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PORTUGAL: An Introduction to Life Sciences

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The life sciences sector in Portugal, in particular the pharmaceutical sector, faces today the same challenges as other European countries: making room for innovation while ensuring the sustainability of the National Health Service.

In many ways, the system is a victim of its own success. Improvement of healthcare standards led to an ageing population, which requires regular, long-term and expensive care. Innovation is more seldom disruptive, and more often incremental. Orphan medicines are steadily emerging, providing great advances for those affected by rare afflictions. New technologies arise. Patients are more aware of innovative pipelines and seek and demand access from public authorities and better care from their physicians. All this generates remarkable budgetary stress.

If this is a challenge common to all health systems across Europe, it is all the more so in Portugal, given the persisting financial constraints and chronic underwriting of the National Health Service. The National Strategy for Medicines and Health Products, approved for the years 2016-2020, and resumed in the 2019 Budget Law, reflects these concerns. It focuses on four strategic pillars: (i) access, innovation, and sustainability; (ii) rational use of medicines and health products; (iii) market supervision and (iv) research, development and competitiveness. It sets out to achieve this, amongst others, persisting in the price revision policy of medicines and in the re-evaluation of health technology assessment, increasing the market share of generics and biosimilars, promoting transparency and enhancing centralised acquisition of pharmaceuticals and other health products by National Health Service bodies. While the pillars are more overarching and ambitious, the proposed measures reveal that the key undertaking is still to contain costs while securing a reasonable standard of care.

For 2019, the Government's target is to achieve a 30% market share of generics in terms of value. The increase in the market share of generics has been a goal persistently pursued by public policy, several measures having been enacted in the past years for such an effect, such as the development of mandatory prescribing and dispensing by non-proprietary name (INN) save in exceptional circumstances, creating

incentives for pharmacists to substitute at the point of dispensing and educating patients. This is a path which the Government will continue to follow.

Public centralised purchasing has accompanied this trend, with the State approving measures that ensure rapid entry of generics following patent expiry and market access approval by the regulatory agency Infarmed, relieving hospitals from the National Health Service system from purchasing within framework agreements approved at a national level, regardless of their term, and setting the lowest price as the award criterion.

The same can be said about biosimilars. Although the steps taken are more cautious, conscious of the fact that, contrary to generics, interchangeability is not always guaranteed, therapeutic guidelines have consecutively been approved, pushing to the extent medically admissible for substitution while market shares of biosimilars that need to be achieved are levied upon National Health Service hospitals.

Where does innovation stand in such an environment? Struggling to come through. In spite of being formally cherished both in law and policy, and regardless of being hailed as a driver of economic development, innovation is frequently put on hold in favour of alternatives that are more affordable in the short term.

This trend has grown worse in the last few years. Indeed, in 2015, the System of Assessment of Health Technology ("SiNATS") was created, gathering in a single legal act the provisions applicable to pricing, reimbursement and access of hospital products. To a great extent, SiNATS concentrated regimes that used to be scattered across several legal acts. However, it also brought about significant changes, such as:

(a) The regulatory agency Infarmed was granted the power to unilaterally, and practically without limitations, amend contracts executed with pharmaceutical companies regarding reimbursement and hospital access, thus subjecting those companies to extreme uncertainty, and placing them in a fragile position vis-à-vis their co-contractors;
(b) These same contracts can now be terminated based on the re-evaluation of the State's budgetary priorities, and pharmaceutical companies that suffer such a termination are not entitled to any kind of compensation or restoration of the contract's financial balance;
(c) The award of an unprecedented concentration of powers to Infarmed; and
(d) The referral of several critical matters to regulations issued by the Government or Infarmed, which allows for the swift modification of the regulatory setting.

Pharmaceutical companies have been fighting with this legal framework in the past years and will have to keep doing so in upcoming years. The regulatory agency is more and more demanding. Added therapeutic value in comparison with the existent alternatives is no longer enough. Cost-effectiveness is the priority, and costs are often

perceived as overwhelming, in a context where the public budget for pharmaceuticals is lacking.

It is true that, in 2018, there was an improvement in the approval of innovative products, following a 2017 amendment that decreased the deadlines for decision of reimbursement and hospital access procedures. However, Portugal remains behind most European Union countries in terms of access to innovative medicines. While in Europe the average time to obtain a reimbursement approval for innovative medicines was approximately 10 months, in Portugal the average is 21 months – longer when it comes to hospital products, where the average is between 29 and 38 months.

In parallel, pharmaceutical companies have been persistently required to contribute to the containment of public health expenditure. For several years, the Government has been executing agreements with the pharmaceutical industry association whereby pharmaceutical companies are required to pay a contribution (a percentage of the respective sales) to maintain public expenditure with pharmaceuticals within levels which are deemed acceptable for the Government. A similar arrangement is expected for 2019.
Such a state of affairs is not expected to change in the years to come. Innovative pharmaceutical companies will continue to strive to reward innovation, while the State will continue to strive to contain costs. New technologies are rapidly emerging, impacting on health care, while the legal and regulatory setting is not yet prepared for them, still trapped in the traditional environment.

As a community, Portugal longs to be a forerunner. Patients are sophisticated, forward-thinking and equipped to manage their health from their mobile devices. As a State, however, Portugal seems to seek a balance that cannot be struck – between cost containment and progress, between disruption and maintenance of the status quo. A new framework law for health is currently under discussion. Among other notable amendments, the law provides that the National Health Service should, in principle, be secured by public healthcare providers, and that the private sector's involvement in the provision of healthcare should be residual and ancillary.

The deadlock is only apparent. Patient organisations, as well as health corporations and professional classes, have matured and grown more independent. Their needs, aspirations and commitment to improving the life of patients should ultimately press the country forward.

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