Pricing & Reimbursement 2024

Seventh Edition

Contributing Editor:

Grant Castle

Covington & Burling LLP

glg Global Legal Group

TABLE OF CONTENTS

Portugal

Francisca Paulouro
Pedro Fontes
Beatriz Albuquerque

Vieira de Almeida & Associados

Abstract

Following a reform in 2015, the Portuguese pricing and reimbursement system has become more sophisticated and comprehensive. Nevertheless, substantial discretion is permitted to the competent national authority, and this is the source of most challenges for innovators.

Market introduction/overview

Portugal is a relatively small country, with about 10.4 million inhabitants. The main indicators of public health have registered a positive and steady evolution over the last decade. According to the most recent data (2023), the average life expectancy at birth is 80.96 years old, and was increasing, just like life expectancy at 65 years old, until the COVID-19 pandemic. The period 2021–2023 registered a life expectancy at 65 years old of 19.75 years, an increase of 0.14 years when compared to the same period of the previous triennium. The infant mortality rate is currently 2.6 in 1,000.

The steady increase of life expectancy of the last few decades was therefore only disturbed by the COVID-19 pandemic. Adjustments in the Portuguese Health System have yielded increased life expectancy, particularly for those suffering with respiratory, digestive and infectious diseases.

Some indicators, however, raise concerns.

Portugal suffers from the ailments that are associated with an ageing and decreasing population.

Healthy life years are steadily decreasing. Chronic diseases are growing factors of mortality. Heart diseases, cancer, respiratory, nutritional, endocrine and metabolic diseases are the greatest causes of premature mortality, and still play a significant role in later deaths. Risk factors such as inadequate eating habits, hypertension, smoking and high body mass greatly contributed to this outcome.

The Portuguese Health System is thus a mature, complex and rather successful structure that – as with many other developed countries – is now faced with the consequences of its success.

Higher life expectancy is associated with an ageing demographic and an increase in health-related costs. The better the system becomes, the harder it is to ensure its sustainability.

Policies are headed towards preventing diseases rather than curing them. While innovation is commendable, the State is not focused on rewarding innovative therapies, but rather in taking steps to guarantee that they are not necessary.

Pricing and reimbursement of medicines is therefore perceived as a double-edged sword; while it satisfies basic needs of citizens and fulfils fundamental duties from the State, it should be achieved without excessive sacrifice of a declining Public Budget. Public regulators very much agree that this paradox should not be settled at the taxpayer's expense. Pressure on innovators is therefore at its highest.

Insofar as the legal regulatory framework is concerned, the Portuguese legal framework follows EU legislation closely. Decree-Law 176/2006, of 30th August, consolidated in one single piece of legislation the regime applicable to, among others, the marketing authorisation ("MA"), manufacture, import, export, marketing, classification, labelling, promotion and pharmacovigilance of medicines, transposing into Portuguese law several directives, including Directive 2001/83/EC, as amended.

Pricing and reimbursement, in contrast, are exclusively dealt with at national level, being beyond the scope of EU legislation, with the exception of transparency measures and procedural requirements provided for in Council Directive 89/105/EEC of 21st December, relating to the transparency of measures regulating the pricing of medicinal products for human use ("Transparency Directive").

The general regime applicable to pricing and reimbursement is provided for in Decree-Law 97/2015, of 1st June, as amended. This decree-law approved the National System of Evaluation of Health Technologies ("SiNATS"), congregating in one single piece of legislation topics related to pricing and reimbursement of pharmaceuticals. This general framework is complemented by several Ministerial Orders and condensed by the Practice and Informative Notes of the Portuguese Agency, *Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.* ("Infarmed"). In addition to its competence for technical health regulation, Infarmed's powers also cover pricing and reimbursement. Price approval of prescription products, including products for hospital use, is also attributed to this Agency. Infarmed plays a significant role in the reimbursement of medicines, being the entity responsible for conducting the relevant procedures and proposing decisions to the Ministry of Health.

Pharmaceutical pricing and reimbursement

Regulatory classification

The classification of medicines is identical to that arising from EU legislation.

Two major classifications exist: prescription; and non-prescription products.

Medicines are subject to medical prescription where they (a) are likely to present a danger either directly or indirectly, even when used correctly, if used without medical supervision, (b) are frequently and to a very wide extent used incorrectly, and as a result are likely to present a direct or indirect danger to human health, (c) contain substances or preparations

thereof, the activity and/or adverse reactions of which require further investigation, or (d) are to be administered parenterally.

Prescription medicines are then divided into sub-categories, including, for renewable delivery, special medical prescription and restricted medical prescription for use in certain specialised areas. Concerning this last sub-category, products will be classified as subject to restricted prescription when, in general terms, the respective use is reserved for a hospital setting or requires special supervision throughout the treatment.

Prescription products can only be sold in pharmacies or, in the case of a restricted medical prescription, dispensed and/or exclusively sold at a hospital setting (including hospital pharmacies).

In turn, all medicines that do not meet the criteria to be classified as subject to medical prescription, are classified as non-prescription products.

Under this broad classification of medicines – whether subject to medical prescription or not – medicines can be of several types, depending essentially on the MA procedure followed and composition of the product.

The following types may be identified:

Branded medicines

Branded medicines are divided into six sub-categories: (a) full application; (b) well-established use applications; (c) fixed combination applications; (d) informed consent applications; (e) hybrid applications; and (f) biosimilar applications.

Full application products are commonly known as "reference medicines"; i.e., medicines that have been granted an MA by a Member State or by the European Medicines Agency ("EMA") based on a complete dossier, i.e., with the submission of quality, pre-clinical and clinical data. These medicines may be biological or not, depending on their composition.

Products arising from well-established use applications are those connected to the results of pre-clinical and clinical trials, which are replaced by detailed references to published scientific literature if it is demonstrated that the active substances of the product have been in well-established medicinal use within the community for at least 10 years, with recognised efficacy and an acceptable level of safety.

Fixed combination applications are those related to medicines containing active substances used in the composition of authorised medicines but not hitherto used in combination for therapeutic purposes. In these cases, the results of new pre-clinical tests or new clinical trials relating to that combination must be provided, it not being, however, necessary to provide scientific references relating to each individual active substance.

There are also the so-called informed consent applications, in which following the granting of an MA, the authorisation holder permits the pharmaceutical, non-clinical and clinical documentation contained in the dossier of its medicinal product to be used, with a view to examining subsequent applications relating to other medicinal products possessing the same qualitative and quantitative composition in terms of active substances and the same pharmaceutical form.

Hybrid applications, which rely in part on the results of pre-clinical tests and clinical trials for a reference product and in part on new data, differ from generic applications in that the results of appropriate pre-clinical tests and clinical trials must be submitted. This occurs in the following circumstances, where: (a) the strict definition of a generic medicinal product is not met; (b) bioavailability studies cannot be used to demonstrate

bioequivalence; and (c) there are changes in the active substance(s), therapeutic indications, strength, pharmaceutical form or route of administration of the generic medicinal product compared to the reference medicine.

Finally, there are the biosimilars, i.e., biological medicines, similar to a reference biological product but which do not meet the conditions of the definition of generic medicinal products, owing to, in particular, differences relating to raw materials or differences in the manufacturing processes of the similar biological medicine and the reference biological medicine, and, therefore, the results of appropriate pre-clinical tests or clinical trials relating to these conditions must be provided.

All the above categories are considered "branded products" for the purposes of pricing and reimbursement rules, except for biosimilars, which are under a specific regime.

Generics

Generics are products that have the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicines, which in turn have been authorised for no less than eight years in a Member State or in the community. The applicant is not required to provide the results of pre-clinical tests and clinical trials; however, bioequivalence with the reference medicinal product must be further demonstrated by appropriate bioavailability studies.

In terms of pricing and reimbursement, the following categories are relevant, the rules differing depending on which category the product falls under: (a) branded products (which include full applications, well-established use applications, fixed combination applications, informed consent applications and hybrid applications); (b) generics; and (c) biosimilars.

Generics are subject to specific pricing and reimbursement rules.

The critical distinction for the purposes of reimbursement is whether the product is subject to medical prescription or not.

Whereas non-prescription medicines are not subject to price control and, as a rule, are not eligible for reimbursement, save in exceptional circumstances, prescription medicines are subject to a price control regime and are eligible for reimbursement. This principle applies to all types of products identified above (i.e., branded, generics, biological and biosimilar).

Who is/who are the payer(s)?

The payer varies depending on the product's classification.

Non-prescription products and medicines subject to common medical prescription, renewable and special medical prescription can be purchased directly by individuals – should they be sold in street pharmacies – and by private hospitals and national health service hospitals ("NHS Hospitals") for internal use. Restricted medical prescription products are only purchased by hospitals, be it private or NHS Hospitals, with patients having access to these products via the hospital pharmacies.

Should the product be reimbursed, part or the whole of its sales price is borne by the Ministry of Health's share of the State Budget.

What is the process for securing reimbursement for a new pharmaceutical product?

A distinction should be drawn between products that are to be sold and dispensed at street pharmacies and those that are to be sold to NHS Hospitals.

The first follows a reimbursement procedure. The second follows a very similar procedure with a view to being sold in NHS Hospitals – the so-called prior evaluation procedure.

The ratio underlying both procedures is, in essence, the same: evaluating whether, in light of the therapeutic alternatives, it is justifiable from an economic and therapeutic perspective for the State to purchase the product – be it via reimbursement or through the budget of NHS Hospitals.

The reimbursement procedure is initiated by the MA holder, or its representative, before Infarmed. The MA holder is encumbered with demonstrating that the product fulfils the criteria for reimbursement; i.e., that the medicine is innovative, or therapeutically equivalent to current alternatives and presents an economic advantage. This being the general principle, the law further lists the situations which can give rise to reimbursement and specifies the criteria which should be met – particularly to demonstrate the economic advantage.

The reimbursement request should be accompanied by a comprehensive set of documents, comprising both technical and scientific information about the product that demonstrates its efficacy, safety, and effectiveness for the claimed therapeutic indications and an economic evaluation study. Such a study is not required for generics, which follow a simplified procedure.

Reimbursement of generics is subject to specific rules strictly linked to the respective price – be it by comparison with the reference medicine or other reimbursed generics, depending on how many generics are already present in the market.

The same logic applies to the reimbursement of biosimilars: a price is also set for reimbursement purposes. The first biosimilar will be reimbursed provided its price does not exceed 80% of the price of the reference biological product. Said percentage decreases to 70% provided there are more biosimilars in the market representing at least 5% of the market share of the respective active substance.

The reimbursement procedure is conducted before Infarmed. The Ministry of Health, however, is responsible for the reimbursement decision, although said power may be delegated to Infarmed.

Reimbursement may be subject to the execution of a contract between the MA holder and Infarmed which sets forth the terms and conditions subject to which a reimbursement is dependent upon. These conditions may include:

(a) a maximum amount of public expenditure with the product, considering the number of patients and applicable therapeutics;

(b) consequences of exceeding this maximum amount, such as the MA holder being required to (i) pay back the amounts in excess, or (ii) lower the price of the product concerned or of other products;

(c) existence of a limited period of time, elapsing which the amount of reimbursement is reduced with a consequent reduction of the price of the product or the product is delisted; and

(d) risk-sharing arrangements.

Even though the execution of a reimbursement contract is not mandatory, if the product is innovative, Infarmed typically chooses to execute a contract with the MA holder. If Infarmed proposes to enter into a reimbursement contract, negotiations should be concluded within 30 days. In practice, however, contract negotiations take significantly longer.

Although contracts are bilateral, reimbursement is a unilateral decision, which almost entirely depends on Infarmed's discretion. Accordingly, Infarmed has an exceptional edge in contract negotiations.

While MA holders may try to influence the reimbursement decision or contract – especially the maximum amount of public expenditure with the product – through negotiation, the decision ultimately depends on Infarmed and on its assessment, taking into account available public funds or budgetary concerns, of the market and the product's expected performance.

The MA holder should be able to demonstrate that the medicinal product always complies with the reimbursement criteria.

Infarmed can exclude medicines from reimbursement or change their reimbursement conditions upon re-evaluation of market conditions – especially if new medicines are either therapeutically innovative or economically advantageous in relation to the reimbursed medicine.

The situations that may trigger exclusion from reimbursement or the change in reimbursement conditions are provided for in the law. Amongst these we find, for instance: the medicine becoming less effective in relation to other reimbursed medicines with the same therapeutic purpose; consumption data demonstrating that the medicine has been used off-label, in indications that are not covered by the reimbursement; the price of the product becoming 20% higher than non-generic reimbursed alternatives; and the medicine no longer being subject to medical prescription or changing its classification to restricted medical prescription. Illegal promotional practices may also determine exclusion from reimbursement.

As noted above, prescription medicines must undergo a prior evaluation procedure with a view to being bought by NHS Hospitals – unless otherwise decided by the Ministry of Health or Infarmed, should the Ministry delegate the competence to take this decision. Non-prescription products may also be subject to such a procedure if their sales volume to NHS Hospitals is very significant.

The purpose of the prior evaluation procedure is very similar to that of the reimbursement procedure: the applicant must demonstrate that the medicine is innovative, or therapeutically equivalent to current alternatives and presents an economic advantage. Also, and similarly to what happens with reimbursement, the law specifies the criteria which should be met for a favourable decision to be awarded – particularly in order to demonstrate the economic advantage.

If favourable, the prior evaluation decision sets a maximum price of acquisition for NHS Hospitals and entails the execution of a contract between the MA holder and Infarmed. These contracts, further to being entered into for a fixed term, can provide for conditions similar to those we have seen above for reimbursement. The most common are establishing mandatory discounts over the maximum sales prices and the setting of a maximum amount of public expenditure with the purchase of the product which, if exceeded, should be paid back by the MA holder.

Medicines subject to prior evaluation cannot be purchased by NHS Hospitals until a favourable decision is issued and a valid contract executed. In exceptional circumstances, for example, in the absence of a therapeutic alternative and should the patient's life be at risk, Infarmed may, on a case-by-case basis, authorise the purchase of these products.

Rules of procedure specify clear deadlines for issuing a reimbursement and a prior evaluation decision, as follows: (a) 30 calendar days for generics and biosimilars; (b) 75 calendar days for new therapeutic indications of an active substance which is already reimbursed; and (c) 180 calendar days for new active substances. These deadlines are suspended and extended if, during the process, Infarmed requests additional elements from the applicant, or opinions from independent Committees.

Decision deadlines are merely indicative, with no consequences arising from non-compliance. Should a decision not be issued within these timeframes, the applicant cannot assume that its product has been reimbursed or approved – neither can it assume that it has not. Unfortunately, reimbursement and prior evaluation procedures of innovative products, both new active substances and new therapeutic indications, take far more time than that provided for in the law.

Negative decisions in the context of reimbursement and prior evaluation procedures are subject to appeal. MA holders are entitled to file an administrative appeal before Infarmed or the Ministry of Health – depending on who issued the final decision. This appeal, which is not mandatory to resort to judicial action, has extremely limited chances of success. A judicial challenge before administrative courts is also admissible, even though the court's powers are limited to judicial review. A judicial claim can take as long as two years to be decided in the first instance.

How is the reimbursement amount set? What methodology is used?

The general rule is for reimbursement to be set as a percentage of the maximum public sales price of the product.

The reimbursement amount is set in one of four tiers, ranging between 15% and 90% of the product's maximum public sales price (15%, 37%, 69%, 90%). A Ministry of Health Order provides the pharmacotherapeutic groups that correspond to each reimbursement tier – i.e., the reimbursement tier in which medicines are included depends on the diseases they are indicated to treat. The reimbursement tier rises in accordance with the priority the Government assigns to the treatment (or access to treatment) of a certain disease.

In addition to this general regime, medicines can be included in special or exceptional reimbursement regimes, which may follow specific rules and set specific reimbursement amounts. Specially or exceptionally reimbursed medicines are usually reimbursed in full and concern specific diseases which raise significant health concerns. HIV and Hepatitis medicines, for instance, benefit from a special reimbursement regime and are dispensed at no cost to patients at NHS Hospital pharmacies.

How are drug prices set? What is the relationship between pricing and reimbursement?

Medicines subject to medical prescription (yet not restricted medical prescription), including both generics and non-generics, must undergo a price approval procedure before Infarmed prior to being launched in the market. Price approval – contrary to reimbursement – is a condition to market the product.

In the context of the price approval procedure, a maximum sales price is approved, which, in the case of branded products, is determined by reference to the wholesale price applied in four reference countries. The reference countries are defined annually (in 2024: France; Italy; Slovenia; and Spain). The maximum sales price cannot exceed the average of the wholesale price applied in the reference countries (with exclusion of applicable margins and taxes). If the medicine does not exist in the reference countries, the price cannot be

higher than the price of identical or essentially similar medicinal products in those markets (excluding generics). If such a product does not exist, the price should not be higher than the price of identical or essentially similar products in the national market. If similar medicines are not marketed in Portugal or the reference countries, the price cannot be higher than the price in force at the country of origin. This maximum sales price is subject to annual revision according to the same criteria.

Branded medicinal products subject to medical prescription that are not reimbursed and are sold before NHS Hospitals are also subject to a price approval and annual revision procedure. The logic, similar to what happens with retail pharmacy products, is that in comparison with the price applied in three reference countries, it is the same as those defined for the pharmacy setting. However, in the case of these products, the maximum sales price to hospitals cannot exceed the lowest wholesale price applied in three reference countries.

The maximum sales price of generics, in turn, is set by reference to the price of the reference medicine. The price of the generic cannot exceed 50% of the maximum sales price of the reference medicine or 25% of that price, should the reference product's wholesale price be lower than €10. Generics are also subject to an annual price revision. Under said revision, the price of the generic should continue to maintain the same price difference *vis-à-vis* the reference product.

The price of the generic may, however, be affected for reimbursement purposes.

In fact, the placement of a generic in the market gives rise to the creation of a "homogenous group", composed of branded medicines and generics (with the same active substance, dosage, method of administration and pharmaceutical form). The creation of the "homogeneous group" triggers the approval of a reference price for the products that make up said group. The reference price corresponds to the average of the retail sales price of the five lowest-priced products included in the group. Following approval of the reference price, the maximum amount of reimbursement for products included in the group will be determined by applying the applicable reimbursement percentage to the reference price. With a view to being reimbursed, the maximum sales price of generics entering the market after the group's creation must be at least 5% lower than the price of the cheapest generic already in the group (up to the limit of 20% of the reference medicine's maximum sale price). This successive lowering of the price of generics and of the reference price leads to significant savings in expense with reimbursement, but also to a substantial gap between over-the-counter prices of generics and branded medicines.

Finally, generics that are not reimbursed and are sold to NHS Hospitals are also subject to a price approval and revision procedure. Under this regime, the price of the generic should be at least 30% lower than the price of the reference product.

While biosimilars are not subject to a specific price approval procedure, price control of these products is set within the context of the reimbursement procedure. As noted above, reimbursement of a biosimilar can only be approved if the respective price does not exceed 80% of the reference medicine's price.

Similar to what happens with generics, a biosimilar entering the market also triggers the creation of a "homogeneous group", and of a reference price as well. Two differences occur. Reimbursement of similar biological medicines can only be approved if their price does not exceed 80% of the reference medicine's price, and, in case a "homogeneous group" with at least one biosimilar medicine already exists, the price of the following biosimilar cannot exceed 70% of the reference medicine's price.

Lastly, discounts can be granted throughout the medicine's marketing circuit (manufacturer, wholesaler and pharmacy). However, discounts can only be granted in relation to the non-reimbursed part of the sales price of the medicinal product.

Issues that affect pricing

As noted above, Portugal follows a referencing system in which price definition is concerned.

Limiting public expenditure is therefore carried out, on the one hand, through price control and, on the other, through reimbursement or prior evaluation procedures – in general terms, market access. The major factor influencing market access is cost. Rather than assessing the medicine's performance and market behaviour independently, public authorities are compelled to lower maximum amounts of public expenditure, based almost exclusively on the budget that is allocated for the expense of medicinal products.

Although launching a generic does not directly affect the price of reference medicines, competition of generics and therapeutic alternatives – particularly if cheaper – greatly influence the sales of branded products.

This is achieved through several means:

- Firstly, through the renegotiation of the maximum public expenditure levels provided for in reimbursement/prior evaluation contracts.
- Secondly, because of substitution. In fact, the general rule where generics are concerned is for mandatory substitution.

Prescription of medicines should be carried out by the International Non-proprietary Name – although the brand of the product may be added. Once generics are placed in the market, the rule is that of substitution and the physician is only permitted to prevent substitution in the limited and exceptional cases provided for in the law. Similarly, pharmacists, when confronted with a prescription, are required to inform patients of the existence of products with an identical active substance, pharmaceutical form, dosage and presentation of the prescribed product, as well as whether these are reimbursed and those that have the lowest sales price. Pharmacies should have available for sale at least three products with the same active substance, pharmaceutical form, dosage and presentation, between the five products with the lowest sales price. Unless the patient chooses otherwise, the pharmacist should dispense the medicine with the lowest price. The patient is further entitled to replace the prescribed product with one with the same active substance, pharmaceutical form, dosage and presentation, unless the physician has prevented substitution. Even in the latter case, the patient may choose to replace the product with a cheaper product if the circumstance on the basis of which the physician prevented substitution was due to the fact that the product was destined to a long-term treatment (i.e., that which is anticipated to last over 28 days).

On the other hand, and concerning NHS Hospitals, medicines are purchased pursuant to mandatory public procurement procedures. Supply contracts awarded through these procedures are overwhelmingly awarded to the bidder with the lowest price – meaning that generics and biosimilars are expected to take over the market as soon as they begin marketing. Several instructions have also been directed to NHS Hospitals with a view to increasing the purchase of biosimilars.

Finally, the Ministry of Health has taken measures to ensure that NHS Hospitals and Services can begin purchasing generics and biosimilars as soon as they enter the market.

Policy issues that affect pricing and reimbursement

Portugal's population is currently estimated at around 10.4 million people. The population has been growing due to immigration. The elderly population keeps growing steadily and significantly.

While no aggregated data are immediately available, authorities recognise that the increase of the elderly population considerably contributes to the growing prevalence of chronic diseases.

As of 2022, the cost of State-funded healthcare is estimated at 10.5% of the GDP and the cost of medicines covered by the State Budget in 2022 in continental Portugal was €1,567.3 million (source: https://www.pordata.pt). In this same year, the total NHS expense was €14,032.4 million, the cost of medicines amounting to approximately 11.2% of the NHS's expenses (source: https://www.pordata.pt).

These demographic and financial data strongly suggest that public authorities will be confronted with additional pressure to lower the prices of medicines.

Aside from pricing policies and budget-oriented evaluations, the most significant political influence over pricing and reimbursement policy is a shift of priorities, from treatment to prevention. Public authorities are focusing on disease deterrence programmes that concern lifestyle and nutrition changes, and essentially pursue the prevention of chronic diseases. Health authorities are favouring this approach over counting on the approval of innovative medicines. This naturally involves a transfer of State Budget funds towards prevention. Notwithstanding this growing inclination in policy, an increase in the prevalence of chronic diseases has generated a need to create disease-specific programmes, which may involve the increase of reimbursement for diseases that are becoming more frequent (such as cancer and cardiovascular and respiratory diseases).

Emerging trends

Considering that the pricing and reimbursement system was completely overhauled in 2015, with the approval of SiNATS, and then again in 2017, no significant changes in legislation are currently anticipated. The COVID-19 pandemic, however, raised awareness to the price of medicines. The budget constraints arising from the pandemic, together with an uncertain economic outlook bolstered by the war in Ukraine, have further increased pressure to achieve efficient pricing.

The enactment of this legislation and the renovated interest in health and life sciences did not, however, remedy challenges with which Innovative Pharma Companies are faced. Delays in deciding prior evaluation and reimbursement procedures have not been dealt with. Even though legal deadlines exist, the procedure regularly exceeds these deadlines, insofar as branded medicines are concerned, with practically no consequences.

Another recent trend following the approval of SiNATS is the increased imbalance between Infarmed and MA holders in reimbursement and prior evaluation contracts. Such imbalance is particularly evident when the yearly maximum amounts of public expenditure with the medicine – which, if exceeded, trigger payback of the excess – are automatically renewed for the following years, unless Infarmed decides or agrees to modify them.

Despite recent improvements, transparency in reimbursement and prior evaluation procedures still raises concerns. The regime's application is far from compliant with the Transparency Directive, which clearly provides that measures regulating the pricing of medicinal products should resort to objective and verifiable criteria.

Finally, inflation raises important concerns in medicine pricing. The regime is seemingly built under an assumption of economic stability and is only able to raise the price of medicines in exceptional circumstances, pursuant to an equally exceptional procedure. Accordingly, not only the regulator should be reluctant to increase prices, as an increase depends on a rather complex assessment. For these reasons, companies should expect to bear a significant part of the inflationary burden.

Successful market access

The top factor to secure successful market access is to protect the MA holder's credibility before Infarmed. During the submission of reimbursement or prior evaluation requests, the negotiation of contracts, or the re-evaluation of the medicine's compliance with the applicable criteria, the MA holder may feel tempted to overstate the product's economic advantage or therapeutic added value – which may happen, for instance, if the economic evaluation study submitted with the request heavily relies on less tangible or probable economic advantages.

This strategy will often backfire, and lead Infarmed to disregard the information submitted by the MA holder and delay the procedure focusing solely on price. Lack of consistency of the data submitted with the reimbursement request may therefore result in poorer conditions than those that could be approved if the MA holder resorted to more agreeable estimates and projections.

Credibility is an asset in subsequent re-evaluations and negotiations. If effective consumption is very wide off the mark of a former estimate of consumption, the Agency will feel strongly compelled to ignore the MA holder's revised estimates and acutely lower the expenditure limits.

Flexibility can also be considered a success factor. Considering the frequent changes in regulation and policy orientation, MA holders should be open to several scenarios, and have sufficient strategic insight to negotiate contracts in a fast-changing environment, where several reimbursement or payback solutions are theoretically possible.

Francisca Paulouro

Tel: +351 21 311 3451 / Email: fp@vda.pt

Francisca joined VdA in 2002 and is currently Head of the Life Sciences practice. She has been active in various operations and projects in the health sector, particularly in the pharmaceutical sector, offering extensive experience in matters related to the regulation of this sector, particularly in pricing and reimbursement, marketing and promotional activities, distribution and contracts.

Pedro Fontes

Tel: +351 21 311 3640 / Email: pfo@vda.pt

Pedro joined VdA in 2013 and is currently a Managing Associate of the Life Sciences practice. In that capacity, he has been involved in several transactions and projects in the health, telecoms, transport, and water and waste sectors. In the health sector, Pedro has been active in various operations and projects, particularly in pharmaceutical regulation, focusing on pricing and reimbursement and pharmaceutical litigation.

Beatriz Albuquerque

Tel: +351 21 311 3501 / Email: bal@vda.pt

Beatriz is an Associate at VdA in the Life Sciences practice area. Beatriz has been working with pharmaceutical and medical device companies in several regulatory matters, including marketing and promotional activities, market access, clinical trials, and pricing and reimbursement.

Vieira de Almeida & Associados

Rua Dom Luis I, 28, 1200-151 Lisbon, Portugal
Tel: +351 21 311 3400 / URL: www.vda.pt

Global Legal Insights – Pricing & Reimbursement provides analysis, insight and intelligence across 18 jurisdictions, covering:

- Market introduction/overview
- Pharmaceutical pricing and reimbursement
- Policy issues that affect pricing and reimbursement
- Emerging trends
- Successful market access

globallegalinsights.com

glg Global Legal Group