ACCESS TO INNOVATIVE MEDICINES:
THE CASE OF GREECE, CYPRUS AND MALTA

There are several reasons behind delays in accessing innovative medicines. These reasons can be found mainly in the health systems and the reimbursement procedures that the Member States choose to implement, whether they concern slow procedures, delays in pricing, delays in HTA and reimbursement procedures, etc.

One of the European Commission's proposals is to link incentives for innovation to the availability of the medicine in all member states within 2 years. This is a fundamentally flawed EU approach as it essentially penalizes innovation. The vast majority of delays in accessing new medicines are known to occur after a company has submitted an application for pricing and reimbursement and is awaiting the decision from the respective health system so that the new treatment can be made available to patients.

EXAMPLES OF ACCESS BARRIERS TO MEDICINES IN EU MEMBER STATES

GREECE

Findings from 2023 EFPIA Patients W.A.I.T. report (Waiting to Access Innovative Therapies) indicate that time between marketing authorization of a new medicine and its inclusion in the reimbursement list, has been increased by 176 days, due to the introduction of local HTA process by the Greek State (from 498 to 674 days). According to the same report, out of the total of 168 medicines approved by the European Medicines Agency between 2018-2021, only 90 are available in our country, with only 42% of them being fully available to patients.

A characteristic example of an access barrier set by the State is the legislation of external criteria as prerequisite for HTA application by MAH. The external HTA criterion (reimbursement in 5/11 European countries with established HTA systems) introduces delays in patient access to new products/indications for a significant period after EMA approval as no evaluation of submissions can be initiated before this criterion is fulfilled. Moreover, there is no predictability in the publication of the positive list, as there are no fixed points in time that results to delays of the implementation of negotiation agreements and to delays of access to newly reimbursed treatments.

Another key driver for restricted access to innovative treatments is the consistent underfunding and the insufficient public pharmaceutical budget. This results to extremely high level of mandatory returns that negatively affect the launch of a new medicine, since many innovative medicines cannot enter the market due to non-sustainable net prices derived.

CYPRUS

Cyprus healthcare system is still in a transition period, following the introduction of General Health System (GESY) in 2019. Significant progress has been made in patient access to the Primary Care. However, in the hospital care the situation is quite opposite, with delays in the assessment process, issues with national guidelines/ Therapeutic Protocols and an increasing cost-driven mindset due to the insufficient pharma budget. All these, affect and put barriers on the equitable access of patients to innovative medicines (most innovative medicines in this sector). Significant delays in the assessment of new medicines by the Advisory Committee for Medicines. There are cases where requests from 2021 have not yet been assessed, although the legal framework states that the process should be completed within 90 days. As a result, evaluation for more than 90 innovative medicines is pending. Furthermore, of the 168 medicines launched between 2018-2021, only 49 are available in the health system and from these only 8% are fully available to citizens.

At the same time, Cyprus also focuses on cost containment policies, with the result that the Health Insurance Organization promotes and allows only the use of the cheapest medicine for diseases such as prostate, rheumatoid arthritis. Therefore, other available medicines are excluded while at the same time creating a barrier to entry of new medicines. As in other small countries, the insufficient pharmaceutical budget is a key factor of new medicines delays.

MALTA

The competent authorities evaluate and approve the medicines, however, transparency is a major issue as the timetables set by the European Directive are not respected, while the recommendations and reasons behind rejecting requests are also not sufficiently communicated to the companies. At the same time, the pharmaceutical companies do not know the stage at which the respective request is, whether it has been rejected or approved.

Furthermore, there is lack of proper communication between the pharmaceutical industry and the authorities, which makes it impossible for the industry to propose new pricing and reimbursement methods to enhance patient access and support the sustainability of the health system. Currently, the "winner-takes-all" approach to bidding is perhaps the most significant barrier to expanding the choice of medicines available to doctors and patients. More specifically, by issuing tenders for a class of pharmaceuticals in which the cheapest medicine in that class is the only one accessible for the period of the tender, the system automatically excludes alternative medicines in the same class. In addition, if another medicine from the same class is the cheapest in the next tender, patients will be forced to switch to this other treatment after years of consistent treatment.

According to the findings of the 2023 EFPIA Patients W.A.I.T. report (Waiting to Access Innovative Therapies), the time between marketing authorization of a new medicine and its inclusion in the reimbursement list in Malta is 1.351 days, while only 10 medicines are available to patients.