternative administration vehicles such as dermal and buccal patches, biodegradable implants, and others. The problems faced in research today have shown that traditional approaches are not precise or versatile enough for the formulation and discovery of personalized medicines. The scientific practice shows the need to adopt and produce new strategies to solve this kind of problems due to the existence of rigorous compensations between the drug discovery rate, the personalization of the dose and the scalability of obtaining pharmaceutical products.

Volume 3 Issue 5 May 2019

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