Pricing & Reimbursement

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Portugal

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Following a recent reform in 2015, the Portuguese pricing and reimbursement system is now sophisticated and comprehensive. Nevertheless, substantial discretion is extended 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 10.3 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 (2016), average life expectancy at birth is 80 years old, and increasing, just like life expectancy at 65 years old, while the infant mortality rate is 2.9 per 1,000.

Adjustments in the health system have yielded life-year gains in respiratory, digestive and infectious diseases. Some indicators, however, raise concerns.

Portugal suffers from the ailments that are associated with an ageing and declining population. Healthy life years are steadily decreasing. Chronic diseases are growing factors of mortality. Heart disease, 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 contribute 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 to 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 on 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 the basic needs of citizens, and fulfils fundamental duties from the State, it needs to be achieved without excessive sacrifices from a declining Public Budget. Public regulators very much agree that this paradox should not be settled at the taxpayer's expense. Pressure on innovators has therefore never been higher.

As far as the legal regulatory framework is concerned, the Portuguese legal framework follows the EU legislation closely. Consolidated in a single piece of legislation, Decree-

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Law 176/2006, of 30th August, the regime is applicable to, among others, the marketing authorisation, manufacture, import, export, marketing, classification, labelling, promotion and pharmacovigilance of medicines, transposing into Portuguese Law several directives, including Directive 2001/83/EC, as amended (the Directive).

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 1988, 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 in Decree-Law 97/2015, of 1st June, as amended. This diploma approved SiNATS, the National System of Evaluation of Health Technologies, congregating in a single piece of legislation topics related to pricing and reimbursement of pharmaceuticals. This general framework is complemented by several Ministerial Orders and densified 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 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 utilised 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 subcategory, products will be classified as subject to restricted prescription when, in general terms, their 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 at a hospital setting (including hospital pharmacies).

In turn, all medicines which 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 – subject to medical prescription or not – medicines can be of several types, depending essentially on the marketing authorisation (hereinafter "MA") procedure followed and composition of the product.

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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 which 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 regarding the results of preclinical 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 allows use to be made of the pharmaceutical, non-clinical and clinical documentation contained in the dossier of its medicinal product 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 need to be submitted. This occurs in the following circumstances: where (i) the strict definition of a generic is not met; (ii) bioavailability studies cannot be used to demonstrate bioequivalence; and (iii) there are changes in the active substance(s), therapeutic indications, strength, pharmaceutical form or route of administration of the generic 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 as "branded products" for the purposes of pricing and reimbursement rules, with the exception of biosimilars in respect of which a specific regime exists.

Generics

Generics are products which have the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicines, which is or has 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, provided

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bio-equivalence with the reference medicinal product must further be demonstrated by appropriate bio-availability 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, biologic and biosimilar).

Who is/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, may be purchased directly by individuals – if they are 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 they 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 Health Ministry'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 which are to be sold and dispensed at street pharmacies and those which 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 must demonstrate 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.

In fact, 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,

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depending on how many generics are already present on 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 if its price does not exceed 80% of the price of the reference biologic product. The said percentage decreases to 70% if there are more biosimilars on 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 to which a reimbursement is subject. These conditions may include:

(a) a maximum amount of public expenditure on 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; (ii) lower the price of the product concerned or of other products;

(c) existence of a limited period of time, on expiry of 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, in the case of innovative products, Infarmed typically chooses to execute a contract with the MA holder. If Infarmed proposes to enter into a reimbursement contract, negotiations should be concluded in 30 days. In practice, however, contract negotiations take significantly longer.

Although contracts are bilateral, reimbursement is a unilateral decision, almost entirely at the discretion of Infarmed. 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 on the product – through negotiation, the decision ultimately depends on Infarmed and its assessment of the market and the product's expected performance, taking into account available public funds and budgetary concerns.

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

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

Situations that may trigger exclusion from reimbursement or a 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.

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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 so as 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 ones are the establishment of obligatory 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 patients' life be at risk, and on a case-by-case basis, 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: (a) 30 business days, for generics and biosimilars; (b) 75 business days, for new therapeutic indications of an active substance which is already reimbursed; and (c) 180 business days, for new active substances. These deadlines are suspended and extended if, during the process, Infarmed asks for additional elements from the applicant, or opinions from independent committees.

Decision deadlines are merely indicative, with no consequences arising from non-compliance therewith. 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 is not. Unfortunately, reimbursement and prior evaluation procedures of innovative products, both new active substances and new therapeutic indications, take far more time than is 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 for recourse 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 much 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.

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The reimbursement amount is set in one of four tiers, ranging between 15–90% 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 – so 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), 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 2019: Spain; France; Italy; and Slovenia). 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 which are not reimbursed and are sold before NHS Hospitals are also subject to a price approval and annual revision procedure. The logic, similarly to what happens with retail pharmacy products, is that in comparison with the price applied in three reference countries, it is the same as that defined in a 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 the 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 which

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make part of 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 a 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 which 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.

Similarly 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 as far as price definition is concerned.

Limiting public expenditure is therefore done, 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 the launching of a generic in the market does not directly affect the price of the reference medicines, competition of generics and therapeutic alternatives – particularly if cheaper – greatly influence the sales of the 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, in which generics are concerned, is for mandatory substitution.

Prescription of medicines should be done by the International Non-proprietary Name ("INN") – although the brand of the product may be added. Once generics are placed on

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the market, the rule is one of substitution, and the physician is only allowed 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 which 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 that has 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 for a cheaper product if the circumstance on the basis of which the physician prevented substitution was due to the fact that the product was designed for 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 has stagnated and is not expected to grow in the coming years. The elderly population is growing steadily and significantly. According to the latest census (2011), the population of all age groups up to 30 years old decreased between 2001 and 2011, while the population of older age groups increased in all tiers. Significantly, the 75+ age group increased from 701,366 to 961,925 between those years, and other senior age groups substantially increased their population (source: www.pordata.pt).

While no aggregate data is immediately available, the authorities recognise that the growth in the elderly population considerably contributes to growth in prevalence of chronic diseases, and that these are responsible for more than 80% of disease-related mortality.

As of 2017, the cost of State-funded healthcare was estimated at 4.5% of GDP and the cost of drugs covered by the State Budget was €1.2135m. (source: www.pordata.pt). In this same year, total NHS expenses were €8,757.70m, the cost of drugs amounting to approximately 13.8% of the Health Budget (source: www.pordata.pt).

These demographic and financial data strongly suggest that public authorities will be faced with great 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 seek to prevent the appearance 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

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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 (the National System of Evaluation of Health Technologies), which was later revised in 2017, no significant changes in legislation are currently anticipated.

The enactment of this new legislation did not, however, remedy the challenges with which innovative pharma companies are confronted. Delays in deciding prior evaluation and reimbursement procedures have not been dealt with. Even though legal deadlines exist, the delay of the procedure significantly exceeds these deadlines, as far as branded medicines are concerned, with practically no consequences attached to it.

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 Infarmed has the power to unilaterally change the contract and the maximum amounts of public expenditure with the medicine – which, if exceeded, trigger payback of the excess.

Reimbursement contracts have lately seen an important development. Infarmed usually sets the maximum public expenditure cap by product and indication. Recently, the agency proposed reimbursement contracts that provide a maximum expenditure cap for an entire therapeutic indication, covering all products indicated for treatment of the said disease. In this case, if there is an excess, companies will pay it back *pro rata*, based on their market share.

Despite recent improvements, there are still concerns about transparency in reimbursement and prior evaluation procedures. The regime is far from compliant with the EU Transparency Directive which clearly provides that measures regulating the pricing of medicinal products should use objective and verifiable criteria.

The entry of biosimilars in the market is still surrounded by some uncertainty. While a regime – largely based on what is applicable to generics – has been approved, it is too soon to tell whether this will be effective.

Successful market access

The top factor in securing 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.

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

Flexibility can also be accounted 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.

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