

AVAILABILITY OF RISK SHARING AGREEMENTS IN THE TURKISH PHARMACEUTICAL SECTOR

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OBJECTIVES

Risk sharing agreements are among the recent trends in pharmaceutical sector as a tool for controlling drug expenditures and increasing patient access to innovative drugs. The objective of this study is to elaborate the availability of risk sharing agreements in the Turkish pharmaceutical sector.

METHODS

A literature review was undertaken to identify the existing risk sharing schemes in the European countries using "risk sharing agreements", and risk sharing schemes" as key words.

RESULTS

Risk sharing agreements are mainly classified as financial based and performance based schemes. The vast majority of those agreements are implemented in oncology area, others are mostly implemented in ophthalmology, blood diseases and multiple sclerosis areas. Countries mostly prefer financial based schemes as they are easier to implement and track. Performance based agreements are relatively rare as they are more complicated due to the long length of follow up, lack of reliability of data generation/registration, administrative burden for all stakeholders.

Figure 1: Taxonomy of risk sharing agreements/managed entry agreements

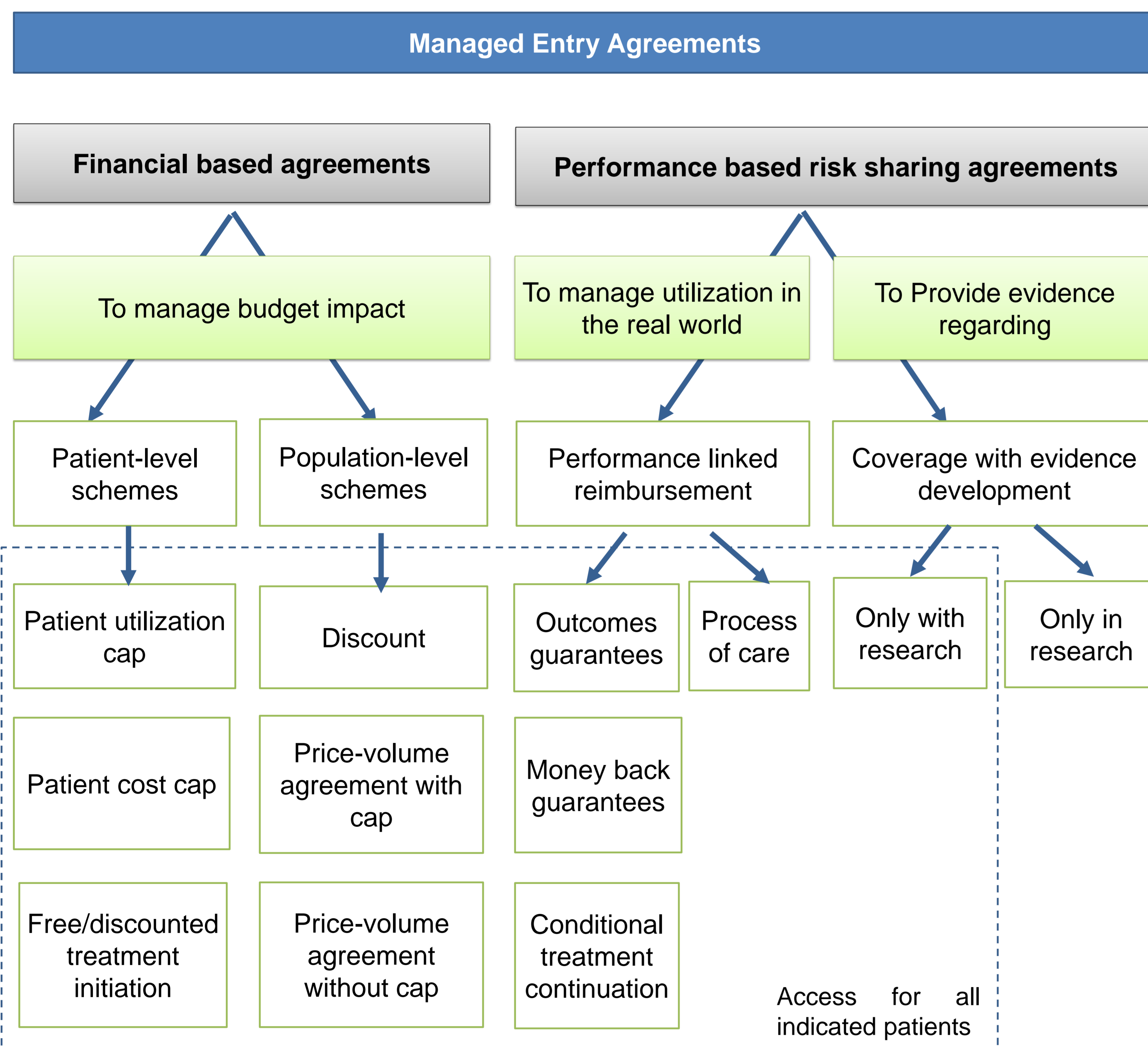


Figure 2: Examples of countries implementing risk sharing agreements

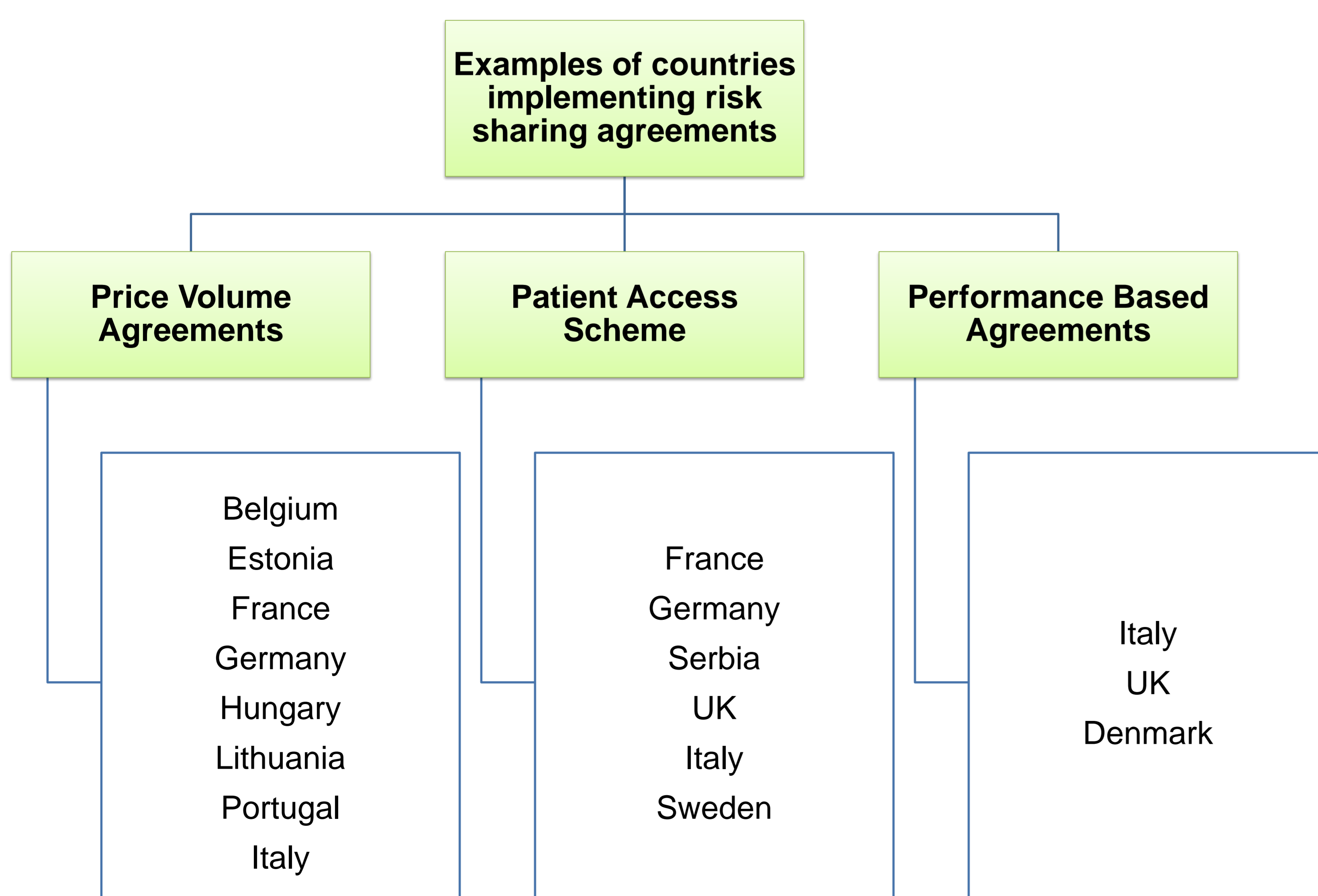


Table 1: Examples of risk sharing agreements

Country	Examples of Price Volume Agreements (PVAs)/budget impact schemes
Italy	<p>Compensation schemes exist where there is excessive prescribing and costs of pharmaceuticals above agreed limits. Current limits for the share of pharmaceutical expenditure in total NHS expenditures are 14% for primary care and 2.4% for hospital care. Rebates amounted to €773 mn in 2005</p> <p>Examples of patient access schemes involving price caps</p>
UK - England, Wales	<p>Schemes include the Ranitizumab Reimbursement Scheme. Under the scheme, the first 14 injections in the eye for the management of wet age-related macular degeneration (AMD) are paid for by the national health service with patients demonstrating an 'adequate response' to therapy to continue with treatment. The drug costs of any subsequent ranitizumab injections will be reimbursed by the company (Novartis) either as free drug or as a credit note</p> <p>Other schemes include Lenalidomibe for patients with multiple myeloma who have received prior therapy. This scheme was approved to enhance the cost effectiveness of lenalidomibe. Under this scheme, the manufacturer pays the cost of the drug if more than 26 cycles are needed for any patient (approximately 2000 patients in the UK) - equating to any patient needing more than 2 years of therapy. Ustekinumab for moderate to severe psoriasis is another example. Under this scheme, two 45 mg vials (90 mg) are provided for people who weigh more than 100 kg at the same cost as a single vial in the form of free drug</p> <p>Examples of performance-based or outcome-based models</p>
Italy	<p>CRONOS scheme for Alzheimer drugs</p> <p>Initially the acetyl cholinesterase inhibitors were 'C' classification in Italy, i.e. 100% co-payment</p> <p>However, under the CRONOS scheme, companies initially provided acetyl cholinesterase inhibitors such as donepezil free of charge to specialist clinics for the first four months of treatment</p> <p>The NHS subsequently covered the drug costs in responders, with patient outcomes recorded</p> <p>This observational study, which demonstrated health gain in patients with mild to moderate AD, resulted in the NHS subsequently funding these drugs ('A' classification) provided patients were treated in specialist outpatients. However, there were no quality checks on the completed forms</p>
Denmark	<p>A population based 'no cure, no pay' strategy for valsartan to lower BP was initiated to enhance market share</p> <p>Money back initiative for nicotine chewing gum if patients do not like the taste of any of the four flavors on offer</p> <p>'No play; no pay' schemes for drugs for erectile dysfunction</p>

CONCLUSIONS

Although Turkey is very well experienced in applying statutory discounts both at the pricing and reimbursement stages discussions around risk sharing agreements are quite new. Evidence from other countries show that these schemes can improve access to innovative drugs for a large group of population. It can be concluded that risk sharing schemes can provide invaluable opportunities for both the government and pharmaceutical companies.

Lack of infrastructure to track drugs or non-responders may impede the success of performance-based risk sharing schemes and the complicated nature of these schemes can be an obstacle for both the public and private sector. In addition to this, additional legislative changes are needed to be introduced to implement these schemes. The transaction and administration costs of these schemes should be considered carefully before embarking on implementation. However, despite these difficulties, these schemes could provide budget control and patient access to highly innovative and expensive treatments.

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