

# EU Pricing & Reimbursement

Pricing & reimbursement schemes in major European countries

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## Introduction

Welcome to this special edition of the Hogan Lovells EU Pricing & Reimbursement newsletter.

This newsletter provides comprehensive overviews of the system of pricing and reimbursement of medicinal products and medical devices in EU Member States Belgium, the Czech Republic, France, Germany, Italy, the Netherlands, Spain and the UK as well as in Russia. The EU Member States covered by this newsletter account for approximately three quarters of the EU 28 pharmaceutical market value<sup>1</sup> and a similar proportion of market value for medical devices.

Pricing and reimbursement of medicinal products and medical devices is not harmonised on a European level, but belongs to the exclusive competence of the EU Member States. As a result, there are different statutory health schemes within each European country and the pricing and reimbursement of pharmaceuticals and medical devices is subject to very different rules. There is however some harmonisation as regards the transparency of measures regulating the pricing and reimbursement of pharmaceuticals through the European Transparency Directive. The Transparency Directive basically provides that such measures should be based on objective and verifiable criteria. It also provides for timelines within which pricing and reimbursement decision should be taken. The European Commission issued a proposal for a new Transparency Directive in 2012. Since the proposal was not adopted within the former legislated period which ended in spring of 2014, the legislative process on a new Transparency Directive will likely have to start over again (though a continuation of the legislative process is technical feasible under the Parliament's Rules of Procedure). This means that new EU legislation on this topic is likely still far away.

Notwithstanding the lack of harmonised EU legislation on pricing and reimbursement there is cooperation on an EU level regarding Health Technology Assessment (HTA) between national HTA organisations. This cooperation takes place within the HTA Network. The HTA Network was established recently pursuant to the Cross Border Healthcare Directive, the first meeting of the

HTA Network took place in October 2013. The HTA Network will deal with strategic and political HTA cooperation between Member States. Another cooperation of HTA organisation, the EUnetHTA will focus more on the scientific and technical elements of HTA.

In spite of the different national systems of pricing and reimbursement there is a general trend throughout Europe regarding the increase of cost containment measures to control public spend on medicinal products and medical devices. Most countries apply pricing measures where the price of a medicinal product or the margins are set or controlled on a government basis. Such pricing restrictions are in some countries based on HTA procedures which aim at determining the patient benefit of therapies. In other countries reference pricing schemes apply. Thus, the price of a pharmaceutical in one European country, e.g. in Germany, has a significant impact on the prices in several other EU countries – as well as the prices in other EU countries. Thus, the launch of a new product and the pricing strategy has to be carefully aligned throughout Europe.

There are furthermore regulations or incentives to promote generic and in some case therapeutic substitution of medicinal products. Most regulations and incentives are aimed at healthcare professionals prescribing and dispensing medicinal products, e.g. physicians and pharmacists. In some countries such incentives are also aimed at patients by providing reimbursement levels and mandatory out-of-pocket payments.

Each country chapter provides a summary of the pricing and reimbursement system, an overview of legislation and key players and describes how the pricing and reimbursement systems works in each such country.

We hope that you will find this special edition of our Pricing & Reimbursement newsletter practical and interesting.

November 2014 - Hogan Lovells International LLP

<sup>1</sup> EFPIA, The Pharmaceutical Industry in Figures – Edition 2013 p.15.

# Belgium

## 1. SUMMARY

- The majority of medicinal products in Belgium are reimbursed by the statutory health insurance funds.
- The level of reimbursement depends on the reimbursement classification of the medicinal product.
- Patients are often required to contribute to the cost of the medicinal products. The amount of the patients' co-payment is, however, limited by the law.
- The Belgian healthcare system combines a statutory healthcare insurance and optional additional healthcare insurance:
  - Compulsory health insurance is organized through private, non-profit-making national associations of health insurance and a public national association of healthcare insurance funds.
  - The role of the healthcare insurance funds is to reimburse treatment received by the patients.
- Key features of the pricing and reimbursement of medicinal products:
  - positive list of reimbursed medicinal products;
  - medicinal products could be subject to restricted or unrestricted reimbursement;
  - different regimes for the reimbursement of ambulatory care and hospital care;
  - differentiated reimbursement levels;
  - reference reimbursement system;
  - risk sharing;
  - hospital tenders.

- Various measures are in place or are being introduced by the government to cut back the costs of medicinal products:
  - maximum prices for medicinal products;
  - reference pricing groups;
  - differentiated reimbursement levels;
  - limitations of the pharmacists and wholesaler margins.

## 2. THE HEALTHCARE SYSTEM IN BELGIUM: OVERVIEW

The Belgian healthcare system is funded from social security charges levied from salaries and social security contributions from self-employed individuals. Additional funds are collected from other sources, such as social security contributions collected from companies. The responsibility for health policy is shared between the federal state and the federated entities, including regions and communities.

### 2.1 Payers – Healthcare insurance funds

The Belgian healthcare system combines a statutory healthcare insurance and optional additional healthcare insurance. Compulsory health insurance is organized through private, non-profit-making national associations of health insurance, and a public national association of healthcare insurance funds. The role of the healthcare insurance funds is to reimburse treatment received by the patients. There are no differences in the tasks performed by the different types of insurance funds in relation to the reimbursement of costs for treatment of patients.

The National Institute for Health and Disability Insurance (hereafter the "INAMI") is a public social security institution that reports to the Minister of Social Affairs and Public Health. INAMI is responsible for the general organization and financial management of the compulsory healthcare insurance.

Medicinal products prescribed to patients are generally reimbursed but patients may be required to contribute to the cost of these medicinal products. The amount of the patients' co-payment is, however, limited by the law.

## 2.2 Key features of the pricing and reimbursement of medicinal products

The key features of the pricing and reimbursement of medicinal products in Belgium include:

- positive list of reimbursed medicinal products;
- medicinal products could be subject to restricted or unrestricted reimbursement;
- different regimes for the reimbursement of ambulatory care and hospital care;
- differential reimbursement depending:
  - on the status of the patient: self-employed vs. employee;
  - category of the medicinal product: A, B, C, Cs, Cx or D.
- reference reimbursement system;
- risk sharing;
- hospital tenders.

## 2.3 Legal basis

- The major Laws and Royal Decrees governing the pricing and reimbursement of medicinal products in Belgium include:
  - the Law of 14 July 1994 on the compulsory healthcare insurance;
  - the Law of 10 August 2001 on measures adopted in the area of healthcare;
  - the Law of 27 December 2005 on measures adopted in various areas, including healthcare insurance;
  - the Royal Decree of 8 June 1994 on the medical prescription
  - the Royal Decree of 21 December 2001 on the procedures, timelines and conditions in relation to the reimbursement of medicinal products;
  - the Royal Decrees of 16 May 2006 on the procedures, timelines and conditions in relation to the reimbursement of medicinal products.

## 2.4 Prescribers – physicians and dentists

In Belgium, prescription-only medicinal products are prescribed to patients by physicians and dentists. Nurses are not permitted to prescribe medicinal products to patients.

## 2.5 Patients who are entitled to reimbursement of their medicinal products

Almost all patients in Belgium are entitled to a reimbursement of their medicinal products. The categories of patients that are entitled to reimbursement include, among others:

- employees who are affiliated with a compulsory health insurance fund;
- employees who are not capable to work;
- unemployed individuals;
- employees on maternity or paternity leave;
- self-employed who are affiliated with a compulsory health insurance fund;
- individuals who are retired.

Some categories of individuals are entitled to reimbursement of their medicinal products under specific conditions that are subject to constant evolution and revisions. These categories of individuals include, among others:

- members of religious communities; and

## 3. SELF-EMPLOYED AND MEMBERS OF RELIGIOUS COMMUNITIES WHO ARE NOT CAPABLE TO WORK DUE TO THEIR HEALTH CONDITION. OUTLINE OF THE PRICING AND REIMBURSEMENT PROCEDURE FOR MEDICINAL PRODUCTS IN BELGIUM

Only medicinal products that are authorised to be placed on the market in Belgium could be granted pricing and reimbursement status in the country. This includes medicinal products that were centrally authorised by the European Commission. It also includes medicinal products that were authorised by the Belgian Federal Agency for Medicinal Products and Healthcare Products ("AFMPS") through the national, decentralised and mutual recognition marketing authorisation procedures.

### 3.1 Pricing of medicinal products

A key step in the procedure is the determination of the maximum ex-factory price for the medicinal product. This maximum price is determined by the Belgian Ministry of Economy.

The marketing authorisation holder for the medicinal product should submit an application to the Ministry of Economy for the establishment of a maximum ex-factory price for the medicinal product. The application should include a proposal for such maximum price. The Minister of Economy determines the maximum ex-factory price after the Commission for the Prices of Medicinal Products ("CPMP") has issued its opinion. The CPMP is composed of experts who are appointed by a Decree of the Belgian government.

The Minister also fixes the final price of the medicinal product as sold in the pharmacies. This price includes the maximum ex-factory price, the pharmacists and wholesalers margins and the VAT of 6%. The determination of the pharmacists and wholesalers margins is discussed in further detail in the following Sections of this Document.

The Minister is required to adopt the decision within 90 days following the submission of the application by the marketing authorisation holder. This period is reduced to 45 days for medicinal products that are subject to parallel import into Belgium. If the Minister does not adopt a decision within these timelines the marketing authorisation holder is permitted to use the maximum ex-factory price that was proposed in its application.

The same procedure applies if the marketing authorisation holder wishes to apply for an increase of the maximum ex-factory price for the medicinal product. The CPMP is required to give an opinion before the Minister decides to accept or refuse the application for an increase of the maximum ex-factory price of the medicinal product.

The prices of medicinal products in pharmacies in Belgium are composed of the ex-factory price of the medicinal product, the margins for the pharmacists and wholesalers and 6% VAT.

### 3.2 Reimbursement of medicinal products

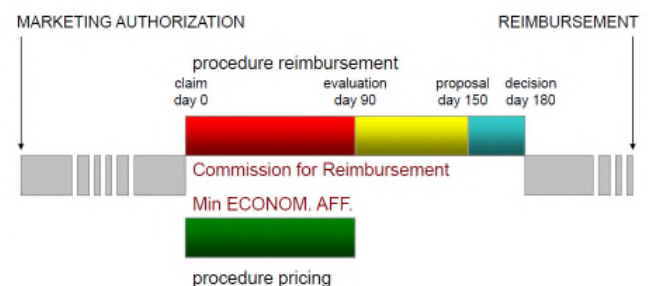
The marketing authorisation holder that wishes to obtain a reimbursement status for its medicinal product is required to submit an application for the inclusion of this medicinal product in the list of reimbursed medicinal products. The application should be submitted to the Commission for Reimbursement of Medicinal Products ("CRM"). This application could be submitted at the same time as the submission of the pricing application to the Ministry of Economy.

The decision concerning grant or refusal of reimbursement status for a medicinal product is adopted by the Minister responsible for Social Affairs and Public Health. The Minister is required to provide the grounds supporting the decision.

The Minister adopts the decision for grant or refusal of reimbursement status for a medicinal product on the basis of a proposal by the CRM. The Minister is required to adopt this decision within 180 days following the submission of the application for reimbursement by the marketing authorisation holder.

The elements taken into account by the CRM and the Minister in their assessment include:

- the efficacy of the medicinal product;
- the safety and convenience of use of the medical product;
- impact of the medicinal product on morbidity, mortality and quality of life of patients;
- importance of the medicinal product in clinical practice;
- budgetary impact;
- ratio between cost and therapeutic value.



Source: INAMI / RIZIV

#### (a) The CRM

The members of the CRM with voting rights include:

- seven representatives of Belgian academia;
- eight representatives of the Belgian health insurance funds;
- three representatives of the professional organisations of pharmacist;
- four representatives of the professional organisations of physicians.

The members of the CRM who do not have voting rights include:

- two representatives of the associations of pharmaceutical industry;
- two representative of the Ministry of Social Affairs and Public Health;
- one representative of the Ministry of Economy;
- one representative of the Medical Control Department of INAMI.

The tasks of the CRM include:

- draft proposals for grant or refusal of reimbursement status for a medicinal product;
- upon the request of the Minister responsible for Social Affairs and Public Health, prepare opinions concerning the policy for the reimbursement of medicinal products;
- draft proposals for guidance concerning the interpretation of the rules governing the reimbursement of medicinal products.

#### **(b) List of reimbursed medicinal products**

The list of reimbursed medicinal products is divided in various Chapters. The Chapters reflect the nature of the medicinal products and the therapeutic indications that are covered by reimbursement.

As a general principle, only medicinal products that are authorised to be placed on the market in Belgium are eligible for inclusion in the list of reimbursed medicinal products. Moreover, only the therapeutic indications that are covered by the marketing authorisation may be subject to reimbursement.

This list is available at [http://www.inami.fgov.be/inami\\_prd/ssp/cns2/pages/SpecialityCns.asp](http://www.inami.fgov.be/inami_prd/ssp/cns2/pages/SpecialityCns.asp).

The medicinal products included in Chapter I of the list of reimbursed medicinal products qualify for unrestricted reimbursement. These medicinal products are reimbursed when prescribed:

- for all of their approved therapeutic indications;
- for all patients;
- by any prescriber.

The medicinal products included in Chapters II and IV of the list of reimbursed medicinal products are subject to restricted reimbursement. These medicinal products are reimbursed when prescribed:

- for selected approved therapeutic indications;
- to selected patients;
- by selected prescribers.

Medicinal products falling in the scope of Chapter II are reimbursed for all common therapeutic indications. These indications are established by or on the basis of a recommendation by the CRM. The prescriber is required to keep documents that demonstrate compliance with the conditions for restricted reimbursement. The documents could be subject to a control by the competent authorities.

Medicinal products falling in the scope of Chapter IV are reimbursed in accordance with specific reimbursement conditions. These conditions relate to:

- the therapeutic indication and the diagnostic of the medical condition;
- the budgetary impact of the reimbursement;
- history of the treatment of the patient and comorbidities;
- specialisation of the prescriber and experience in the treatment of the medical condition;
- characteristics of the patients: age, sex, weight, etc.;
- quantity of medicinal products prescribed;
- duration of the treatment.

Due to their specific nature, some medicinal products are classified in special Chapters of the list of reimbursed medicinal products:

- Chapter III: perfusion liquids;
- Chapter IVbis: imported medicinal products that are not authorised to be placed on the market in Belgium;
- Chapter V: human fibrinogen;
- Chapter VI: radio-isotopes.

### (c) Categories of reimbursement

Each medicinal product that is included in the list of reimbursed medicinal products is attributed to a reimbursement category. The category corresponds to the percentage of the cost of the medicinal product that is reimbursed by the health insurance funds in Belgium. The categories are A, B, C, Cs, Cx, Fa and Fb.

The attribution of a medicinal product to a reimbursement category is made by the Ministry of Social Affairs and Public Health. The decision of the Ministry is based on a proposal by the CRM.

The medicinal products in categories A, B, C, Fa and Fb are considered to be "necessary" treatments. These medicinal products are classified in accordance with their "medico-therapeutic value". This value is determined by the CRM.

Medicinal products in category A and Fa have vital importance. These medicinal products include treatments for diabetes and cancer. Medicinal products classified in these categories are reimbursed at 100% of their maximum reimbursement price.

Medicinal products that are considered important for the treatment of patients are classified in category B and Fb. Antibiotics are an example of such medicinal products. Medicinal products classified in categories B and Fb are reimbursed at up to 84% of their maximum reimbursement price.

Medicinal products for symptomatic treatment, such as the treatment of chronic bronchitis, are classified in category C. Medicinal products classified in category C are reimbursed at up to 46% of their maximum reimbursement price.

Medicinal products in category Cs are reimbursed at up to 35% of their maximum reimbursement price. The maximum reimbursement level for medicinal products in category Cx is 14%.

The reimbursement levels for medicinal products in categories B, C, Cs, Cx and Fb depend on the maximum reimbursement price of the medicinal products. Medicinal products that cost less than €14.38 are reimbursed at lower levels.

The cost for the medicinal product that is paid by the patient is, however, limited for certain categories of medicinal products. The limit for patient co-payment for medicinal products in categories B, C and Fb is €14,50.

### 3.3 Reference reimbursement

Specific rules apply to the determination of the reimbursement level for medicinal products that are covered by reference pricing. Reference groups contain medi-

nal products that share the same active substance. As an example, innovative medicinal products and their generics are included in the same reference group.

The reimbursement level for the innovative medicinal product is reduced automatically by 30% if a generic version of this medicinal product is available on the market in Belgium. Moreover, the maximum price for such medicinal products is equal to the base of reimbursement plus a "safety margin" of 25% of the base of reimbursement. The safety margin cannot, however, exceed €10,80.

The base of reimbursement for innovative medicinal products that have been included in the reference pricing system for two years is reduced by 6%. This base is further reduced by 5.5% after the fourth year of inclusion of the innovative medicinal product in the reference pricing system.

### 3.4 Reimbursement of medicinal products administered to patients in hospitals

The costs of medicinal products administered to patients in hospitals are partly covered by a hospitalisation budget that is attributed to each patient. The amount of this budget is determined depending on the medical condition and therapeutic needs of the patient. The budget covers 75% of the cost of the medicinal products administered to the patient.

The remaining 25% are reimbursed in accordance with the general reimbursement rules discussed in the previous Sections of this Document. The same applies to the cost of the medicinal products that exceed the limits of the patient budget.

In accordance with the applicable rules, hospitals in Belgium are required to organise public tenders for the purchase of medicinal products. These tenders should either be based on a single stage procedure where price is the only criterion or on a multiple stage procedure where a mix of quantitative and qualitative criteria is used.

This requirement applies to both public and private hospitals in Belgium. This is because the hospitals perform a mission of public interest and 50% of their funding is provided by public finances. Two or more hospitals may choose to organise common public tenders for the purchase of medicinal products.

### 3.5 Social Solidarity Fund

The Solidarity Fund established by the Belgian State provides funding for the treatment of patients with medicinal products that are:

- not reimbursed;



- not authorised to be placed on the market in Belgium;
- expensive;
- intended to treat rare diseases.

Funding from the Solidarity Fund is provided to individual patients or identified groups of patients.

#### 4. PRESCRIPTION OF MEDICINAL PRODUCTS

Physicians are permitted to prescribe a number of medicinal products to a single patient in the course of the same medical visit. The validity of the prescriptions is, however, limited to three months.

The CRM has established Recommendations for Good Medical Practice. These Recommendations provide guidance for the physicians concerning the establishment of prescriptions for medicinal products. The Recommendations reflect the principles of "evidence based medicine".

The medicinal products falling in the Scope of Chapter IV cannot be reimbursed by the health insurance funds unless the physician who is appointed as a medical advisor by the health insurance fund authorises this reimbursement. The decision of the medical advisor is based on the medical history of the patient and his or her therapeutic needs.

#### 5. MARGINS FOR PHARMACISTS AND WHOLESALE INCLUSIONS IN THE PRICE OF MEDICINAL PRODUCTS

The price of medicinal products in the pharmacies in Belgium includes a margin for the pharmacists and wholesalers. The margin for the pharmacists is composed of two elements:

- economic margin: this margin is equal to 6.04% of the ex-factory price of medicinal products if this ex-factory price does not exceed €60. If the ex-factory price exceeds €60 the economic margin is equal to €3.62 plus 2% of the portion of the ex-factory price that exceeds the €60 limit;
- basic honorarium equal to €4.11;

The margins for wholesalers depend on the ex-factory price of the medicinal product:

- the margin is equal to €0.35 if the ex-factory price is less than €2.33;
- the margin is equal to 15% of the ex-factory price if this price is more than €2.33 and does not exceed €15.33;

- if the ex-factory price of the medicinal product exceeds €15.33 the margin is equal to €2.30 plus 0.9% of the portion of the ex-factory price that exceeds the €15.33 limit.

#### 6. PRICING AND REIMBURSEMENT OF MEDICAL DEVICES

Some medical devices, such as medical devices used for the diagnostics of a medical condition or the administration of a medicinal product, are included in the list of reimbursed medicinal products. These devices are classified in the reimbursement categories applicable to medicinal products. The reimbursement of the costs of the medicinal devices included in the reimbursement list is governed by the rules governing the reimbursement of medicinal products.

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# The Czech Republic

## 1. SUMMARY

- The majority of the medicinal products are fully or partially reimbursed from a basic health insurance package, which is mandatory for each citizen.
- There is one major health insurer in the Czech Republic that controls almost 60% of the health insurance market.
- The price and reimbursement system in the Czech Republic is currently very complicated and therefore, the Ministry of Health intends to adopt new regulations (at least in relation to medical products) within the next few years.
- The Czech Republic is the only state within the EU which has chosen a strict international reference system for the determination of the manufacturer price, as well as the reimbursement determination.
- The State Institute for Drug Control plays a key role in the price and reimbursement regulation. Its decisions can be reviewed by the Ministry of Health.
- In the Czech Republic, medical devices are also subject to price and reimbursement regulation.

## 2. THE CZECH HEALTHCARE SYSTEM: OVERVIEW

Under Act No. 48/1997 Coll., on Public Health Insurance (*zákon o veřejném zdravotním pojištění*) (the "**Insurance Act**"), which came into force more than 16 years ago, it is mandatory for all persons with permanent residence in the Czech Republic to be part of the public health insurance system. Moreover, persons who do not have permanent residence in the Czech Republic are obliged to participate in the public health insurance system, provided that their employer has its seat or permanent residence in the Czech Republic.

### 2.1 Major legislation

The pricing of medicinal products and medical devices is regulated in particular by the Insurance Act, and by the price regulations and price decisions that are issued by the Ministry of Health. The reimbursement of medi-

cal products and medical devices is regulated by the Insurance Act and by various decrees.

### 2.2 Key participants

The public health insurance system in the Czech Republic identifies the following three key participants:

- insured person;
- healthcare services provider; and
- health insurance company.

It is a basic right of each person to freely choose the insurance company (with limited exceptions). The health insurance company is obliged to accept each person who meets the requirements for participation in the public health insurance program (i.e. a person who has permanent residence in the Czech Republic or whose employer has a registered seat or permanent residence in the Czech Republic).

The right to choose the insurance company became effective in the Czech Republic on 1 January 1993. In 1992, all persons with permanent residence in the Czech Republic automatically became insured by the health insurance company, *Všeobecná zdravotní pojišťovna ČR*, which is still the health insurance company with the biggest percentage of policyholders in the Czech Republic. According to its annual report, as of 31 December 2012, 59.2% of policyholders in the Czech Republic were insured by this insurance company. The remainder is insured by one of the remaining six health insurance companies providing public health insurance.

Similarly, as with the right to choose the insurance company, each person is also entitled to choose the healthcare service provider (with limited exceptions to this rule).

### 2.3 Payers

The three categories of subjects obliged to contribute to the public health insurance system is as follows. The first category covers the insured party (i.e. the employee, self-employed person and person without earned income). The second category is represented by the employer, who is obliged to provide the payment for its employees. The third category covers the state, which

is obliged to pay the insurance in the case of seniors, children, students and further subjects listed in the Insurance Act.

Within the employment relationship, the employer pays 2/3 of the insurance premium and the employee pays the remaining 1/3. The insurance premium represents 13.5% of the employee's gross income.

#### 2.4 Decision-makers – the State Institute for Drug Control and Ministry of Health

Since 2008, the State Institute for Drug Control has decided on the maximum price of the medicinal products, as well as reimbursement of medicinal products. The participants of these proceedings are marketing authorisation holders and health insurance companies. The Ministry of Health acts as the appellate body in these administrative proceedings.

### 3. PRICING OF MEDICINAL PRODUCTS AND MEDICAL DEVICES

The pricing of medicinal products is regulated by the Insurance Act, pricing regulations issued by the Ministry of Health (i.e. with effect from 1 January 2013 Price Regulation No. 1/2013/ FAR) and a pricing decision issued by the Ministry of Health (ie. effective from 1 January 2013 Price Decision No. 1/13-FAR). Decree No. 376/2011 Coll. also applies to the pricing of medicinal products. The pricing of medical devices is regulated by the pricing regulations issued by the Ministry of Health (i.e. with effect from 1 May 2012 Price Regulation No. 3/2012/FAR) and pricing decisions issued by the Ministry of Health (i.e. with effect from 1 January Price Decision No. 2/13-FAR). A special price decision applies to stomatology medical devices.

#### 3.1 Pricing of medicinal products

In the Czech Republic, the medicinal products which are reimbursed from the public health insurance are subject to price regulation. According to the information from the State Institute for Drug Control, there are currently around 5,600 reimbursed medicinal products which are present on the market (from which around 1,450 are fully reimbursed). In addition to the reimbursed medicinal products, around 2,500 medicinal products which are not reimbursed are present on the market. The latter category of medicinal products can be placed on the market for a freely chosen price and distributors and pharmacies may apply a freely chosen margin.

Generally speaking, two elements of the price of the reimbursed medicinal products are regulated, i.e.:

- manufacturer price; and

- margin.

As the margin is regulated in the case of all reimbursed medicinal products (with limited exceptions), the manufacturer price is regulated only in a specific situation. This specific situation is represented by the case where there is an insufficiently competitive market. The market is considered as insufficiently competitive if there are not at least four medicinal products from at least four different manufacturers relating to one active substance and one method of application. The general method by which the manufacturer prices and margins are regulated is by determination of the maximum price.

#### (a) Calculation of maximum manufacturer price

The maximum manufacturer price is basically the highest price for which the manufacturer may sell the medicinal product to the first distributor in the distribution chain. As stated above, the determination of the maximum manufacturer price is provided in the administrative proceedings before the State Institute for Drug Control (and before the Ministry of Health in the potential appellate proceedings).

The rules for the calculation of the maximum manufacturer price are prescribed by the Insurance Act. As a **general rule**, if the medicinal product is on the market of at least three countries from the so-called reference basket, the maximum price is determined as the average of the three lowest manufacturer prices in those countries. The "reference basket" consists of the Member States of the European Union excluding: Bulgaria, the Czech Republic, Estonia, Luxemburg, Germany, Austria, Romania, Cyprus and Malta.

If the medicinal product is not marketed in three countries from the reference basket, then the **second rule** applies. The price is determined as the manufacturer price for the medicinal product, stated in a written agreement and concluded in the public interest by and between a health insurance company and the marketing authorisation holder of the medicinal product, provided that such agreement is concluded for at least one year with a notice period of at least three months for any and all deliveries of the medicinal product to the Czech market.

If neither the first rule nor second rule applies, a **third rule** applies and the price is determined as the manufacturer price of a therapeutically comparable medicinal product that is available in the reference basket countries or in the Czech Republic. If the therapeutically comparable medicinal product is available in the Czech Republic, the lowest manufacturer price recorded in the Czech Republic applies. If the marketing authorisation holder of such therapeutically comparable medicinal product is the same as for the medicinal product under

review, then this price shall be applied, provided such price has been determined pursuant to the first (general) rule above. In cases where such procedure cannot be followed, the lowest manufacturer price recorded in the reference basket countries shall be applied. When selecting the most therapeutically comparable medicinal product, the relevant criteria shall be taken into account in the following order: active ingredient, form of medicinal product, strength of medicinal product, package size.

Specific price regulation applies to special types of medicinal products, such as individually prepared medicinal products in pharmacies, radiopharmaceuticals, and transfusion medicinal products, as well as under other specific circumstances.

### (b) Calculation of maximum margin

Within the determination of the margin, the highest percentage which can be added to the manufacturer price by all subjects within the distribution channel (including all distributors and pharmacies) is stipulated. In practice, the highest part of the margin is applied by the pharmacies.

Contrary to the determination of the maximum manufacturer price, the maximum margin is not determined in the administrative proceedings before the State Institute for Drug Control, but directly stipulated by the price regulation issued by the Ministry of Health (i.e. from 1 January 2013 by Price Regulation No. 1/2013/ FAR). The following table shows the current maximum margins:

Zone	Manufacturer price from (CZK)	Manufacturer price to (CZK)	Rate	Amount which can be added (CZK)
1	0.00	150.00	37%	0.00
2	150.01	300.00	33%	6.00
3	300.01	500.00	24%	33.00
4	500.01	1,000.00	20%	53.00
5	1,000.01	2,500.00	17%	83.00
6	2,500.01	5,000.00	14%	158.00
7	5,000.01	10,000.00	6%	558.00
8	10,000.01	9,999,999.00	4%	758.00

As follows from the above table, the percentage of the margin and the additional amount of money which can be added is prescribed. The following example may

help to understand the margin calculation: If the manufacturer price is CZK 2,000, the margin is 17% of CZK 2,000 plus CZK 83, i.e. CZK 423.

### 3.2 Pricing of medical devices

As with the medicinal products, medical devices which are reimbursed from the public health insurance are subject to price regulation. Also, in the case of medical devices, the following two elements are subject to price regulation:

- manufacturer price; and
- margin.

However, the methods of price regulation are different in the case of medical devices. According to Price Regulation 3/2012/FAR, the manufacturer price cannot exceed the lowest wholesale price for which the medical device is placed on the market in the EU. The manufacturer price must be documented by wholesale price list. The maximum increase of 5% per year from the price stated in the wholesale price list is permitted.

In the case of certain interchangeable medical devices, the Ministry of Health deregulates the prices. The medical devices with deregulated prices are currently listed in Price Decision No. 2/13-FAR.

As regards the price regulation of margin, the maximum percentage applied in relation to the manufacturer price may amount to 25% (subject to limited exceptions).

## 4. REIMBURSEMENT OF MEDICINAL PRODUCTS AND MEDICAL DEVICES

The reimbursement of medicinal products is regulated by the Insurance Act and Decree No. 376/2011 Coll. and Decree No. 384/2007 Coll. The reimbursement system is even more complicated than the price regulation system described above.

### 4.1 Reimbursement of medicinal products

The Czech medicinal reimbursement system is based on the so-called reference system. As stated above, the State Institute for Drug Control and the Ministry of Health in the appellate proceedings decide on the medicinal products reimbursement. Under this system, the first step is to categorise the medicinal product into a reference group containing therapeutically interchangeable products. Currently, there are almost 200 different reference groups. However, there are many medicinal products which do not have any therapeutically interchangeable products. Such products cannot therefore be classified under any reference group and are therefore treated as an independent reference group.

The Insurance Act prescribes various methods of calculation of such reimbursement. The two most common types of calculation are:

- the external price reference; and
- the internal price reference.

#### **(a) External price reference**

The external price reference is a primary method of calculating reimbursements for the majority of medicinal products. The prices of all medicinal products belonging to the respective reference group in all EU states are decisive for the determination of the reimbursement according to the external price reference. The cheapest price of the medicinal product is selected from an overall list of prices and such price is used as the basic reimbursement of the entire reference group. Common daily doses of the medicinal products are compared. Therefore, the basic reimbursement of the reference group is the lowest price for the common daily dose of any medicinal product belonging to the reference group in any EU member state.

#### **(b) Internal price reference**

The internal price reference rule applies in relation to groups of medicinal products listed in Annex No. 2 to the Insurance Act. According to the Insurance Act, there must be at least one fully reimbursed product within these groups of medicinal products. These groups of medicinal products do not correspond to the reference groups described within the description of external price reference above, are not heterogeneous and do not necessarily comprise interchangeable products. This results in a practical problem where the reimbursement is stipulated under the external price reference system and after such calculation it is ascertained that no medicinal product in the respective group of Annex No. 2 would be fully reimbursed. In such a case, the basic reimbursement of the reference group (stipulated according to the external price reference rule) must then be extended so that the cheapest medicinal product in the respective reference group in the Czech Republic is fully reimbursed.

#### **(c) Reimbursement of individual medicinal product**

Once the basic reimbursement is calculated, the reimbursement of an individual medicinal product within each reference group can then be established. Generally, such calculation multiplies the basic reimbursement by the amount of common daily doses in the package of the respective medicinal products. There are, however, many exceptions to the general rule.

The above rules only apply to outpatient care. Within the provision of inpatient care, it is generally not permitted to request any direct payment from the patient.

#### **4.2 Out-of-pocket payments by patients**

There are certain types of medical procedures where an insured person is required to make an out-of-pocket or co-payment contribution to the cost of care. These types of procedures cover, inter alia, plastic surgery, certain dental procedures or issuance of health status certification.

Moreover, four types of co-payments were introduced by the Ministry of Health in 2008. These co-payments relate (or related) only to medical procedures, medicinal products, and inpatient stays that are covered (or at least partially covered) by public health insurance. Only the three following co-payments are currently valid:

- CZK 30 (approx. EUR 1.2) for a physician's visit, during which a clinical examination was performed and further specific types of visits of specialised doctors;
- CZK 30 (approx. EUR 1.2) for a medical prescription (formerly each item on the prescription); and
- CZK 90 (approx. EUR 3.6) for a visit to an emergency medical services provider or emergency dental services.

The fourth type of co-payment (for the provision of inpatient care) was cancelled as a result of the 2013 Constitutional Court Decision. It does not currently seem likely that this co-payment will be re-implemented.

The prescription co-payments and co-payments for physician and specialist doctor visits may be cancelled in the near future as a result of a decision from the new government.

#### **4.3 Reimbursement of medical devices**

According to the Insurance Act, reimbursement also applies to medical devices prescribed for a patient for one of the following reasons:

- to continue the healing process;
- to stabilise the patient's health, to distinctly improve the patient's health or to avoid its worsening; or
- to compensate or reduce the effects of a handicap, including the replacement or modification of an anatomical structure or physiological process.

As a general rule, the medical devices are reimbursed at 75% of the lowest consumer price of the medical device in the market. There are various exceptions to this rule and as a result, certain medical devices are not reimbursed at all and certain medical devices are reimbursed only in specified amounts.

The above rules only apply to outpatient care. Currently, there are no statutory rules for inpatient care and the system is basically governed by the agreements entered into between the insurance companies and the healthcare providers. *(Michal Nulicek/Kristyna Sledrova).*

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# Germany

## 1. SUMMARY

- The health care system in Germany comprises two elements:
  - A statutory system of health care provision funded by income-related contributions and tax subsidiaries. Approx. 90 per cent of the population are mandatorily insured within the statutory system; the remainders are mainly either self-employed or individuals with high income. Physicians and hospitals cater for both groups.
  - Private insurance companies offering insurance coverage for those not insured in the statutory system (funded by income-unrelated insurance rates which reflect the individual risk and scope of services insured).
- Apart from legislator which here and then changes the statutory health system, decisions are frequently not taken by governmental bodies. Instead, self-governing bodies (associations) of physicians, statutory (public) sick funds, hospitals etc. are in charge of major decisions regarding the scope of health care services available in the statutory system, pricing and reimbursement.
- There are a number of statutory cost-cutting instruments in force, including i.a. mandatory rebates, quota for generics and imported medicinal products, fixed reimbursement caps (reference pricing) and health technology assessments.
- Free pricing of new medicinal products is limited to an only short period after market launch. Thereafter a negotiated price kicks in - based on the outcome of an early benefit assessment.
- There is no positive list for medicinal products. However, some pharmaceuticals are excluded from reimbursement by law (non-Rx products and lifestyle drugs) or decree (pharmaceuticals generally deemed inefficient). In addition, prescription restrictions and prescription guidelines may be applicable for individual products.

- The distribution chain for pharmaceuticals is rigidly regulated, whereas it is quite liberal for medical devices. Discounts and rebates for medicinal products are generally not permissible throughout the distribution chain, but may be granted to health insurance funds (for out-patient care) and hospitals (for in-patient care). Medicinal products for which manufacturers conclude rebate agreements with statutory health insurance funds are dispensed on a preferential basis.
- For medical devices, there is a medical technical aids reimbursement list for out-patient care. Although not binding, reimbursement of medical devices is facilitated by the medical device being listed. Medical devices used for in-patient care are sold directly to hospitals. Their costs are covered by diagnosis related groups (DRG) lump sums.

## 2. GERMAN HEALTHCARE SYSTEM: OVERVIEW

Germany is the largest market for pharmaceuticals and medical devices in Europe and the fourth largest market in the world. The annual sales of pharmaceuticals in Germany reached €40 billion in 2012. 21,000 privately run local pharmacies generate about 87% of these sales and hospitals account for the remainder. Generics account for about 30% of the overall sales volume of medicinal products (on pharmacy price level).

For distributing pharmaceuticals to patients, manufacturers conclude sales contracts with regional or national wholesalers or also sell directly to pharmacists and hospitals.

End-user medical devices are usually sold by manufacturers to wholesalers or directly to pharmacies, medical supply stores or to home care service providers which use or apply the respective devices. Devices being medical equipment (be it bandage material or a magnetic resonance tomograph) are bought by healthcare service providers and hospitals directly from manufacturers or, as the case may be, via wholesalers.

## 2.1 Major legislation

The German law on medicinal products and medical devices is laid down in a variety of national laws, mainly differentiating between pharmaceuticals (medicinal products) and medical devices. The Drug Act (*Arzneimittelgesetz* - "AMG")<sup>2</sup> and the Medical Devices Act (*Medizinproduktegesetz* - "MPG") contain central provisions on clinical trials, marketing requirements, product safety and vigilance, information requirements, importation, liability and distribution. The Act on Advertising of Medical Products (*Heilmittelwerbegesetz* - "HWG") regulates – and restricts – the advertising and promotion of medicinal products and medical devices as well as healthcare services.

The Social Security Code V (*Sozialgesetzbuch V* - "SGB V")<sup>3</sup> regulates prescription and reimbursement of medicinal products and medical devices for the 90% of the German population which is insured by public sick funds. The SGB V is accompanied by a variety of amendment acts and ordinances as well as binding contracts and decisions of the major players. Most notably is the Act on the Reorganisation of the Pharmaceutical Market (*Arzneimittelmarktneuordnungsgesetz* - AMNOG) which entered into force on 1 January 2011 and which substantially changed the legal landscape for the pricing and reimbursement of medicinal products.

## 2.2 Payers – insurance funds

Healthcare products are paid for by private or public (statutory) insurance funds. Nearly 90% of the population are insured by one of the roughly 130 statutory health insurance ("SHI") funds and around 9% are insured by private insurance companies. The biggest SHI funds are AOK, a cluster of 11 funds with approximately 24 million members, Barmer GEK and Techniker Krankenkasse each insuring more than 8 million members. Since 1 July 2008, all SHI funds are represented by a single national head organisation, the Federal Association of SHI Funds (*GKV-Spitzenverband* - "GKV-SV"). Patients insured with the SHI pay income-dependent contributions which are collected by a central health insurance fund (*Gesundheitsfond*). The fund then allocates payments to individual SHI funds based on a calculation which factors in the number of insured patients, the risk structure of the respective patients and social aspects.

This article mainly features the rules regarding prescription and reimbursement for patients insured in SHI funds (as said, 90 % of the population).

<sup>2</sup> For an English version see the homepage of the national regulator BfArM at [www.bfarm.de](http://www.bfarm.de).

<sup>3</sup> For the latest major reform act of April 2007 see Schulz S, The Regulatory Affairs Journal – Pharma, 2007, 18(4), 225-227.

Private insurers pay for medicinal products on the basis of individual insurance contracts which differ widely. Basic contracts cap reimbursement to the level of SHI funds, whereas prime contracts guarantee reimbursement of any reasonable treatment costs.

## 2.3 Prescribers and healthcare providers – physicians and hospitals

Prescription only ("Rx") medicinal products can only be prescribed (to SHI insured patients) by SHI accredited physicians or general practitioners. In out-patient care, these SHI accredited physicians and practitioners are mandatorily organized in and represented by regional and federal Associations of SHI accredited Physicians (*Kassenärztliche Vereinigung* - "KV"). The regional and federal Associations conclude agreements with SHI funds or their associations regulating – and limiting – the amount of overall fees for SHI accredited physicians and practitioners, set up budgets for pharmaceuticals, implement statutory cost-cutting tools and establish personal sanctions for physicians not complying with these regulations and the statutory stipulations in the social security laws. The above mentioned agreements are binding on each physician and have a direct impact on reimbursement. In other instances, influence is wielded in a softer manner by agreements which offer additional bonuses for physicians when certain prescribing quotas are reached (i.e. quota for prescribing many cheap generics or only a limited amount of so-called me-too-products).

Major rules for prescribing medicinal products and medical devices are described below more specifically.

## 2.4 Deciders – Federal Joint Committee

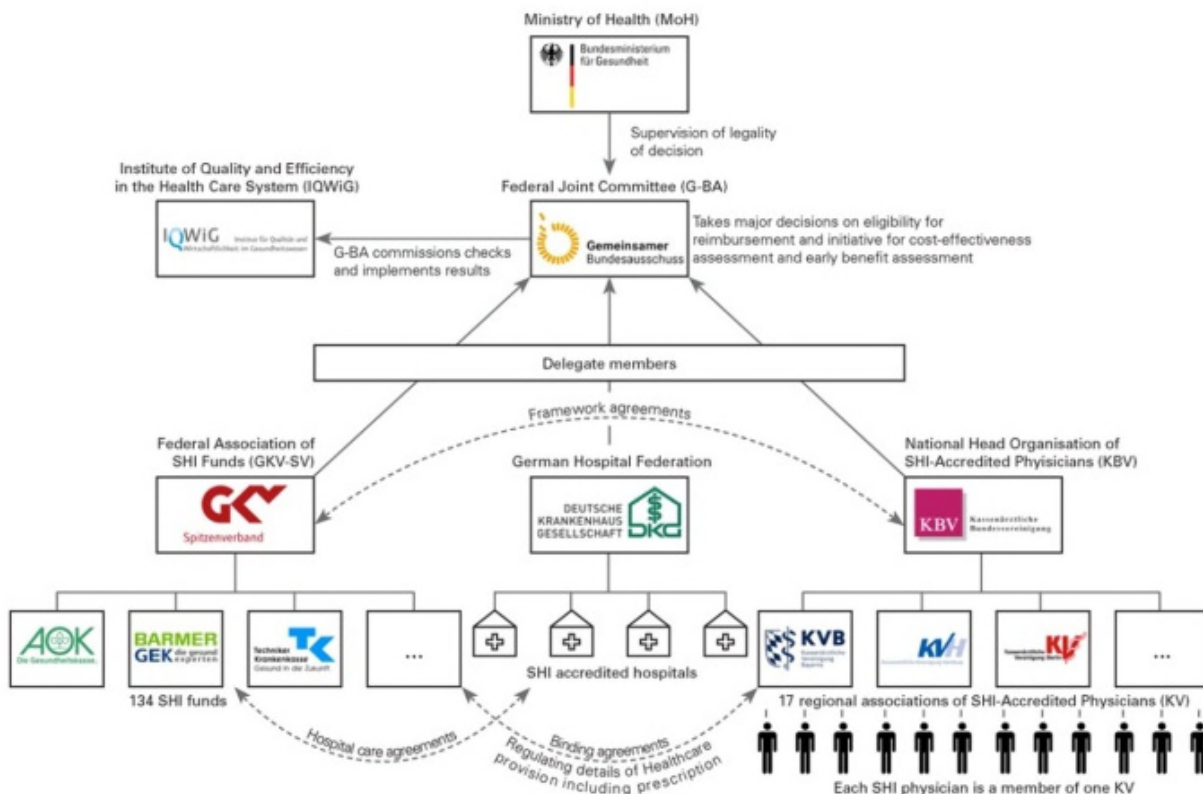
The head organisations of SHI funds, SHI-accredited physicians and hospitals form the Federal Joint Committee (*Gemeinsamer Bundesausschuss* - "G-BA"). This public body is legally vested with power to, among other things, permit or foreclose the prescription of individual or groups of pharmaceuticals and medical devices, initiate checks of their benefits and cost-effectiveness and take other major decisions which apply nationwide. The G-BA is supervised by the Ministry of Health and is – apart from the Parliament and the Ministry of Health – the key regulator for healthcare service provision as well as prescription and use of medical products and medical devices.

The G-BA is assisted by the Institute for Quality and Efficiency in the Health Care System (*Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen* - "IQWiG"). Similar to the British NICE, the IQWiG collects data on methods of medical treatment, medicinal products and medical devices, and verifies their cost-effectiveness on behalf of the G-BA. Its medical and



scientific assessments are not binding, but are often adopted by G-BA and implemented.

The following diagram shows the major players in German reimbursement:



### 3. PHARMACEUTICALS

#### 3.1 Initial price setting and price maintenance

The initial price for a medicinal product can be freely determined by the manufacturer. This price has to be notified to an agency which is responsible for the data management with regard to medicinal products in Germany. Safe for some exceptions for certain pharmaceuticals, the notified price has to be applied for every sale of the product through Germany. However, the freely determined price can only be charged for a very limited period (12 months after market launch of a product). After this period, different price control mechanisms kick in (c.f. below).

Medicinal products – though they have an official manufacturer's selling price – are allowed to be sold to hospitals at a lower price and actually prices towards hospitals are usually lower than in out-patient care. In other words, whereas rebates and discounts are not permissible for products sold to wholesalers or pharmacies, rebates and discounts granted by pharmaceutical manufacturers to hospitals are permissible.

Pharmaceuticals sold to pharmacies – in addition to the price maintenance – are subject to mandatory discounts (c.f. below).

#### 3.2 Margins in the distribution chain

The Ordinance on Drug Prices fixes the margins of wholesalers and pharmacies for prescription-only pharmaceuticals. As a result of such fixed margins, the retail price for every pharmaceutical is predetermined by the set manufacturer's price which will be increased by the fixed wholesale margin and the fixed pharmacy margin. So, the price for every prescription-only pharmaceutical is the same in every pharmacy in Germany.

Prices are calculated as follows (all excl. VAT):

(Initially) freely set price exfactory	€100.00
+ Wholesale margin	€3.85 (3,15% per package, however maximum €37.80 plus €0.70 per package as a fixed additional charge)
+ Pharmacist margin	€11.86 (€8.35 lump sum + €0.16 lump sum + €3.12 (that is 3% of the wholesale price))
<hr/>	
Retail price (excl. VAT)	€115.53

According to recent case law these fixed margins apply also to deliveries made to Germany by mail-order pharmacies located outside of Germany. Margins for pharmaceuticals which have been subject to the early benefit assessment are calculated based on the reimbursement price (see 3.4 below).

For special drugs whose use requires a high degree of preparation work in the pharmacy, for example formulations in the oncology sector, pharmacists receive compensation as individually agreed with SHI funds. Also special charges apply for repacking or mixing of pharmaceuticals by pharmacists.

### 3.3 Reimbursement of drugs dispensed by pharmacies and used in in-patient care

So, generally a manufacturer of a medicinal product applies the notified manufacturer's price when selling a product to the customer (i.e. the wholesalers). The wholesalers sell the products to pharmacies with a mark-up reflecting the fixed wholesale margin. Pharmacies dispense the product to patients with an additional mark-up reflecting the fixed pharmacist margin.

Pharmacies out in the field are reimbursed for such dispensing either directly by way of receiving the retail price from the patient or by way of reimbursement by a public sick fund.

In case a patient is not insured by a public sick fund (self-pay) the patient pays the retail price for a product to the pharmacist. Such patient, if insured by a private sick fund, will seek reimbursement of the moneys spent from its private sick funds.

In case a patient is insured by a statutory health insurance fund (which mandatorily is the case for 90 % of the German population) the pharmacist will dispense the product without receiving the retail price from the patient, but will seek reimbursement from the very SHI fund which insured this very patient. However, the pharmacist will not be able to claim reimbursement of the entire retail price for a pharmaceutical. For mainly all pharmaceuticals which are not grouped in reference prices groups (c.f. below) mandatory discounts are deducted from the pharmacists reimbursement claim against a public sick fund:

Manufacturers discount	7% on ex-factory price for SHI and private health insurance fund (6% on ex-factory price in case of generic drugs)
Generic's discount	10% on ex-factory price for SHI and private health funds
Pharmacist's discount	€1.80 (to be granted by pharmacists out of their margin to SHI funds)

As can be seen above, there is a mandatory manufacturer's discount in force at 7% on ex-factory price. Until 31 December 2013, the law provided for a mandatory manufacturer's discount at even 16%. Additionally, a price freeze rebate is in force: If a manufacturer increases the price for a pharmaceutical compared to the price level at a certain date in the past, the amount of the mark-up has to be paid as an additional discount to the sick funds. This effectively leads to a price moratorium since any price increase will not go in the pocket of the manufacturer but in the pocket of the sick funds. This price freeze was expected to cease to be in force as of 31 December 2013, but has been 31 December 2017.

As said, these discounts do not affect the retail price. In case a pharmaceutical eventually goes to a publicly insured patient, they are deducted from the pharmacists reimbursement claim against a public sick fund. The pharmacists have to bear the pharmacists' discount, whereas the pharmacist will claim back from pharmaceutical manufacturers the manufacturers' discount, the generics discount and the price moratorium discount (as far as applicable). In case a pharmaceutical eventually goes to a privately insured patient the applicable manufacturers' discounts have to be paid to the private sick funds which reimbursed the patient.

Thus, although a manufacturer will, for example, initially receive € 100 for a pharmaceutical when selling it to a wholesaler, it will somewhat later have to pay a discount to a pharmacy, for example the manufacturers' discounts and, thus, eventually receiving only €93 from such sale.

#### Pharmaceuticals used in hospitals

With regard to reimbursement for pharmaceuticals used in hospital, the following applies: SHI funds reimburse hospitals treating SHI insured patients by way of lump sums for overall treatment depending on the type of disease (Diagnosis Related Groups - DRG). Thus, the costs of pharmaceuticals applied in a hospital usually have to be covered by the DRG lump sum which the hospital receives for the entire treatment of the patient. Certain very expensive drugs are reimbursed by sick funds separately by way of supplementary reimbursement (*Zusatzentgelte* – ZE).

#### **3.4 Benefit assessment for New Pharmaceuticals**

Once a drug is authorised, such product is, in general and within its indications, immediately eligible for reimbursement by sick funds. However, recent developments tend to put further pressure on the reimbursement of patented innovative medicinal products which are placed on the market for the first time.

Pharmaceuticals are classified into prescription-only (Rx), pharmacy-only and over-the-counter ("OTC") products. The first two categories may only be dispensed to patients by pharmacies.

Formerly, pharmaceutical manufacturers were allowed to freely set the manufacturer's selling price and this applied for the lifetime of a medicinal product; the manufacturer was certainly also allowed to change the price in its free discretion. The Act on the Reorganisation of the Pharmaceutical Market 2011 (referred to as AMNOG, c.f. above) still allows initial free pricing but after an initial period of 12 month after launch, the AMNOG introduces a so-called reimbursement price for pharmaceuticals with new active ingredients; the reimbursement price is negotiated on the basis of an early assessment of the additional benefit a product brings to the patient compared to existing products or therapies.

#### Early benefit assessment – Section 35a SGB V

Under AMNOG, the price of an innovative pharmaceutical is based on the additional benefit that it demonstrated over comparable therapies. The comparable therapy is a therapy which is considered as an appropriate and efficient therapy and is determined for each indication of the product under assessment. The additional benefit is assessed by the G-BA.

The early benefit assessment process applies to pharmaceuticals which are placed on the German market which contain a new active substance. Also products which have been placed on the German market for the first time after 1 January 2011 and which obtain a line extension after this date will be mandatorily assessed. The same applies to a product with new line extensions which have been placed on the German market for the first time prior to 1 January 2011 but were since then already assessed by the G-BA in its initial indications.

For the mandatory benefit assessment, the manufacturer has to submit a dossier – without being requested to do so by the G-BA – at the latest in the moment of placing the pharmaceutical on the market or receiving the line extension.

Afterwards, the G-BA evaluates the submitted pharmaceutical or, rather, assigns the evaluation to the Institute for Quality and Cost-effectiveness in the Healthcare Sector (IQWiG). The IQWiG evaluation must be completed and the results published within three months. Subsequently, there is an advisory procedure under which the G-BA has to hear comments from the manufacturer concerned and other specialists from the health sector. The G-BA takes a final decision within three months of the results being published. With this decision, the G-BA determines whether an innovative pharmaceutical has an additional benefit or not and specifies the degree of this additional benefit. Please note that neither the evaluation of the benefit nor the decision of the G-BA determining the benefit is immediately contestable in court, but only very much later (c.f. under Price negotiations.)

#### Orphan Drugs

Orphan drugs are also subject to the early benefit assessment. However, they do not have to undergo the benefit assessment and the expensive dossier drafting as long as the sales for such product in the out-patient SHI market do not exceed 50 million € during a 12 months period. There is a presumption that orphan drugs do have an additional benefit and only the degree of their additional benefit has to be proven. This requires submitting only a scaled down version of the dossier and benchmarking the benefit of the orphan drug against the comparator from the pivotal phase III study. If the 50 million € threshold is exceeded the additional benefit has to be proven by way of submitting a full dossier.

### Price negotiations – Section 130b SGB V

After the decision of the G-BA on the benefit of a product was submitted, there are mainly two possible scenarios: If the manufacturer was not able to demonstrate that its product has an additional benefit, it will be allocated into a group of comparable substances within Germany's reference price scheme (c.f. 3.5 re Reimbursement Caps). This decision is not immediately contestable either. Where there is no reference price group, the company has to enter into negotiations on the reimbursement price with the GKV-SV. The reimbursement price in this case may however not be negotiated at a higher level than annual price of the appropriate comparator therapy (which the G-BA in its decision has found to be not inferior to the pharmaceutical assessed). This price level can be quite painful for the manufacturer of a newly developed pharmaceutical, since the comparator therapy may be a low priced generic. Certainly, a manufacturer may pull the product off the German market if the negotiated price is too low. Though this may also be a quite painful decision it may be best to protect the selling price in other European and ex-European markets. This is because more than 20 countries directly or indirectly make reference to the German prices of pharmaceuticals for their price determination.

If the manufacturer was able to demonstrate an additional benefit of its pharmaceutical, it has to enter into negotiations with the GKV-SV as well. The reimbursement price will be negotiated on the basis of the assessment and the degree of additional benefit. The prices which have been negotiated so far vary widely. However, it is clear that the early benefit assessment for innovative pharmaceuticals is a governmental means to curb costs of the SHI.

If the parties do not agree on a reimbursement price within six months after the publication of the G-BA's decision on the benefit assessment, the reimbursement price will be fixed by an arbitration body. Only this decision (and then impliedly also the G-BA decision on the amount of benefit of a product) can be challenged by a manufacturer.

### **3.5 Reimbursement caps (Reference Pricing) – Section 35 SGB V**

A substantial number of pharmaceuticals (approx. 75% of effected prescriptions<sup>4</sup>) are subject to a fixed reference price scheme (*Festbeträge*). These reference prices are basically reimbursement caps determined by the G-BA and the Federal Association of SHI funds for groups of similar or therapeutically comparable sub-

stances. The commercial result of a pharmaceutical being included into a reference price group is that SHI funds reimburse only the reimbursement cap which is to be determined for each product in this group based on a mathematical algorithm. If a product costs more than this cap (i.e. the manufacturer not being willing to cut the price to the level of the reimbursement cap), the exceeding amount has to be paid for by the patient. In the likely event a patient does not wish to make any out-of-pocket payment, he/she may choose to be served with another medicinal product of the same therapeutic value which is fully reimbursed by his/her SHI fund. Because patients are reluctant to make additional payments, pharmaceutical companies in general demand prices above reimbursement caps only for few medicinal products.

Reference price groups are widely established for generic products. Patented substances are affected by reimbursement caps, if there are three or more therapeutic alternatives (mainly in a group of substance on ATC level 4). SHI funds try to benchmark patented medicines against molecules that are already available as generics. Innovative pharmaceuticals, whose mode of action is new and which bring a therapeutic improvement by proven higher efficacy or reduced side effects, are exempt from the scheme. The fixed price is calculated – very roughly speaking – by the SHI as the average of the prices of all the pharmaceuticals contained in the relevant group.

### **3.6 Import quotas – Section 129 SGB V**

Subject to the EU doctrine of free trade within the EU, importers are free to buy a pharmaceutical for a cheap price in another EU member state and sell it in Germany at a higher price. SGB V encourages such parallel imports. Pharmacists when dispensing pharmaceuticals are obliged to replace domestic pharmaceuticals with respective parallel imports, if they cost at least 15% or €15 less than the equivalent original products sourced in Germany. However, dispensing parallel imports can be prevented by domestic pharmaceutical entrepreneurs by the means of individual rebate contracts with SHI funds (see 3.8 below).

### **3.7 Generic substitution (*aut-idem*) – Section 129 SGB V**

Physicians are invited to prescribe the generic name of an active ingredient (the international non-proprietary name - "INN"), although they are not precluded from prescribing a brand. If several generic versions of a prescribed active pharmaceutical ingredient ("API") are available, pharmacists are legally obliged to dispense a generic version. However, if a pharmaceutical containing the prescribed API is subject to a contractual rebate agreement between an SHI fund and the marketing

<sup>4</sup> <http://www.bmg.bund.de/krankenversicherung/arzneimittelversorgung/wie-arzneimittelpreise-entstehen.html>  
(source of the Federal Ministry of Health).

authorisation holder, pharmacists are obliged to dispense the rebated pharmaceutical.

### 3.8 Rebate contracts – Section 130a SGB V

In addition to the mandatory discounts (c.f. 3.3) manufacturers are invited to grant contractual rebates to individual SHI funds.

In 2012, rebate contracts covered 65% of all distributed patent-free pharmaceuticals<sup>5</sup>. Usually, SHI funds invite all manufacturers of generic substances to participate in tender procedures. The manufacturer being awarded with the supply contract will have exclusive supply for all patients of this very SHI fund; sometimes the exclusive supply is only granted for a specific region and in another region another manufacturer will be granted exclusivity. This means pharmacies have to dispense exclusively pharmaceuticals for which rebate agreements have been concluded. Tender law applies.

For innovative substances the above system of tendering and granting exclusivity does not apply (except for certain vaccines). However, the law gives various incentives mainly for manufacturers of patented substance to voluntarily enter into rebate agreements. For example, pharmacists are obliged to preferentially dispense rebated pharmaceuticals if available instead of non-rebated alternatives. Drugs subject to rebate contracts are to a certain extent exempt from the cost-effectiveness test that physicians regularly undergo regarding their drug issuing prescriptions (see below 3.9). In issuing prescriptions, physicians use certified computer programmes displaying information on rebate contracts of all SHI funds. Finally, patients can be exempted from the personal out-of-pocket payments in respect of rebated pharmaceuticals.

Rebates may only be granted to SHI funds, other social insurance funds and private insurers, but – as mentioned above – not to wholesalers or pharmacies.

### 3.9 Personal budgets for physicians – Section 84 SGB V

Each physician has a personal budget for prescriptions of pharmaceuticals (*Richtgrößenvolumen*). It is calculated on the basis of an average value per patient (benchmark value) multiplied by the number of patients. Performance is controlled by quasi-public bodies. Physicians exceeding this sum by more than 15% are subject to an official inquiry and an obligatory consultation process. Physicians exceeding this sum by more than 25% are liable to pay damages to the respective SHI fund.

### 3.10 Prescription quotas, "me-too" – and generics-quotas – Section 84 SGB V

Top selling groups of pharmaceuticals are subject to quotas which are quite often agreed jointly by physicians and SHI funds on a regional level. The achievement of a quota by an individual physician is incentivized by certain benefits granted to a physician (e.g. a monthly lump payment) or by establishing sanctions for physicians in cases of non-compliance (service fee reductions). In some regions manufacturers are able to obtain an opt out of the quota system for a pharmaceutical by entering into rebate contracts with single SHI funds. A quota may for example be a so-called me-too quote: For example, the SHI fund AOK Northrhine publishes a list of pharmaceuticals which it considers me-too product and – by way of an agreement with the regional association of SHI accredited physicians – imposes on general practitioners the obligation to only prescribe the listed products at a maximum in 3.9% of the value of all prescription.

Moreover, in some regions physicians are obliged to prescribe generics above a certain threshold and not to undercut the threshold. For example a general practitioner in the region of North Rhine is requested to prescribe at least 90.5 % of all prescription issued by this practitioner. Another quote is the DDD quote: Top selling groups of pharmaceuticals are subject to quotas jointly agreed by physicians and SHI funds. Physicians have to prescribe certain recommended API within these groups instead of other API. For example, simvastatin has to make up 90% of all statin prescriptions, with all other statins sharing the remaining 10%.

A physician missing these levels may be obligated to attend prescription courses teaching economic prescribing or eventually be liable to pay damages to the regional SHI funds.

### 3.11 Prescription restrictions and prescription guidelines – Section 92 SGB V

The Federal Joint Committee can issue advice on the cost-effectiveness of individual pharmaceuticals or preclude them from prescription for certain indications. Physicians disregarding the advice risk paying damages to SHI funds. Moreover, SHI funds inform physicians about therapeutic alternatives and their respective prices.

<sup>5</sup> <http://www.bmg.bund.de/krankenversicherung/arzneimittelversorgung/wie-arzneimittelpreise-entstehen.html>  
(source of the Federal Ministry of Health).

### 3.12 Off-label use

Pharmaceuticals prescribed for off-label use are, in principle, not reimbursable. However, if (1) the drug aims at curing or alleviating a life threatening disease, (2) there is no authorised drug available for this indication or patient, (3) scientific data indicate good prospects of success and (4) the risk/benefit balance is positive, then the drug will be reimbursable.

### 3.13 Non-Rx drugs, lifestyle drugs and other non-reimbursable products – Section 34 SGB V

Except for children and disabled adults, non-Rx pharmaceuticals are not reimbursable by SHI funds. Patients have to pay for such pharmaceuticals themselves. However, the Federal Joint Committee has listed indications where treatment with specific non-prescription pharmaceuticals is considered reimbursable. Pharmaceutical entrepreneurs may apply for a drug to be put on that list.

Pharmaceuticals only improving private lifestyle, for example, treating non-pathological obesity or erectile dysfunction, are not reimbursable, whereby exceptions may apply.

Moreover, the Ministry of Health has drawn up a list of APIs which are considered as "unnecessary" for reaching the intended medical goals and thus are not reimbursable. Drugs combining these APIs in a way described in the Ordinance on Inefficient Pharmaceuticals (*Verordnung über unwirtschaftliche Arzneimittel*) are barred from reimbursement.

### 3.14 Out-of-pocket payments to patients - Section 31 SGB V

Each SHI-insured person is required to pay a fixed amount for each prescription, currently between €5 and €10 but not more than the price of the pharmaceutical. Pharmaceuticals can be exempted from this patient contribution if their price is at least 30% below the fixed reimbursement cap.

## 4. MEDICAL DEVICES

### 4.1 Supply and reimbursement of Medical Devices

The market place for medical devices is differentiated depending on the kind of device.

#### (a) Devices used directly by or for out-patient care

Medical devices substituting or supporting natural bodily functions and complying with the marketing requirements of the Medical Devices Act, (for example, the requirement that such devices have a CE mark) are, in principle, eligible for prescription and reimbursement.

However, several medical devices are generally exempt from any reimbursement.

For devices which are used by or for patients (for example, wheelchairs, ostomy or incontinence products, etc.) there are specialised retailers or healthcare service providers who use or supply the respective device, e.g. pharmacies, medical supply stores, home care service providers, opticians, hearing aid technicians or medical supply stores or homecare service providers. Manufacturers sell their products to those intermediaries permitted to supply the patient with the device upon a physician's prescription. In principle, pricing is not regulated and rebates are permissible. However, reimbursement by sick funds (which greatly determines the manufacturer price) is subject to reference price schedules and contractual agreements with SHI funds (see 4.7 below).

Reimbursement of medical devices used by or for patients, in general, depends on such products being listed in the medical technical aids reimbursement list (*Hilfsmittelverzeichnis*). Products are initially listed or adjusted at the request of the manufacturer (or by third parties authorized by them). The listing takes into account the relevant statutory requirements imposed by the Federal Association of SHI funds (GKV-SV). The products available on the market are classified according to their applications different product groups. The list provides quite comprehensive information on the performance, the type and quality of products available as well as the requirement for the prescription. Each category contains a breakdown and a definition with high legal notices and a list of indications that justify a supply. It is continuously updated.

The medical technical aids reimbursement list is not binding in a legal sense, i.e. also products which are not listed can be reimbursable. However, manufacturers seek listing their products to facilitate broader and easier reimbursement for their products. As said, the list contains the minimum quality requirements for each product group and related service requirements. These requirements are referenced in contracts which the sick funds conclude with healthcare providers such as pharmacies, medical supply stores, home care service providers and, thus, have to be abided by when a medical device which is listed or belongs to a specific product category is applied or used for a patient.

The preconditions for the listing of a device in the medical technical aids reimbursement list are mainly: the efficacy/functionality of the product, its safety and the fulfilment of the already stipulated requirements for the product group to which the device belongs. If the product introduces a new diagnostic or treatment method into the German out-patient care a further precondition for the listing is that the G-BA has assessed this new

diagnostic or treatment method and has approved it for the out-patient care.

### **(b) Devices used directly for in-patient care**

Products mainly used in the in-patient care (e.g. stents, implants etc.) are sold to the hospital using these devices. The hospitals' costs for these products are not directly reimbursed by SHI funds. They are covered in the DRG lump sums which the hospitals receive for the in-patient treatment.

In contrast to out-patient care, the use of innovative new devices which represent a new diagnostic or treatment method in in-patient care does not require the prior approval of the G-BA. Thus, new diagnostic or treatment method (which may involve using an innovative medical device) can be done in hospitals and such in-patient care is generally reimbursable, though the administrative hurdles to obtain reimbursement coding and a reimbursement agreement are troublesome for hospitals. However, if the G-BA establishes that the new method is not effective, not safe, not necessary or not commercially viable, the G-BA can exclude the method from reimbursement in the SHI.

### **(c) Devices in reimbursement test period for in-patient or out-patient care**

As just mentioned above, the G-BA is entitled to decide upon the application and reimbursement of new diagnostic or therapeutic methods (which often involve the use of an innovative medical device). Simply speaking, in out-patient care the application of a new diagnostic or treatment method can only be done and is only reimbursed (some exceptions apply), if the G-BA has explicitly approved the new method; whereas in in-patient care the new method can be applied and is reimbursed as long as the G-BA has not explicitly excluded the method from reimbursement. There may be the situation that the G-BA has not yet sufficient data to decide whether a new method/ a device is effective, safe, necessary and commercially viable and, thus, not in a position to decide upon the reimbursement of the same. In this situation a rather new reimbursement test procedure was implemented: Subject to this procedure the G-BA can allow the application of the new method in hospitals and/or out in the field for a test phase. The services rendered by hospitals, physicians and other healthcare service providers will be reimbursed subject to reimbursement agreements concluded between the service providers and SHI funds. The test phase will be accompanied by a scientific body.

If the new method is mainly based on the use of a medical device, the reimbursement test phase can only be implemented by the G-BA, if the manufacturer of the

respective medical device is obliging itself to contribute to the costs of the test phase.

The reimbursement test procedure is still quite new and it has to be seen how it will be applied in the future.

### **(d) Devices used as a means for diagnosis or treatment**

Other medical devices which are intended to be used by healthcare providers as a mere means to diagnose or treat patients (e.g. an MRT) are simply sold by device manufacturers or their distributors to physicians, hospitals or other healthcare providers. Such long-term investment goods are paid for by physicians and hospitals and are not reimbursed. However, SHI funds reimburse such healthcare providers treating SHI insured patients for their services. The costs of the providers for the purchase and maintenance of medical devices used within such service rendering need to be amortized by the service fee (in hospitals, the DRG lump sum).

## **4.2 Medical necessity for certain aims – Section 34 SGB V**

In order to qualify for prescription, any medical device must be medically necessary to ensure the success of a medical treatment, to compensate for an impairment, to remedy a weakness supposedly leading to a disease, to ensure the healthy development of a child or to prevent the need for permanent care. Devices not serving one of these goals are not eligible for reimbursement. Moreover, the Ministry of Health has drawn up a list of medical devices which are excluded from reimbursement, because they are considered as being of little therapeutic benefit or low value (for example, eye patches).<sup>6</sup>

## **4.3 Prescription of devices listed in the medical technical aids reimbursement list (Hilfsmittelverzeichnis)**

As said, there is no positive list for reimbursable medical devices. However, the burden of proof of the necessity of a medicinal product is shifted from the patient (and prescribing physician) to the SHIs if a medical device is included in the medical technical aids reimbursement list (*Hilfsmittelverzeichnis*).

## **4.4 Reimbursement caps – Section 36 SGB V**

A substantial number of medical devices substituting natural bodily functions are subject to a fixed reference price scheme (*Festbeträge*). The associations of SHI funds classify comparable devices and set a fixed amount to be reimbursed by SHI funds. Sums exceed-

<sup>6</sup> Ordinance on medical devices of little therapeutic benefit or low value (*Verordnung über Hilfsmittel von geringem therapeutischen Nutzen oder geringem Abgabepreis*).

ing this amount have to be paid for by the patients themselves.

#### 4.5 Advice on prescription of medical devices – Section 92 SGB V

The G-BA has issued detailed binding advice on the prescription of selected medical devices such as artificial limbs, orthopaedic equipment or vision aids. Physicians disregarding the advice risk paying damages to SHI funds.

#### 4.6 Drug-device combinations – Section 31 SGB V

Since 1 July 2008, combination products, which primarily consist of drug substances and which are regulated as medicinal products, are no longer reimbursed by SHI funds unless they are on the list of reimbursable products drawn up by the G-BA. This applies mainly for substances and solutions which do not have a pharmacological but rather physical mode of action, e.g. solutions for the irrigation of wounds or operation areas. To be eligible for reimbursement these "pharmaceutical-like" devices – defined as such by Section 3 of the Medical Devices Act – will have to meet certain criteria. If the G-BA has not automatically added a product to the list, the manufacturer may apply for the product to be included. The decision and justifications for inclusion or otherwise on the list may be contested in court.

#### 4.7 Contracts on provision of medical devices and public tenders – Section 126 SGB V

SHI funds conclude contracts with service providers (e.g. homecare companies) on the provision of healthcare services which entail the supply, use or application of medical devices. For comparable services and related devices used when rendering these services, the contracts contain detailed provisions on prices and quality requirements etc. Such contracts are subject to public tender procedures if, within such a contract, the service provider is retained by a SHI fund on an exclusive basis. If there is no exclusive retaining foreseen in a contract the public tender procedures are not applied since other healthcare providers may also enter into similar contract with the respective SHI funds and, thus, will also be allowed to render healthcare services for the patients of this very SHI fund based on such contracts. Healthcare providers which do not have any contract with the SHI fund are generally not entitled to render healthcare services (and supply, use or apply medical devices) to the patients of such SHI fund. However, recent judgements confirm the patients' right to procure a necessary medical device themselves and have it reimbursed by the respective SHI if the product supplied by the service provider, for which the patient's SHI concluded a contract, does not prove to be sufficient, appropriate or functional.

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# France

## 1. SUMMARY

- The French statutory public health insurance called *Assurance Maladie* pays, under certain conditions, for healthcare products and is complemented by private health insurance which is subscribed by the majority of the population.
- There are two key markets for distribution of pharmaceuticals: the pharmacy market (out-patients) and the hospital market (in-patients).
  - On the out-patients market, prescription only drugs are the only drugs which may be reimbursed by the statutory health insurance. Pharmaceutical companies entering the out-patient market must choose whether to enter the reimbursable market or the non-reimbursable market. Pricing is set freely for non-reimbursed drugs. In contrast, special pricing mechanisms apply for reimbursed drugs, and margins of wholesalers and pharmacists are also regulated.
  - On the hospital market, drugs must first be admitted onto a list of drugs agreed for use in hospitals and prices are freely negotiated subject to public procurement rules.
- Various measures are laid down in order to limit medical expenses as regards pharmaceuticals, such as excluding off-label use from reimbursement, generics substitution, agreements with healthcare professionals to involve such professionals in the control of health expenses and commitments from pharmacists regarding dispensation of generics. A certain control on medical expenses is also sought via contributions awarded by pharmaceutical companies (clawback mechanism, contribution based on turnover, "safeguard clause", contribution based on promotional expenses).
- The market place for medical devices is more varied than the one for drugs, depending on the kind of device: medical devices may be sold to patients by specialised retailers or supplied to patients by intermediaries upon a physician's prescription (out-patient market); they may also be sold to health establishments (hospital market).
  - On the out-patient market, pricing is regulated only for reimbursed medical devices. In parallel to requesting admission of devices onto the list of reimbursed medical devices, companies must follow a specific procedure before the Economic Committee for Medical Products to set the public sale price of such devices. Margins made on reimbursed medical devices may also be regulated.
  - On the hospital market, devices must also be admitted onto a specific and restrictive list of medical devices, after evaluation of the device.
- There is no specific limitation as regards prescription of medical devices by authorized health professionals who can prescribe medical devices necessary for quality, security and efficiency of the care to be provided to patients. However, such freedom is controlled since healthcare professionals must comply with the strictest economy compatible with the good quality of the care to be provided to patients. As for drugs, control on medical expenses for medical devices also takes place via contributions to be awarded by medical devices companies (clawback mechanism, a contribution based on promotional expenses).

## 2. FRENCH HEALTHCARE SYSTEM: OVERVIEW

France is the second largest market in Europe for pharmaceuticals and medical devices<sup>1</sup>. In 2012, the consumption of pharmaceuticals in France slightly decreased but still reached €27.2 billion<sup>2</sup> (sales to pharmacies fell but sales to hospitals increased in 2012); use of medical devices (by turnover) reached more than €15 billion<sup>3</sup>. In 2012, turnover of generic groups (that is drug groups defined by regulations and comprising branded drugs and generics) was €5.3 billion (€2.2 billion for the branded drugs and €3.1 billion for the

<sup>1</sup> Source: LEEM, economic assessment, ed. 2013.

<sup>2</sup> Source: ANSM, drug sales analysis, July 2013; LEEM, economic assessment, ed. 2013.

<sup>3</sup> Source: Centre d'analyse stratégique, October 2013.

generics<sup>4</sup>, that is 28% of the market for reimbursed products<sup>4</sup>.

## 2.1 Major legislation

The French law on pharmaceuticals, medical devices and reimbursement is encoded in a variety of rules which are, for the most part, included in two codes: the Social Security Code (*Code de la Sécurité Sociale* - "CSS") and the Public Health Code (*Code de la Santé Publique* - "CSP"). These codes are subject to frequent amendments. For instance, every year, Parliament passes an Act on Social Security, often amending the CSS, which sets the national expenditure target for health insurance for the following year (*Objectif National d'Evolution des Dépenses d'Assurance Maladie* - "ONDAM") and contains new provisions concerning benefits and regulation. The rules set out in the above codes are accompanied by a variety of governmental decrees, binding contracts and decisions of the major players.

## 2.2 Payers – insurance funds<sup>5</sup>

Healthcare products are paid for by statutory public health insurance ("SHI") called *Assurance Maladie*, complemented by private health insurance which is subscribed for by the majority of the population. The SHI is made up of three main schemes: the general scheme, the agricultural scheme and the social scheme for independent professionals. These three schemes cover the majority of the population. Other special schemes exist for specific professions. Each of the three major insurance schemes comprises a national health insurance fund and local funds. The general scheme, covering most of the population, is managed at national level by the French National Health Insurance Fund (*Caisse Nationale de l'Assurance Maladie des Travailleurs Salariés* - "CNAMTS"). At a local level, the general scheme is managed by over 130 local funds consisting of Pension and Occupational Health Insurance Funds (*Caisse d'Assurance Retraite et de la Santé au Travail* - "CARSAT"), Local Health Insurance Funds (*Caisse Primaire d'Assurance Maladie* - "CPAM" - Metropolitan France) and general Social Security Funds (*Caisse Générale de Sécurité Sociale* - "CGSS" - overseas departments and Lozère).

## 2.3 Prescribers - physicians

Prescription only ("Rx") drugs are prescribed by qualified physicians, surgeon-dentists, midwives or podiatrist. Collective national agreements, as well as individual agreements, are in place with these health professionals to increase their involvement in the control of

health expenses. These agreements deal with various aspects of the health professionals' activities and may involve commitments from the health professionals to amend practices, such as increasing the prescription of generics with a view to limiting medical costs.

## 2.4 Decision makers – Ministry of Social Affairs and Health, HAS, CEPS and UNCAM

Various entities participate in the decision-making process in the French healthcare system. The Ministry of Social Affairs and Health (along with other ministries) is in charge of a large part of the regulation and policy of healthcare expenditure, on the basis of the framework established by the French Parliament. The key players in admitting a drug for reimbursement are the Economic Committee for Medical Products (*Comité Economique des Produits de Santé* - "CEPS"), which sets prices for drugs with the industry, and the Transparency Committee (*Commission de la Transparence*), a body of the French National Authority for Health (*Haute Autorité de Santé* - "HAS") which is in charge of the assessment of the medical benefit provided by drugs. The key players in admitting a medical device for reimbursement are CEPS, which set prices for medical devices with the industry, and the National Committee for Assessment of Medical Devices and Health Technology (*Commission Nationale de l'Evaluation des Dispositifs Médicaux et des Technologies de Santé* - "CNEDiMTS"), a body of the HAS which is in charge of assessment of medical devices and associated services. Health insurance schemes are under the supervision of the Social Security Directorate which depends on the Ministry of Social Affairs and Health and the Ministry for Economic Affairs and Finance. Another important player in this organisation is the French National Union of Health Insurance Funds (*Union Nationale des Caisses d'Assurance Maladie* - "UNCAM"), which comprises representatives from the three main health insurance schemes.

## 2.5 Pricing

### (a) Pharmaceuticals

Having obtained a marketing authorisation for its drug, a pharmaceutical company must choose the market where it will distribute the drug. The two key markets are the pharmacy market (out-patients) and the hospital market (in-patients) (the pharmaceutical company can market to both).

### (b) Pharmaceuticals for outpatient care

Pharmaceuticals are classified into Rx and over-the-counter ("OTC") products. Only Rx drugs are reimbursed by the SHI. Generally, drugs may only be dispensed to patients by pharmacies. When choosing to enter the out-patient market, a pharmaceutical company

<sup>4</sup> Source: LEEM, economic assessment, ed. 2013.

<sup>5</sup> See <http://www.ameli.fr/l-assurance-maladie/connaitre-l-assurance-maladie/getting-informed-about-health-insurance/index.php>, for presentation in English on the French health insurance organisation.

must choose whether to enter the reimbursable market or the non-reimbursable market.

For non-reimbursed drugs, pricing is set freely. For reimbursed drugs, special pricing mechanisms apply. In parallel to requesting admission of the drug onto the list of reimbursed drugs (see 2.1 below) and the rate of reimbursement (see 2.2 below), a procedure must be followed to set the price of the drug. The ex-factory price and the pharmacy retail price are both regulated.

Under this procedure, the pharmaceutical company proposes a price and justifies the reasons for that price. This is then negotiated with CEPS. The main criteria taken into account in the context of these negotiations are the improvement to medical benefit compared to other drugs, the price of other drugs for the same therapeutic application, the volume of existing or projected sales, and the foreseeable or actual conditions of use of the drug. This assessment is made with input from the Transparency Committee.

Negotiations with CEPS results in a contract which is revised each semester and which may last up to 4 years. This contract sets out the company's commitments in terms of prices of drugs (according to the volume of sales), the control of its promotional practices and its participation in the Health Ministry's global policies. The contract provides for sanctions in case of breach by the company of such commitments (for example, repayments). The contract may also provide for a price variation clause. If the company and CEPS fail to reach an agreement (which is rare), the price may be set by CEPS unilaterally.

More globally, a framework agreement governs the relationships between the industry (via the industry association LEEM) and CEPS. The current agreement was adopted on December 5, 2012 and is due to expire on 31 December 2015. This framework agreement deals with several matters relating to reimbursed products, and in particular guarantees for companies a minimum price for drugs providing enhanced medical benefit compared to other drugs for a 5 years renewable period (such minimum price is set with reference to the lowest price of the same product applied in Germany, Italy, Spain or UK). This agreement also provides for a fast-track procedure, subject to conditions (including clawback payments), for setting the price of innovative drugs.

In addition to regulated pricing, the margins of wholesalers and pharmacists are regulated. Wholesalers may apply a unique rate of 6.68% to the drug's ex-factory price to calculate margins, such margin being subject to a lower limit of €0.30 (if the calculation based on the rate of 6.68% results in an amount lower than €0.30) and to an upper limit for products which drug's ex-

factory prices are above €450.00 (the maximum margin is of €30.06). Margin of pharmacists are regulated pursuant to a regressive mark-up scheme. Under this scheme, different margin rates apply on the basis of a regressive scale applied to the drug's ex-factory price. Pharmacists dispensing generics, unless the generic is subject to TFR (see 2.3 below) or the dosage or packaging of the generic is different, benefit from the same margin as the related branded product.

The general structure of the price of a reimbursed Rx drug is as follows:

Ex-factory price exclusive of tax ("PFHT")	€100.00
+ Wholesale margin	€6.68 (6.68% of the PFHT)
+ Pharmaceutical margin	€14.22 (€0.53 per pack + (6% - 26.1% of the PFHT, depending on the PFHT))
<hr/>	
Retail price (excl. VAT)	€120.90

Discounts, rebates and other financial advantages in relation to sales of reimbursed drugs granted by wholesalers, or pharmaceutical companies selling directly to pharmacists, cannot exceed 2.5% of the ex-factory price of the drug per calendar year, per product line and per retail pharmacy. Generics, apart from those subject to TFR (see 2.3 below), may benefit from discounts of up to 17% of the PFHT.

### (c) Pharmaceuticals sold to hospitals

Drugs sold to hospitals must first be admitted onto a list of drugs agreed for use in hospitals. Once the drug is on the list, prices are freely negotiated subject to public procurement rules (if applicable).

### (d) Medical devices

The market place for medical devices is more varied than that for drugs, depending on the kind of device. For some devices there are specialised retailers, like opticians, hearing aid technicians or homecare service providers. Medical device companies sell their products to intermediaries entitled to supply the patient with the device upon a physician's prescription.

### (e) Medical devices for outpatient care

The pricing (tariff) for medical devices is only regulated for reimbursed medical devices. Similar to the mechanism for setting the price of drugs, medical device companies must, in parallel to requesting admission of the device onto the list of reimbursed medical devices (*Liste*

*des Produits et des Prestations remboursables* - "LPP"), follow a procedure before CEPS to set the price at which the device is sold to the public. The main criteria taken into account in the context of these negotiations are the improvement to medical benefit compared to other medical devices, the price of the device compared to other medical devices, the volume of projected sales and the foreseeable or actual conditions of use of the medical device. This assessment is made with input from the CNEDiMTS. The price is negotiated with CEPS. If the medical device company and CEPS fail to reach an agreement, the price may be set by CEPS unilaterally.

CEPS may also enter into agreements with medical device companies which may provide for sales volumes, relevant prices and specific discounts on the turnover made in France. Within this framework, the medical device companies may grant to the SHI the benefit of the discounts (see 3.6 below).

In addition to regulated prices, margins may also be regulated by way of an order issued by the Ministry of Social Affairs and Health.

#### **(f) Medical devices sold to health establishments**

Medical devices sold to health establishments must also be admitted onto a specific and restrictive list of medical devices, established by the Ministry of Health and the Ministry of Social Security, after the CNEDiMTS has evaluated the device.

### **3. PRESCRIPTION AND REIMBURSEMENT OF PHARMACEUTICALS**

Only Rx drugs may be reimbursed, but the process for reimbursement is not automatic. To qualify, the drug must be added to the list of reimbursed drugs and be prescribed in accordance with applicable law. Even if the drug is placed on the reimbursement list, French law provides for several mechanisms to limit the expense to the SHI.

#### **3.1 General conditions for a pharmaceutical to be reimbursed**

A threefold procedure applies to adding a drug onto the list of reimbursed drugs. To determine eligibility, the drug is subject to a scientific review by the Transparency Committee to verify whether the drug provides a medical benefit (*Service Médical Rendu* - "SMR") which makes it eligible for reimbursement. In parallel, the pharmaceutical company negotiates the price of the drug (see 16.5(b) above) and requests a rate of reimbursement (see 17.2 below).

If there is no SMR, or if there is no improvement in the SMR (*Amélioration du Service Médical Rendu* - "ASMR") in relation to other existing drugs or no sav-

ings in the cost of treatment, the drug cannot be reimbursed. If there is SMR, then an SMR rating is granted to the drug (for example, major, moderate, low) together with a rating in terms of ASMR (for example, major therapeutic improvement, moderate improvement in terms of therapeutic efficacy and/or reduction of undesirable side effects). The assessment of the SMR is made taking into account various factors (for example, the risk/benefit ratio of the drug, the seriousness of the disease it intends to cure or positioning in the treatment strategy).

The registration of the drug on the list of reimbursed drugs is valid for a period of 5 years, which is renewable subject to reassessment of the SMR for the drug.

#### **3.2 Setting the rate of reimbursement and co-payment**

The SHI normally covers only a proportion of the total cost of treatment. The rest is owed by the patient and is equivalent to a statutory co-payment. The UNCAM sets the proportion of co-payment payable by the patient, called the *ticket modérateur*, and thus indirectly sets the reimbursement rate. The reimbursement rate varies depending on the drug, notably its level of SMR. The usual reimbursement rate applicable is 65% (for a drug with a major SMR), which may be lower for drugs with low (15%) or moderate (30%) SMR. Full reimbursement rates may apply in certain circumstances (for example, for life-threatening diseases with a major SMR). Specific rules apply for drugs subject to TFR (see 2.3 below).

Often, the main objective for a pharmaceutical company is to have its drug listed as reimbursed. Owing to the fact that the majority of patients have complementary voluntary health insurance policies which cover part or whole of the difference between the reimbursed amount and the actual sale price, the variation of the rate of reimbursement is not always the key issue.

#### **3.3 Reimbursement of generics and the reference price system**

Generics may be added onto the list of reimbursed products more quickly than branded drugs since no opinion is required from the Transparency Committee. A special regime has been established for generic groups (that is a branded pharmaceutical and its generics) where the relevant generics have difficulty penetrating the market. Reimbursement of the drugs included in such groups is based on a reference price (*Tarif Forfaitaire de Responsabilité* - "TFR") and not the price effectively paid by the patient. The reference price is set by CEPS, and corresponds to the average price of the generics (which is less than the price of the branded drug) of the relevant group.

### **3.4 Reimbursement of pharmaceuticals subject to a temporary use authorisation (*Autorisation Temporaire d'Utilisation* - "ATU")**

The price of an ATU drug (for example, a drug supplied on a named patient basis), which is only available in hospitals and clinics, is set freely and is subject to a declaration by the pharmaceutical company to CEPS. That price is fully reimbursed. The pharmaceutical company may be required to repay turnover to authorities if the price declared is higher than the subsequent price obtained for the drug under the standard price setting procedure (once the drug has obtained a standard marketing authorisation).

### **3.5 Measures aimed at patients to limit medical expenses**

#### **(a) Out-of-pocket payments**

Several out-of-pocket payments apply, seeking to place part of the cost on the patient with the aim of increasing individual responsibility and awareness of health expenditure. Notably, these include a €1 deductible applicable to consultations with physicians and other medical acts and, since 2008, a deductible specifically applicable to drugs (50 cents per packaging unit). The out-of-pocket payments are subject to exceptions, exemptions and limitations.

#### **(b) Coordinated treatment pathway**

Patients must choose a treating physician and declare him to the health insurance. This physician acts as a gatekeeper for further (specialist) care. If the patient fails to declare or call upon the treating physician for initial consultation, his co-payment is, subject to certain limitations and exceptions, increased by 40%.

#### **(c) Limitations to the direct payment system**

Patients may benefit from a direct payment system (*tiers payant*) under which the SHI pays the provider directly and the patient is exempt from making payment. Since 2007, this system is subject to the patient accepting a generic instead of the branded drug (exceptions apply). If the patient refuses the generic, he is not entitled to benefit from the direct payment system and must pay for the drug and request reimbursement (see also 2.6(d) below on commitments from pharmacists).

### **3.6 Measures aimed at health professionals to limit medical expenses**

#### **(a) Off-label use**

The drug must be prescribed in accordance with the rules applicable to prescription of reimbursed drugs, including prescribing the drug within the indications specified for the drug to be reimbursed.

#### **(b) Generics substitution**

Generic substitution must be proposed by pharmacists to patients, except if the physician forbids such substitution. Substitution is promoted via higher margins (see 1.5(b) above). Substitution cannot lead to higher cost for the SHI, and pharmacists may be required to take over the amount corresponding to the additional costs resulting from non-substitution cases.

#### **(c) Agreements with health professionals**

Physicians do not have a personal budget. However, a three-level contractual scheme has been established to increase the involvement of health professionals in the control of health expenses. At the first level, a national framework agreement has been signed between the UNCAM and health professional unions, dealing with general matters such as the better coordination of healthcare. At the second level, collective agreements have been signed between the SHI and specific categories of health professionals, defining collective and individual obligations relating to the evolution of the activities of the health professionals. At the third level, the possibility to conclude individual agreements was recast in the national agreement for general practitioners and specialised doctors (convention médicale) concluded on July 26, 2011 which sets up a performance compensation system for physicians based on indicators such as clinical practice, prevention, public health, efficiency of prescription, quality of service and organization of the office practice. Physicians who sign this agreement undertake to provide to the UNCAM additional information necessary to determine the amount of the compensation based on performance.

#### **(d) Commitments from pharmacists**

UNCAM has signed in 2012 an agreement on annual targets (subject to annual amendments) regarding dispensation of generics not subject to TFR with representatives of the pharmacist unions. Where such targets are reached in a département (an administrative division of France), the pharmacists in that département are not obliged to provide a generic for the insured to be able to benefit from the direct payment system (see 2.5(c) above).

### (e) Visits by SHI representatives

Representatives of SHI (*Délégués d'Assurance Maladie* - "DAM") visit health professionals. The DAMs seek to inform the health professionals on various topics, such as generic substitution, overprescription or targets under the individual agreements entered into by the health professionals.

### 3.7 Control on medical expenses via contributions

Pharmaceutical companies selling reimbursed products, or products sold to hospitals, are subject to specific contributions set out below (several other specific contributions and taxes apply to businesses in the pharmaceutical sector).

#### (a) Clawback mechanism

Pharmaceutical companies are subject to a clawback mechanism if their turnover increases faster than a predetermined rate. Different mechanisms apply depending on whether the pharmaceutical company has taken commitments regarding progression of its turnover with CEPS.

#### (b) Contribution based on turnover

Pharmaceutical companies are subject to a specific contribution equivalent for 2013 and 2014 to 1.6% on reimbursed drugs.

Contribution so-called "safeguard clause"

If the turnover made in France during a year by pharmaceutical companies for Rx drugs increased compared to the previous year, of a percentage higher than the ONDAM growth rate (so-called "K rate"), marketing pharmaceuticals are subject to a specific contribution. The "K rate" for 2013 is 0.4%.

#### (c) Contribution based on promotional expenses

Pharmaceutical companies must pay a contribution based on a ratio between their promotional expenses (for example, remuneration of sales reps and advertising costs) and their turnover on reimbursed drugs. Subject to certain conditions, this tax is due when the turnover on such products in France exceeds €15 million.

## 4. PRESCRIPTION AND REIMBURSEMENT OF MEDICAL DEVICES

In principle, individual medical devices complying with the marketing requirements under French law (for example, CE mark) are not automatically eligible for reimbursement and have to have been previously registered on a list.

### 4.1 Eligible devices and prescription

Medical devices may be registered on a list to be reimbursed if they are prescribed by physicians or other authorised health professionals, such prescription not exceeding 12 months and mentioning information regarding its effective implementation.

Most medical devices may only be delivered to patients even though they are not prescribed by physicians or other authorised health professionals, although some devices may only be provided to patients upon a physician's prescription. There is no specific list of such devices as this is regulated on a case by case basis under French law. However, such devices may include contraceptive devices, injection syringes, hearing aids and contact lenses. Certain in vitro medical devices registered on a list adopted by the Ministry of Health, on the basis of a proposal from the Director of the National Health Agency (*Agence Nationale de Sécurité du Médicament et des Produits de Santé* - "ANSM") may only be delivered to patients subject to a physician's prescription.

### 4.2 List of eligible devices

In principle, to be reimbursed, medical devices must be registered onto the LLP, which is established by the Ministry of Social Security and Ministry of Health (some medical devices not included in the LPPR can be reimbursed in particular circumstances, for example: innovative medical devices, ATU medical devices). The registration on the LPP is made either through a generic description of the device without mentioning the brand or company name, or through the brand or the trade name of the device when such device is of an innovative nature or requires specific monitoring.

A medical device may be added on the LPP if it provides a medical benefit, as assessed by the CNEDiMTS. Such medical benefit is assessed on the basis of the therapeutic effect or the technical efficiency of the device, the adverse effects or the risks resulting from its use, its role among the other existing therapies or available means, the common characteristic of the severity of the pathology that it treats and its interest for public health. For medical devices which may impact significantly the expenses of the SHI (for example because of their impact on the health care organization or due to their price), medical devices are assessed by CNEDiMTS on the basis of the medico-economic evaluations.

Any medical device which provides an insufficient medical benefit in comparison with the existing therapies or available means, and which does not result in the reduction of costs for the SHI, cannot be reimbursed.

The listing of the medical device on the LPP is valid for a maximum period of 5 years which is renewable subject to reassessment of the medical benefit.

Following the registration of the medical device on the LPP, the ANSM can perform inspections to ensure that the technical conditions under which the registration has been granted are complied with.

#### 4.3 Specific list of eligible devices for health establishments

The purchase and provision of medical devices by health establishments, and the reimbursement of such medical devices by way of hospital benefits, are limited to medical devices entered in a list established by the Ministers of Health and of Social Security. The registration occurs after the CNEDiMTS has rendered its opinion on the device.

The listing of the medical device is valid for a maximum period of 5 years.

#### 4.4 Setting of a rate of reimbursement and co-payment

The part of the price of the medical device which is reimbursed by the SHI is also negotiated with CEPS (*tarif forfaitaire de responsabilité*) (see 1.5(e) above). If the parties fail to agree, CEPS may set the reimbursed amount unilaterally. The part which is not reimbursed corresponds to the patient's co-payment.

A substantial number of reimbursed medical devices are subject to a fixed reference price scheme. For those devices, the price of the relevant medical device is set unilaterally by CEPS and that price is 100% reimbursed by the SHI.

#### 4.5 Limitations on prescription of medical devices

There is no specific limitation issued by the French authorities as regards prescription. Prescription of medical devices is regulated by the general statutory law which gives physicians and other authorised health professionals the freedom to prescribe medical devices necessary for the quality, security and efficiency of the care to be provided to the patients. However, there is an economic limit: physicians must comply with the strictest economy compatible with the quality, security and efficiency of the care to be provided to the patients.

Physicians do not have a personal budget. A contractual scheme has been established to increase the involvement of health professionals in the control of health expenses. First, a national framework agreement has been signed between the SHI and health professional unions, dealing with general matters such as better coordination of healthcare. Secondly, agree-

ments have been signed between the SHI and specific categories of health professional (for example, opticians and hearing-aid technicians), defining the relationships between the SHI and the health professionals concerned.

#### 4.6 Control on medical expenses via contributions

Medical device companies selling reimbursed medical products, or medical devices sold to hospitals, are subject to specific contributions such as those set out below.

##### (a) Clawback mechanism

Medical device companies are subject to a clawback mechanism if their turnover increases faster than a predetermined rate. Different mechanisms apply depending on whether the medical device company has commitments regarding its turnover with CEPS.

##### (b) Contribution based on promotional expenses

Medical device companies must pay a contribution based on the expenses incurred in the promotion of the medical devices after deduction of an allowance. This tax is due when the turnover on such products in France exceeds €11 million.

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# Italy

## 1. SUMMARY

- A significant part of the medicinal products are reimbursed from the Italian National Health Service, which is funded through taxation, and is managed by the Ministry of Health and the Regions. Medical devices are not subject to reimbursement by the NHS, save indirectly by their usage in hospitals.
- There is a positive list of reimbursed medicinal products, which is handled by the Italian Health Authority (AIFA).
- Pricing and discounts of pharmaceuticals are strictly regulated at each level of the channel: wholesale, distribution, pharmacies.
- Various measures are in place or are being introduced by the government to cut back the costs of medicinal products, e.g.:
  - Maximum expenditure thresholds fixed for the State and for each Region.
  - Maximum prices for medicinal products.
  - Mandatory discounts.
  - Annual budgets for pharmaceutical companies.

## 2. THE ITALIAN HEALTHCARE SYSTEM: OVERVIEW

The Italian National Health Service ("NHS") was established in 1978 and replaced the previous system of state insurance founded after the Second World War. The aim of the NHS was to create an efficient and uniform health system covering the entire population, irrespective of income or contributions, age, gender, employment or pre-existing health conditions.

The NHS provides health care services to all residents and their families and emergency care to visitors irrespective of their nationality. All in-patient treatments, that is, treatments requiring hospitalisation, are free under the NHS.

The NHS is composed of various bodies and entities, namely the Ministry of Health ("MoH"), the Superior Institute of Health, the Italian Agency for Pharmaceutical Products ("AIFA"), the regional health authorities, the regional health institutions ("ASLs") and the hospitals through which healthcare services are provided.

The NHS is approximately 95% funded through direct and indirect taxation, while the remainder is derived from the incomes of the regional health institutions and from patients directly. Regions are allocated a proportion of the healthcare budget. This proportion varies annually and is established by the MoH.

For 2013, the maximum expenditure for each region is fixed at (i) 13.6% of the National healthcare expenditure for pharmaceuticals and (ii) 2.4% of the total health expenditure for hospital healthcare services. If these thresholds are exceeded, any overspend is borne respectively by (i) pharmaceutical companies, wholesalers and pharmacies and (ii) the regions, in proportion to their respective quotas. Pharmaceutical expenditure in 2012 amounted to approximately €10,162 billion.

### 2.1 Major legislation

The main legislative provisions on reimbursement, prescription and distribution of medicinal products and medical devices are contained in Legislative Decree n. 219 of 24 April 2006, which implemented the European Pharma Code, and Legislative Decree n. 46 of 24 February 1997, which implemented EU Directive 93/42/EEC on medical devices.

The provisions regulating the methods of determination of prices for reimbursable medicinal products in class A are mainly contained in the CIPE (Interministerial Committee for Economic Planning) Resolution of 1 February 2001 and the prices of non-reimbursable medicinal products in class C are largely governed by Law Decree n. 390 of 20 September 1995 (as subsequently amended).

In addition, the prices of medicinal products in classes A and C are determined by various subsequent financial laws and the decisions of the major players in the pharmaceutical industry.



## 2.2 Prescribers – physicians

Prescription only ("Rx") medicinal products are prescribed by accredited physicians. Class A Rx medicinal products subject to reimbursement by the NHS are prescribed by the so called "*medici di base*". In principle, there are no provisions limiting the autonomy of prescribers; such prescribers are thus free to prescribe any medicinal product they deem advisable.

However, in practice, prescription behaviour is strictly monitored by national and regional health authorities. In addition, guidelines are normally issued by the regions to address the physicians' prescribing practice in relation to generics.

Furthermore, the power of physicians to use certain medicinal products is often conditioned by the actual availability of products within the hospitals.

## 2.3 Decision makers – the Italian Health Authorities

The AIFA is vested with the power to permit or prevent the reimbursement of individual medicinal products or categories thereof on the basis of cost/benefit evaluations and take other major decisions which apply nationwide. Regions may also provide for partial or total exclusion of medicinal products from reimbursement and may adopt special measures, for example patient co-payment schemes, to reduce regional expenditure.

## 3. PRICING AND REIMBURSEMENT OF PHARMACEUTICALS

### 3.1 Distribution and pricing

Medicinal products sold to hospitals are subject to a compulsory discount equal to 50% of the relevant price (net of VAT) charged to the public. This discount applies to both reimbursable and non-reimbursable medicinal products. No compulsory discounts are required by law for medical devices.

The NHS reimburses hospitals by way of lump-sums for overall treatments, depending on the type of disease and the treatment (*Diagnosis Related Groups*). Thus, the costs of medicinal products applied in a hospital usually have to be covered by the DRG lump sum which the hospital receives for the entire treatment of the patient. The purchase of pharmaceuticals by hospitals is normally carried out through bid and tender procedures, under which further discounts, in addition to the compulsory ones, are provided by pharmaceutical companies.

In out-patient care, the chain of distribution and pricing mechanism is as follows:

- (a) Pharmaceuticals are classified as prescription-only ("Rx") and non-prescription ("non Rx"). Non Rx medicinal products are, in their turn, classified as over-the-counter ("OTC") and so-called "SOP" medicinal products; unlike OTC medicinal products, SOP may not be advertised to the public. Rx medicinal products may only be distributed to patients by pharmacies, while non Rx medicinal products may also be distributed from a dedicated section of a commercial store in the presence of a pharmacist in compliance with Law no. 248 of 4 August 2006.
- (b) The mechanism for determining the prices of medicinal products differs depending on whether they are reimbursable (class A) or not (class C). In principle, the prices of class C medicinal products are freely set by the pharmaceutical companies. However, in practice, the prices of medicinal products in class C have been increasingly regulated by Law no. 149 of 26 June 2005, according to which pharmaceutical companies may only increase the prices of class C pharmaceuticals every other January. There are no compulsory margins for wholesalers and pharmacies with respect to non Rx medicinal products, although the most common practice is to apply the same margins as provided by law for Rx medicinal products (see 2.1(e) below).
- (c) Prices of medicinal products in class A are subject to negotiation with the AIFA, in accordance with the provisions of CIPE Resolution of 1 February 2001 (see 1.3 above). An agreement reached between the AIFA and the manufacturer on the medicinal product price lasts 24 months and is subject to an implied renewal for an additional period of 24 months unless previously terminated by either party. In the event of changes in the therapeutic indications of the medicinal products leading to a potential increase in its use, the negotiation must be reopened before the expiry of the agreement. It is common practice to establish under the negotiation procedure a proportionate relationship between the price paid and the volume of sales of the medicinal product.
- (d) Wholesalers' margins for reimbursed medicinal products are fixed at 3% of the ex-factory price (net of VAT), while pharmacies' margins are fixed at 30% per cent of the ex-factory price (net of VAT).
- (e) In addition, when reimbursing pharmacies the retail price of reimbursable medicinal products, the NHS applies the following compulsory discounts:
  - 3.75% for medicinal products whose price is lower than €25.82

- 6% for medicinal products whose price ranges between €25.83 and €51.65
- 9% for medicinal products whose price ranges between €51.66 and €103.28
- 12.5% for medicinal products whose price ranges between €103.29 and €154.94
- 19% for medicinal products whose price is higher than €154.94.

In addition NHS applies an additional compulsory discount equal to 1.82% of the price.

- (f) In relation to reimbursable class A medicinal products, pharmacies may not grant discounts to patients and pharmaceutical companies and wholesalers may not grant discounts to pharmacies.

### 3.2 Reimbursement

- (a) Once a medicinal product is authorised, it is not immediately eligible for reimbursement. As a very general principle, reimbursement is provided for essential medicinal products, namely products:
- for diseases for which no therapeutic alternative exists; or
  - for which the medicinal products already available on the market do not provide a satisfactory or appropriate answer; and
  - which present a better cost/benefit and risk/benefit analysis than those offered by medicinal products already on the market.

Even in the absence of the above characteristics, medicinal products which are as safe and effective as those already on the market may be reimbursable depending on the result of their cost/benefit evaluation.

When evaluating eligibility for reimbursement, the AIFA also takes into consideration the following factors in relation to the medicinal products: the sales price in other EU countries; the therapeutic class; the foreseen market share in the following 24 months; the impact on expenditures for the NHS; and the place in the industrial environment.

- (b) In certain cases with respect to non-reimbursable medicinal products, AIFA entitles a product to reimbursement but limits the reimbursement to a particular disease and/or specific therapeutic indications. Relevant determinations are known as the "Note AIFA" and are published on the national reimbursement list (*Prontuario Nazionale*). Physicians disregarding the notes without a justifiable reason may be sanctioned and asked by the com-

petent local health institution to refund the price of the prescribed medical product.

- (c) Recently a law has been introduced providing that if a medicinal product (e.g. generic) is granted an MA but infringes the patent protection of another medicinal product such medicinal product (e.g. generic) cannot be reimbursed in Italy until such patent protection has expired.
- (d) As approval of a Marketing Authorization (MA) and pricing (and reimbursement) were decided in the past in the course of the same procedure, it appeared that such disposition could be effectively enforced in order to prevent generic manufacturers from entering the market before patent expiry. However, more recently AIFA issued a communication, according to which the route for the grant of the MA may be split from the procedure of reimbursement and pricing. According to the AIFA's new guidelines, if a MA application concerning a medicinal products which is still under patent protection is filed, AIFA shall decide on the grant of the MA and on the price and reimbursement afforded to the medicinal products, while the latter shall be published in the Official Journal as "C - nn" (i.e. medicinal products in class "C" – not reimbursed by the NHS – and nn as non-negotiated) for the period in which the patent protection is still effective.
- (e) Class C medicinal products are not reimbursed by the NHS.

### 3.3 Generic substitution

Physicians are encouraged to prescribe the generic name of an active ingredient, although they are not precluded from prescribing the brand name of a medicinal product. With respect to reimbursable medicinal products, whenever the prescribing physician does not indicate on the prescription only the name of the active ingredient, if applicable the pharmacist should inform the patient of the availability of a generic version. However, if the prescribing physician inserts the words "*not to be replaced with generics*", or the patient decides to purchase the branded medicinal products regardless of the pharmacist's advice, the difference between the price of the product prescribed and the generic medicinal products shall be met by the patient.

For class C medicinal products which are not reimbursable, if applicable, the pharmacist is obliged to inform the patient of the availability of a generic medicinal product. Moreover, if the prescription does not mention anything to the contrary, upon the patient's request the pharmacist is obliged to dispense the generic version of the medicinal product concerned. Generics are reimbursed to the pharmacist by the NHS up to the lowest

price of the corresponding medicinal products available on the regional distribution channel, on the basis of specific directives provided for by each region.

### 3.4 Import quotas

Due to the low prices of medicinal products in Italy compared to other EU countries, Italy is one of the most important source markets for parallel trades.

Parallel imports of medicinal products are subject to relevant authorisation by the AIFA, in compliance with the Ministerial Decree of 29 August 1997. There is no obligation on pharmacies to replace domestic medicinal products by parallel imports if they cost less.

### 3.5 Off-Label Use

Medicinal products prescribed for off-label use are not reimbursable, unless the relevant use is included in a specific list by the AIFA. In order to be entitled to be included in such a list, no therapeutic alternative should exist and favourable results of at least phase II clinical trials should be available. The relevant request is not submitted directly by the manufacturer, but should come from patient associations, scientific societies, health institutions or universities.

### 3.6 Non Rx drugs, lifestyle drugs and other non-reimbursable products

Lifestyle drugs, for example, treating non-pathological obesity or erectile dysfunction are always classified as non-reimbursable class C medicinal products.

### 3.7 Out-of-pocket payments by patients

In order to reduce and/or cover the regional health expenditure, the regions may require co-payments from patients with respect to certain reimbursable medicinal products. The co-payment policy varies from region to region. Certain categories of people, for example disabled people or people whose income does not exceed certain thresholds, are usually exempted from co-payments.

### 3.8 Price reductions and discounts

Since 2005, for the purpose of regulating national health expenditure, the AIFA has issued resolutions imposing on pharmaceutical companies mandatory reductions and discounts on the retail prices of reimbursable medicinal products. Such reductions have ranged from 5% to 7% of the retail price and have been considered as cumulative.

The Financial Law for 2007 confirmed the reduction set forth in the AIFA resolutions for the previous years. In addition, the Financial Laws for 2007 and 2008 provid-

ed that pharmaceutical companies could switch to the payback system rather than reducing the price of their medicinal products.

The pay back is a financial mechanism that allows pharmaceutical companies to ask for the suspension of the AIFA price reduction of 5%, compared with simultaneous payment in cash (pay back) the relative value of specific accounts identified by the Regions.

### 3.9 Annual budgets for pharmaceutical companies

To reduce expenditure by the NHS, the Financial Law for 2008 introduced a new system whereby pharmaceutical companies were assigned individual budgets for reimbursement.

The budgets are calculated by the AIFA on the basis of the turnover generated by the medicinal products sold during the previous year and taking into account the estimated reduction of such turnover in the subsequent year due to the expiry of patents. How much each pharmaceutical company contributes to overspending by the NHS is determined proportionally to the amount each pharmaceutical company exceeds their budget. In relation to innovative medicinal products, the quota for overspend is allocated to all marketing authorisation owners in proportion to the turnovers resulting from the sale of non-innovative medicinal products covered by patents.

## 4. PRICE AND REIMBURSEMENT OF MEDICAL DEVICES

Medical devices are not subject to reimbursement by the NHS, save indirectly by their usage in hospitals. Similarly, the pricing of medical devices is not regulated. However, the MoH, which is the competent authority for medical devices, establishes the maximum prices at which the latter may be purchased by hospitals.

### 4.1 Registry of medical devices

Medical devices which are not registered on the special register of the MoH (*Repertorio dei Dispositivi Medici*) may not be sold to hospitals and other public institutions within the NHS.

### 4.2 Point of Sale

The point of sale for medical devices varies depending on the kind of device.

Glasses and contact lenses may only be sold by opticians. Medical devices subject to prescription, and/or devices which may be used only with the intervention of a medical practitioner, may only be sold through a pharmacy or delivered directly to the relevant physician by the manufacturer or their distributors. All other kinds

of devices may be sold in specialised stores and certain types may also be sold in commercial stores.

#### **4.3 Advice on the use of medical devices**

The Unique Commission of Medical Devices, a division of the MoH, publishes evaluations of the cost/benefit relationship of medical devices registered on the National Register of Medical Devices in order to provide health operators with guidelines on the appropriate use of the same.

#### **4.4 Contract on the provision of medical devices and public tenders**

The purchase of medical devices by hospitals is carried out through bid and tender procedures.

The relevant starting price for such tenders is established by the Unique Commission of Medical Devices.

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# The Netherlands

## 1. SUMMARY

- The majority of the medicinal products and medical devices are reimbursed from a basic package of health insurance which is mandatory for each citizen.
- There are 4 major health insurers in the Netherlands that dominate the health insurance market.
- There is a positive list of reimbursed medicinal products for outpatient use. The availability of medicinal products within the hospital is decided by the individual hospitals.
- Health insurers apply reimbursement restrictions mainly for outpatient reimbursement:
  - Reimbursement limited to medicinal products designated by health insurer, whereby the insurer is obliged to designate at least one medicinal product of each active substance included in the positive list (preference policy).
  - Various contractual arrangements between health insurers and pharmacists whereby pharmacists are forced to dispense cheaper medicinal products.
  - Provide a fixed budget for which healthcare provider (pharmacist / hospital) must buy medicinal products (closed-end financing of medicinal products).
- Various measures are in place or are being introduced by the government to cut back the costs of medicinal products, e.g.:
  - Maximum prices for medicinal products.
  - Conditional access to reimbursement for more expensive medicinal products, whereby reimbursement may depend on financial arrangements that a manufacturer is willing to agree on.
  - Measures to ensure that certain expensive medicinal products are only reimbursed from the hospital (inpatient) budget, by excluding

these medicinal products from the positive list for outpatient use, because the inpatient system is based on budget (closed end) financing, whereas the outpatient system is based on an open end financing.

- There is a trend towards a more flexible and risk-based organisation of the healthcare system which aims to create more competition between healthcare providers and healthcare insurers and which aims to lessen government influence.

## 2. THE DUTCH HEALTHCARE SYSTEM: OVERVIEW

Under the Health Insurance Act (*Zorgverzekeringswet*) which came into force on 1 January 2006, it is mandatory for all residents of the Netherlands to take out basic health insurance which consists of a standard package of insured services. The healthcare system in the Netherlands is one of private health insurance with public social conditions. The system is operated by private health insurance companies which must accept all Dutch citizens, regardless of their age or condition of health. A system of risk equalisation enables the acceptance obligation and prevents direct or indirect risk selection. All people pay the same nominal insurance premium to their health insurer for the basic health insurance. The Health Insurance Act also provides for an income-related contribution to be paid by the insured. Employers contribute by making a compulsory payment towards the income-related insurance contribution of their employees. The Health Insurance Act aims to increase competition between insurance companies and healthcare providers to economise healthcare costs, while safeguarding the public interest by introducing the standard package of insured services. This system has led to extensive consolidation of the market for health insurance companies through mergers. In addition to mandatory policies, health insurance companies can offer additional insurance packages, for which policies no mandatory acceptance applies.

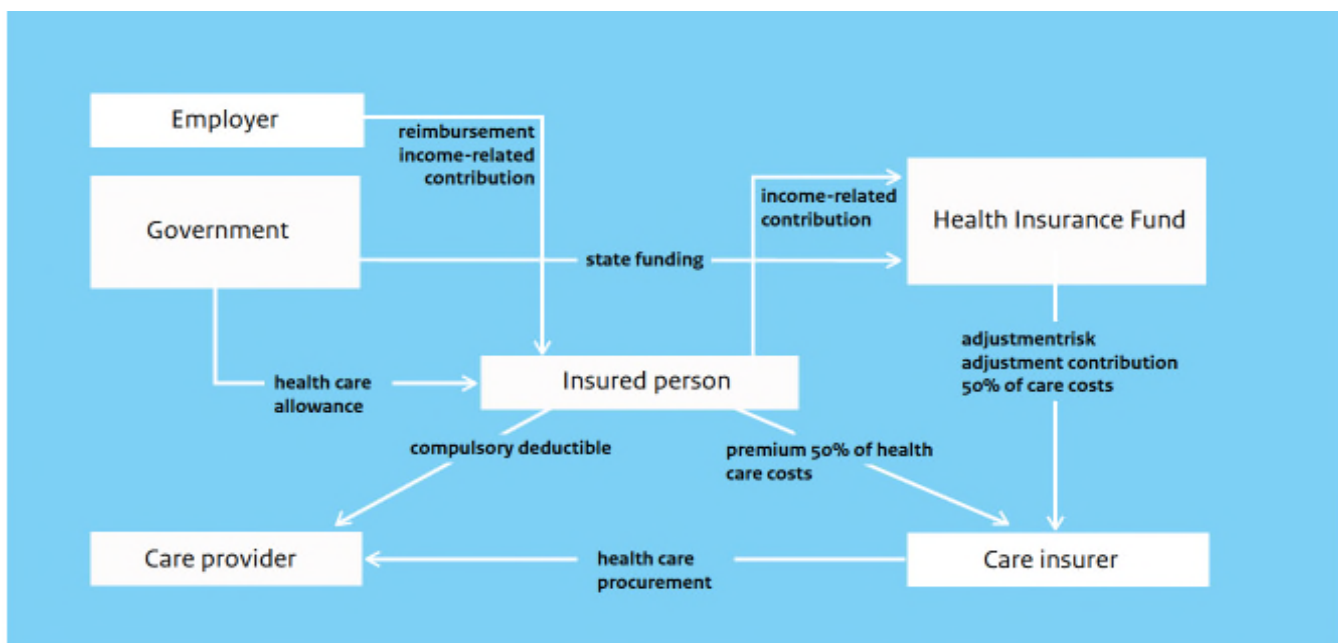
### 2.1 Major legislation

The pricing of medicinal products is regulated by the Medicinal Products Prices Act (*Wet Geneesmiddelenprijzen* - "WGP"). Reimbursement and regulated

tariffs are regulated by the Health Insurance Act (*Zorgverzekeringswet* - "Zw") and the Market Organisation Healthcare Act 2006 (*Wet Marktordening gezondheidszorg*). Extraordinary expenses are covered by compulsory national health insurance, under the Exceptional Medical Expenses Act (*Algemene wet bijzondere ziektenkosten*).

## 2.2 Payers – insurance funds

In the Netherlands, insured parties pay a fixed premium (the nominal premium), which averages approximately €1,273 per person per year. The insurer determines the level of the nominal premium, but is obliged to provide everyone with the same care for this premium. Health insurers are allowed to make a profit. Most healthcare policies provide for benefits in kind, where insurers negotiate with healthcare providers on the price, content and organisation of the care. Insured parties can also choose a restitution policy where they can choose their own healthcare provider. The government set a public framework condition that healthcare must be affordable for all. People who cannot pay for the fixed premium due to low income can apply for a care allowance.



Source: Ministry of Health

## 2.3 Prescribers - physicians and dentists

In the Netherlands, prescription-only medicinal products are prescribed by physicians, dentists and certain designated nurses. Midwives can prescribe certain prescription-only medicinal products in specific circumstances.

## 2.4 Decision makers - the Ministry of Health

The Minister of Health decides which new medicinal products shall be placed on the Drugs Remuneration System (*Geneesmiddelen Vergoedingssysteem* - "GVS"), which consists of a positive list of reimbursed products. Since 1 January 2006, the GVS is included in the Health Insurance Decree (*Besluit Zorgverzekering* - the "Decree") and the Health Insurance Regulation (*Regeling Zorgverzekering* - the "Regulation"). The

execution of the GVS is assigned to the Minister of Health, Welfare and Sport (*Minister van Volksgezondheid, Welzijn en Sport* - the "Minister"). Before the Minister decides on an application, it will consult with the Council for Health Insurance (*College voor Zorgverzekeringen* - "CVZ"), as of 1 April 2014 CVZ will be known as the Healthcare Institute Netherlands (*Zorginstituut Nederland*).

In addition to the formal decision makers there is a trend towards more influence on actual reimbursement decisions by other stakeholders. Health insurers have an increasing influence on actual reimbursement decisions for both the outpatient and the inpatient system as a result of e.g. contractual arrangements and budget measures. Hospitals and other healthcare providers also have an increasing influence as a result of e.g. purchasing decisions and the drafting of treatment guidelines which may include first choice medicinal products.

## 2.5 Pricing

The pricing of medicinal products is regulated by the Medicinal Products Prices Act (*Wet Geneesmiddelenprijzen* - "WGP"). The pricing of medical devices is not regulated.

The WGP allows the Minister to fix maximum prices based on the average official list price of comparable medicinal products in Belgium, Germany, France and the United Kingdom. A maximum price can be calculated if a comparable product is marketed in at least two of the four countries and the product is eligible for reimbursement. A comparable product is a product with the same active substance, unit strength of active substance and pharmaceutical form (including generics and biosimilars). Maximum prices are calculated using set price lists from each country to determine the cheapest available "comparable" product. The average of these prices is equal to an prescription-only medicinal product's maximum price for which the product may be sold to those are authorised to dispense such medicinal product (retail price). The maximum retail prices of generics also fall under the WGP. Hospital prices are also covered by the WGP. The prices of OTC products are not controlled. Currently, there is political discussion regarding the WGP, an individual Member of Parliament has submitted a proposal to amend the WGP by adding more reference countries and to amend the calculation method in order to achieve lower maximum prices and thus additional savings. This proposal for amendment is in an early stage.

In addition to the statutory maximum prices it is common for hospitals, wholesalers and pharmacies to negotiate and obtain discounts and bonuses when purchasing medicinal products.

## 3. PRESCRIPTION AND REIMBURSEMENT OF MEDICINAL PRODUCTS

### 3.1 Drug remuneration system (outpatients)

Once an prescription-only medicinal product has obtained a marketing authorisation, it can be included in the positive list of the Drugs Remuneration System (GVS). The GVS provides a positive list of reimbursable products for use outside the hospital. A medicinal product is reimbursable if it is either (i) interchangeable (equivalent therapeutic value) with one or more other medicinal products on the list with a similar indication or (ii) it has a unique therapeutic value. Furthermore reimbursement may be subject to a statutory condition. This is designed in the Annexes to the Regulation as follows:

- (a) Annex 1A: prescription-only medicinal products grouped in Annex 1A are 'similar' interchangeable products, meaning that the products in the same group have an equivalent range of indications, an equivalent manner of administration, are designed for the same general age group and there is an absence of clinically relevant differences. For interchangeable products the reimbursement is limited to a maximum amount. The reimbursement limit is the average of the pharmacy purchase prices of the products within one group on a particular reference date, which is currently October 1998. There are political discussions to amend the reference date to a more recent date. If a medicinal product is priced above the maximum reimbursement amount, the patient must co-pay the difference.
- (b) Annex 1B: prescription-only medicinal products that are not interchangeable, and which can therefore not be clustered are placed on Annex 1B if such products have added therapeutic value and are cost-effective compared products already included in the GVS. Applicant must provide results of pharmaco-economic research and forecast budgetary implications. These unique products are reimbursed at the manufacturer's recommended price.

Reimbursement may furthermore be conditional on specific indications. Pursuant to Article 2.5.2 of the Regulation, the Minister is permitted to stipulate conditions for the reimbursement regarding e.g. age, indication, etc. These conditions are included in Annex 2 of the Regulation.

An application for admission of a medicinal product in the GVS must be filed at the Ministry of Health. The procedure for such application consists of three parts:

- (a) Filing the official application, containing a standard application along with the supporting dossier.

- (b) The Minister of Health requests advice from the Council for Health Insurance (*College voor Zorgverzekeringen* - "CVZ") establishing a product's therapeutic value and, in some cases, also the financial consequences of including it on the positive list. An important part of CVZ's advice is the opinion of the Scientific Advice Board, previously known as the Commission Pharmaceutical Help (*Wetenschappelijke Advies Raad* - "WAR"). The WAR will assess on the interchangeability of the prescription-only medicinal product. If the medicinal product is not interchangeable, the evaluation relies on the balance of the product's therapeutic value and cost-effectiveness and will take into consideration therapeutic efficiency, therapeutic efficacy, possible side-effects, past experiences, number of patients that could benefit, ease of administration, improvement in the quality of a patient's life and the cost of reimbursement.
- (c) A decision should be made by the Minister within 90 days, excluding any clock-stops. If a decision is made to include the medicinal product in the GVS this decision is published in the Government Gazette (*Staatscourant*) and will have effect thereafter.

If the application is refused, it is possible to request that the Minister reconsiders the application. This is usually done by the marketing authorisation holder in writing and must contain information on new facts or changed circumstances. The procedure for reconsideration is identical to the procedure for a regular application.

The Minister of Health announced several cut-back measures concerning the GVS. For certain specialised and more expensive medicinal products, reimbursement will only be made through the hospital budget and not in the GVS. The Minister started with these cut-back measures as of 2012, e.g. TNF alpha inhibitors and certain cancer medicinal products and growth hormones have been removed from the GVS and will only be reimbursed within the hospital. More specialised and expensive medicinal products will follow.

### 3.2 In-patients

In contrast to the outpatient system there is no independent reimbursement system such as a positive list for medicinal products used in a hospital setting. Medicinal products used in the hospital form part of the general entitlement to medical care. The content of what comprises medical care is defined by the state of scientific knowledge and practice. If a certain medical treatment, including the medicinal product used in the treatment, forms part of the "state of the art" medical care, a hospitalised patient is entitled to such care. CVZ will however assess those intramural medicinal products that claim to have an added therapeutic value and have

a budget impact of more than EUR 2.5 million a year. CVZ may advise that certain medicinal products that are being used in a certain treatment do not form part of medical care or only form part of medical care under certain conditions.

### 3.3 Conditional reimbursement (both in- and outpatient)

As of 2012 a system of preliminary inclusion of authorised products in the insured package has been introduced for more specialised medicinal products. Under this system, certain specialist medicinal products will only be included in the insured package conditionally: coverage with evidence development. The products may be removed if treatment is no longer (cost) effective. Or – in case of a lack of cost effectiveness – if the manufacturer is prepared to make financial arrangements regarding the product, e.g. risk sharing arrangements, price reductions, etc.

### 3.4 Reimbursement

#### (a) Reimbursement out-patients

Insured parties (patients) have the right to reimbursement of medicinal products appointed by the Minister in the GVS to the extent that these medicinal products are also appointed by the health insurer. Health insurers are obliged to appoint at least one medicinal product of all the medicinal products with the same active substance available within the positive list (GVS), this is also known as the "preference policy". In addition to a joint preference policy for certain substances, several health insurers have, as of 1 July 2008, also started an individual preference policy. This means that each health insurer designates different medicinal products it will reimburse and apply such reimbursement conditions in different preferred periods of time at the choice of the health insurer. With the preference policy, for each active substance health insurers aim only to include the medicinal products with the lowest gross pharmacy cost price in the insurance claim of the insured parties. Non-preferred medicinal products are not reimbursed and pharmacists are obliged to dispense the preferred medicinal products, unless the prescribing doctor specifies another product with the instruction "medical need" or "MN".

In addition to the preference policy, health insurers enter into various contractual arrangements with healthcare providers such as pharmacists to cut back on costs of medicinal products, e.g. generic substitution arrangements, lowest price range arrangements or an arrangement in which a pharmacist receives a fixed price per multisource medicinal product regardless of the actual price. Preference policy and all other contractual arrangements are based on the prices included in the general price list Z-Index.



Since 2012 the tariffs regarding dispensing services are free and must be negotiated between the health insurer and the pharmacist. The prices of the medicinal products that are dispensed are not regulated and are also subject to negotiations and contractual arrangements.

Health insurers may set additional conditions for reimbursement aimed at appropriate use of a medicinal product, e.g. limited to prescription of specialised doctors.

### (b) Reimbursement in-patients

The availability of medicinal product used in a hospital is decided by individual hospitals. The purchase of medicinal products is paid for through the total price paid by health insurers for each diagnosis treatment combination (DBC). As of 2012 the prices of the majority of the DBCs must be negotiated between hospitals and health insurers.

Additional financing is available for hospital products (expensive and orphan medicinal products) that are placed on an add-on list.

### 3.5 Homeopathic products and OTC products

Homeopathic medicinal products and OTC products are not reimbursed by the basic health insurance. However, it is possible to conclude a supplementary insurance policy for reimbursement of homeopathic products.

### 3.6 Out-of-pocket payments by patients

Most prescription-only medicinal products are reimbursed by the insurers. However, on the basis of the preference policy and contractual arrangement reimbursement may differ for each insurer and according to the kind of insurance policy the patients have. There are several health insurers that leave the choice of the medicinal products to the patients, physicians and pharmacists. The first €360.00 for the costs of medicinal products has to be paid by the patients themselves, the so-called "personal excess" (*eigen risico*). The patient's own contribution of €360.00 is mandatory for each resident in the Netherlands. The cost of all medicinal products exceeding the personal excess will be reimbursed, unless the patients have set a higher personal excess to reduce the costs of the insurance policy.

### 3.7 Off-label use

Medicinal products listed in Annex 1A and 1B of the Regulation prescribed for off-label use will in principle be reimbursed by the health insurer. This is understandable, as for most of these medicinal products no further requirements in the form of indication limits have

been set. However, this may be different for those medicinal products prescribed for off-label use which are listed in Annex 2 of the Regulation. For Annex 2 medicinal products, requirements must be fulfilled before a patient is entitled to reimbursement of that medicinal product.

## 4. PRESCRIPTION AND REIMBURSEMENT OF MEDICAL DEVICES

Medical devices used in the hospital form part of the general entitlement to medical care. The content of what comprises medical care is – similar to the system for medicinal products – defined by the state of scientific knowledge and practice. For outpatient use of medical devices a different system applies; the Minister of Health appoints certain categories of medical devices. These categories of medical devices are listed in the Regulation.

The categories of medical devices that are listed in the Regulation are reimbursed by the health insurer for all patients with basic insurance. The reimbursement of medical devices is further regulated by the health insurer. The health insurer determines which type of medical device within a certain category is reimbursed; this may differ for each health insurer. The health insurer may also regulate whether the medical device must be prescribed by doctors or specialists and/or whether permission of the health insurer is necessary before a medical device is provided.

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# Spain

## 1. SUMMARY

- In Spain, there is a public health care system which operates in parallel with a network of private health insurance companies. Over 90% of the population uses the National Health System for their medical needs.
- Pharmaceutical assistance is jointly financed by the NHS and patients. Pharmaceutical products financed by the NHS that are dispensed to patients who are not hospitalized are subject to a co-payment system.
- Only doctors, dentists and podiatrists can prescribe medicinal products by means of an official prescription. Nurses and physical therapists can participate in the use and dispensation of non-prescription medicinal products through the dispensing order.
- The inclusion of a medicinal product within the reimbursement system is selective and based on general and objective criteria. Once a medicinal product has been authorised and registered, the Ministry of Health will decide whether or not to include it within the reimbursement system. OTC medicinal products, medicinal products which are not used for a specific pathology, cosmetics, dietetic products, mineral waters, toothpastes and similar products will not be reimbursed.
- The public financing of a medicinal product shall be subject to the reference price system. The reference price ("*precio de referencia*") is the maximum amount with which the medicinal product presentations included in each of the reference groups will be financed, provided they are prescribed and dispensed from public funds.
- In compliance with the principle of rational use of medicinal products, public health authorities must encourage, as a general rule, prescription of medicinal products based on the active ingredient (rather than the brand name) in order to promote the sale of generics and thus reduce the health public expenditure.

- With the exception of the reference price system, in general terms, the principles applicable to financing of medicinal products are also applicable to medical devices.

## 2. THE SPANISH HEALTHCARE SYSTEM: OVERVIEW

In Spain essential changes have been introduced in Law 29/2006, of 26 July, on rational use of medicinal products and medical devices ("Law 29/2006") by Royal Decree-Law 16/2012, of 20 April, on the sustainability of the National Health System ("Royal Decree-Law 16/2012") and by Law 10/2013, of 24 July, incorporating into Spanish law Directives on pharmacovigilance and falsified medicinal products and modifying Law 29/2006 ("Law 10/2013"). Moreover, recently the Government has passed Royal Decree 177/2014, which governs the reference price system of medicinal products financed by the National Health System, the homogeneous groups of these products and information systems related to pricing and public financing ("Royal Decree 177/2014").

This pricing regulation involves a push in favour of generic products. Data from IMS Health covering the 12-month period ending March 2012 shows the medicinal products market with generic prices represents 63.4% of the total prescription market in units in Spain and 38.3% in market value.

Other changes have been introduced such as: new criteria for inclusion in pharmaceutical assistance (the innovation component for undisputable therapeutic advances will be a new criterion), increased co-payment, changing the scale of deductions for the pharmacy or adapting the packaging to the duration of treatment.

### 2.1 Main legislation

The regulation of the pricing of medicinal products is mainly established by Law 29/2006 and Royal Decree 177/2014.

In addition to this regulation, there are other relevant texts such as Order SPI/3052/2010, of 26 November, regulating groups of medicinal products and their reference price, and Royal Decree 823/2008, of 16 May, on

margins, discounts and deductions for distribution and dispensation of medicinal products.

## 2.2 Payers – insurance funds

In Spain, there is a public health care system which operates in parallel with a network of private health insurance companies.

### (a) National Health System

The public health care system provides universal healthcare to all citizens under a tax-financed scheme run by the National Health System ("NHS"). The NHS is comprised of the state healthcare services and the regional healthcare services. According to the Spanish political system, powers regarding health matters are shared between the national and regional government.

Over 90% of the population uses the NHS for their medical needs. The system allows Spanish citizens to choose their primary care doctor, through whom they have access to the rest of the system. In order to consult a specialist, patients must first be referred by their primary care doctor (except in emergencies).

In addition, emergency care is universally available to anyone (irrespective of the patient's nationality and of the patient contributing to the NHS).

### (b) Private health insurance

The private system coexists with the NHS. The private insurance system is used either as a supplement to, or as an alternative to, the NHS. The advantage of private insurance is that the insurance companies have their own network of hospitals, clinics and laboratories.

The patients of private health insurance usually have a shorter waiting time for treatment than patients in the NHS. The only downside is that these insurance companies can insist that patients only use doctors who are members of their group. However, most companies have programs that refund around 80%-90% of the fees charged by physicians outside the approved group.

## 2.3 Prescribers – doctors, dentists and podiatrist

Only doctors, dentist and podiatrist can prescribe medicinal products by means of an official prescription. Nurses and physical therapists can participate in the use and dispensation of non-prescription medicinal products through the dispensing order. Both documents must include the necessary data to identify the prescribing healthcare professional, the patient and the prescribed medicinal products in accordance with Royal Decree 1718/2010, of 17 December, on official prescription and dispensing orders.

Medicinal products are classified as prescription and non-prescription/over-the-counter ("OTC"). OTC medicinal products are excluded from reimbursement by the NHS and may be advertised to the general public.

All medicines are dispensed to patients solely through pharmacies or hospital pharmacies (primary care and specialised care).

Pursuant to Law 29/2006, in compliance with the principle of rational use of medicinal products, public health authorities must encourage, as a general rule, prescription of medicinal products based on the active ingredient (rather than the brand name) in order to promote the sale of generics and thus reduce the health public expenditure.

## 2.4 Decision makers – the Ministry of Health and Regional Health Authorities

The Ministry of Health, Equality and Social Policy (*Ministerio de Sanidad, Servicios Sociales e Igualdad* – "Ministry of Health") proposes and implements the National Government's general guidelines on health and medical care. The Ministry of Health is also the Spanish Government's representative before international organisations.

Due to the transfer of health care services to the Autonomous Regions (*Comunidades Autónomas*), the role of the Ministry of Health has shifted to the supervision of the NHS and the coordination of regional initiatives. Moreover, the Ministry of Health is in charge of pharmaceutical legislation and the evaluation and authorisation of medicinal products and medical devices. The Ministry of Health carries out some of these duties through the General Directorate of Medicines and Medical Devices (*Dirección General de Farmacia y Productos Sanitarios*) and the Spanish Agency for Medicinal Products and Medical Devices (*Agencia Española de Medicamentos y Productos Sanitarios*). The latter is a public body with powers to grant compulsory marketing authorisation for medicines, authorise clinical trials, plan and develop the Spanish pharmacovigilance system and initiate inspection, control or sanction proceedings against administrative infringements by any pharmaceutical agent.

Each of the 17 regional governments in Spain holds health planning powers, as well as the capacity to organise their own health services. The Interregional Council of the NHS (*Consejo Interterritorial del Sistema Nacional de Salud*), composed of representatives of the Autonomous Regions and the National Government, promotes the cohesion of the system.

### 3. PRICING AND REIMBURSEMENT OF MEDICINAL PRODUCTS

#### 3.1 Decision to finance or reimburse the price of the medicinal products

Once a medicinal product has been authorised and registered, the Ministry of Health will decide whether or not to include it within the reimbursement system. The inclusion of a medicinal product within the reimbursement system is selective and based on the following general and objective criteria:

- the seriousness, duration and frequency of the illnesses to be treated with the medicinal product;
- the specific needs of certain groups;
- the therapeutic and social usefulness of the medicinal product;
- the rationalisation of public expenditure;
- the existence of alternative products or treatments for the same illness; and
- the innovative character of the medicinal product

OTC medicinal products, medicinal products which are not used for a specific pathology, cosmetics, dietetic products, mineral waters, toothpastes and similar products will not be reimbursed.

#### 3.2 Fixing the price

To market a medicinal product or medical device in Spain it will be necessary to offer this product to the NHS. Likewise an offer must be made if there are substantial variations in the conditions of approval of the medicinal product or medical device. In any case, the marketing authorization holder may market medicinal products that are dispensed in Spanish territory under the reported price regime, meaning the price communicated to the Ministry of Health, so that the department can object to this price on public interest grounds.

The power to fix the price of medicinal products and medical devices is vested in the Inter Ministerial Price Commission for Medicinal Products, assigned to the Ministry of Health.

As a rule, the price financed by the NHS will be less than the wholesale price of the medicinal product when it is dispensed outside the NHS. Pharmaceutical laboratories, warehouses, wholesalers and pharmacies through Collegiate Pharmaceutical Organisations, should provide the required information so that the pharmacy can reimburse them for such medicinal products as are determined and which have been dispensed outside the NHS.

The Ministry of Health will establish the retail price of medicinal products and medical devices financed by the NHS by adding the authorized wholesale price to the margins for activities of wholesale distribution and dispensing to the public.

#### 3.3 Co-payment

Pharmaceutical assistance is jointly financed by the NHS and patients. Pharmaceutical products financed by the NHS that are dispensed to patients who are not hospitalized are subjected to a co-payment system.

The Government may adjust the patient's contribution taking into account the following criteria:

- the ability to pay;
- the therapeutic and social utility of the medicinal products and medical devices;
- the needs of specific groups;
- the severity, duration and after-effects of the different pathologies for which the products are prescribed;
- the rationalization of public expenditure for pharmaceutical provision;
- the existence of available medicinal products or medical devices or other similar or better alternatives for the same disease.

In general, the patient's contribution will be as follows:

- 60% of the retail price for patients and beneficiaries whose yearly gross income is equal to or greater than 100.000 euros.
- 50% of the retail price for patients and beneficiaries whose yearly gross income is equal to or greater than 18.000 euros and less than 100.000 euros.
- 40% of the retail price for patients and beneficiaries who are not included in the previous groups.
- 10% of the retail price for social security pensioners and beneficiaries.

#### 3.4 Reference prices/selected prices

The public financing of a medicinal product is subject to the reference price system set out by article 93 of Law 29/2006 and developed by Royal Decree 177/2014.

The reference price is the maximum amount with which the medicinal product presentations included in each of the reference groups will be financed, provided they are prescribed and dispensed from public funds.

The reference group is made up of all presentations of a financed medicinal product with the same active ingredient and route of administration and whose actual marketing has been notified. The group must include at least one biosimilar or generic presentation financed by the NHS (unless the medicinal product or its main active ingredient have been authorized for a minimum of ten years in a European Union member state and additionally there is a medicinal product different from the original one and its licenses, in which case the existence of a generic product will not be essential to establish a group).

The reference price shall be calculated by reference to the lower cost per treatment per day of the presentations included in the group. This price will be established dividing the wholesale price of each product by the number of defined daily dosages ("dosis diarias definidas").

There are two other relevant concepts: lower price (*precio menor*) and lowest price (*precio más bajo*), a category which was introduced by Royal Decree-Law 16/2012. These two concepts will have a decisive impact on the prescription and dispensation of medicinal products as will be explained in section 4 below.

The lower price is set by the Ministry of Health, for each homogeneous group (the homogeneous group is made up of presentations of financed medicinal products with the same active ingredient by reference to the dosage, content, pharmaceutical form and route of administration, which could be inter-changed in dispensation) and is incorporated into the NHS "Nomenclátor" (list of products included in pharmaceutical assistance updated every month by the Ministry of Health), but this price does not necessarily have to be the same as the lowest price in the market.

The lowest price is the lowest market price and refers to individual presentations (not to homogeneous groups).

However, the market forces are equating lower prices and lowest prices.

The lower prices of homogeneous groups are reviewed every three months. The new lower price reviewed for each homogeneous group will correspond to the lowest priced presentation at the time of each quarterly update. Therefore, in the month in which the update occurs, lower prices are the same as the lowest prices. But during the next two months following the update, laboratories may request voluntary price reduction for their presentations and in these cases the price will be below the lower price and will be the lowest price of the homogeneous group until the next quarterly update.

After the 4<sup>th</sup> day of each month the Ministry of Health publishes the list of applications for voluntary reduction

which have been accepted. A period of three working days is given to apply for voluntary price reductions in order to match the price of the presentation to the lowest price of the corresponding homogeneous group. After this period a definitive list is published by the Ministry of Health.

Additionally to the above, the new system of selected prices is created by Royal Decree-Law 16/2012 for financed and unfinanced medicinal products and medical devices.

Some people believe this system will involve a covert tender. In order to bring this new system into effect, the Ministry of Health will prepare a reasoned proposal setting out the selected maximum price applicable in each case. In doing so, it will take into account the consumption of the group, the budgetary impact, the existence of at least three medicinal products in the group and that there is no risk of shortages. Among the submissions received in response to the Ministry's proposal, the best price will be selected. The laboratories concerned must expressly declare their commitment to ensure an adequate supply. Medicinal products and medical devices that exceed the maximum price will be excluded from the NHS financing for the time that the selected price applies. This new selected price will be effective for two years and cannot be modified in this period.

#### 4. PRESCRIPTION AND DISPENSATION

As mentioned above, in compliance with the principle of rational use of medicinal products, public health authorities must encourage, as a general rule, prescription of medicinal products based on the active ingredient rather than the brand name.

However, when the prescription is made by active ingredient, the pharmacist must take into account the price of the medicinal products for dispensation and for this purpose the monthly lists related to lower and lowest prices mentioned above are essential.

In accordance with the Eighth Additional provision of Royal Decree 177/2014, when the prescription is made by active ingredient, the pharmacist will dispense the lowest priced medicinal product of its homogeneous group. In the case of shortages or urgent necessity, the available presentations should be dispensed in order of lowest price. If taking this into account it is possible to dispense several presentations, the corresponding generic or biosimilar product will be dispensed. When prescription is made by brand name these rules will be applicable only if the prescribed medicinal product is priced higher than the lower price of the homogeneous group. Accordingly, there is a clear push in favour of the

generic product and a significant pressure on pricing of products generally.

As described above, this situation, which involves price changes every month, was creating stock problems in pharmacies. Moreover, some generic pharmaceutical companies were lowering their prices aggressively and were then unable to meet the demand, which was causing supply problems. To avoid this situation, Law 10/2013 included a new infringement in Law 29/2006. New section 25<sup>a</sup> of article 101.c) of Law 29/2006, considers as a very serious infringement "*Failure, by the marketing authorization holder, in its obligation to adequately supply the market in order to comply with its duties as regards the pharmaceutical provision of the National Health Service and guarantee supplies to pharmacies and pharmacy services of the medicinal products included in homogeneous groups of lowest price and lower price*".

## 5. PRESCRIPTION AND REIMBURSEMENT OF MEDICAL DEVICES

With the exception of the reference price system, in general terms, the principles applicable to financing of medicinal products are also applicable to medical devices.

Only prescription medical devices will be included in the reimbursed system and for this inclusion must comply with the criteria established for the medicinal products and, in particular, with the following ones:

- the seriousness, duration and frequency of the illnesses to be treated with the medicines;
- the specific needs of certain groups;
- diagnostic value, control, treatment, prevention, alleviation or compensation for a disability;
- the therapeutic and social usefulness of the pharmaceutical product;
- the existence of alternative products or treatments for the same illness.

Similar to medicinal products, the official prescriptions of medical devices must comply with the criteria established by Royal Decree 1718/2010, on official prescription and dispensing orders.

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# The Russian Federation

## 1. SUMMARY

- Russian system of healthcare does not provide for reimbursement systems similar to those adopted in European healthcare systems.
- The Russian healthcare system is based on budget and insurance model of funding mainly involving state and municipally owned medical organizations.
- The Russian healthcare system mainly bases on the annually adopted Program of State Guarantees of Free Medical Treatment to Russian Citizens (the "**State Program**").
- The main component of the State Program is the base program of mandatory medical insurance, which guarantees provision of medical aid, medicines and medical devices in hospital settings according to its terms.
- The out-patient provision of medicines and medical devices is performed on the basis of different state-run programs.
- The price for medicines included into the list of essential and most important medicines ("**Essential Drug List**") is regulated and controlled by the state and is subject to state registration. Prices for other medicines, which are not included into the Essential Drug List, and medical devices are not regulated by the state.

## 2. THE RUSSIAN HEALTHCARE SYSTEM: OVERVIEW

The Russian healthcare system is based on budget and insurance model of funding mainly involving state and municipally owned medical organizations.

The Russian healthcare system mainly bases on the annually adopted Program of State Guarantees of Free Medical Treatment to Russian Citizens (the "**State Program**"). This State Program defines the conditions and types of the free medical aid; the list of diseases, the treatment of which is provided free of charge; categories of citizens, the free medical aid to whom is provided; average financial expenses per certain volume of

medical aid; average financial expenses per capita; the rules and structure of the tariffs' formation for the medical aid and ways of their payment; as well as requirements to the territorial programs of free medical aid treatment in the part of defining the conditions and procedure of providing free medical aid, criteria of accessibility and quality of medical aid.

The State Program for 2014 is adopted by the Russian Government's Resolution No. 932 dated 18 October 2013 "On Program of State Guarantees of Free Medical Treatment to the Citizens for 2014 and Planned Period of 2015 and 2016".

According to the State Program for 2014 the following is guaranteed for the citizens for free:

- primary medical aid;
- specialized medical aid (including, high-tech medical aid provided in accordance with list of such aid adopted by the Russian Ministry of Healthcare (the "**MoH**"));
- emergency medical aid (including specialized);
- palliative medical aid.

The sources of financing of the State Program are the state budget (federal, territorial and municipal) and the funds from the mandatory medical insurance, which is the main component of the State Program.

Medical insurance in Russia consists of mandatory medical insurance (the "**MMI**") and voluntary medical insurance (the "**VMI**").

Under the MMI insurance is provided on the basis of a territorial program of the mandatory medical insurance (adopted in each territory of Russia) and base program of mandatory medical insurance (which is fully included into the State Program and is its main component). The base program defines the types and conditions of medical aid to be provided, the categories of citizens who may be insured, etc.

The VMI is a supplementary insurance to the MMI insurance, which is purchased individually. The VMI provides different programs of insurance for different cate-

gories of individuals. Usually such programs provide greater coverage in terms of medical services.

## 2.1 Major legislation

The main legislative acts regulating the Russian healthcare system are the following:

- Federal Law "On the Circulation of Medicines" No. 61-FZ dated 12 April 2010 (the "**Law on Circulation of Medicines**");
- Federal Law "On Fundamentals of Citizens' Health Protection in the Russian Federation" No. 323-FZ dated 21 November 2011 (the "**Law on Fundamentals**");
- Federal Law "On Obligatory Medical Insurance in the Russian Federation" No. 326-FZ dated 29 November 2010 (the "**Law on Insurance**").

## 2.2 Payers of insurance funds

The payments for MMI are mandatory and made mostly by the employers (in relation to working individuals) and state (in relation to non-working individuals).

The VMI programs are usually purchased by individuals for themselves or by the employers as a supplement to the social package for the employee.

## 2.3 Prescribers

The medicines may be prescribed by the treating physician and paramedic or midwife in cases when they are empowered to act as a treating physician in accordance with the rules stipulated by the MoH.

## 2.4 Decision makers

The main decision maker in relation to the standards of medical treatment, list of medicines and medical devices, which are provided in- and out-patient, is the MoH.

## 2.5 Pricing

The basis for the state regulation of prices of medicines is set forth in the Law on Circulation of Medicines and Government Resolution "On the State Regulation of Prices of Medicines Included into the List of Essential and Most Important Medicines" No. 865 dated 29 October 2010 ("**Resolution 865**"), under which the price for medicines included into the list of essential and most important medicines ("**Essential Drug List**") is regulated and controlled by the state and is subject to state registration.

The Essential Drug List stipulates the medicines by their international non-proprietary name (the "**INN**") and medical form, and not by their trade names.

The current Essential Drug List was established by Government Ordinance No. 2199-r dated 7 December 2011, which was re-approved by Government Ordinance No. 2427-r dated 19 December 2013 for the calendar year of 2014.

The state regulation of prices of medicines included into the Essential Drug List is effected by the main following measures:

- (a) State registration of the maximum manufacturer's prices of medicines (which is affected at the federal level):

Such price is calculated on the basis of a methodology approved by the Government of the Russian Federation, which provides for an estimation of (i) average actual selling price, (ii) average actual importation price, and (iii) expenses for development, production and sale of medicines, indication of the minimum manufacturer's prices in the manufacturer's state and other states, where the medicine is registered, taking into account expenses for customs clearance and transportation.

When estimating maximum manufacturer's price, the following is also taken into account:

- in respect of a Russian manufacturer - the price for analogues (as regards their international non-proprietary name, dosage form and dosing) produced on the territory of the Russian Federation or, if there are no such analogues, the price for foreign analogues which are in circulation in the territory of the Russian Federation;
- in respect of a foreign manufacturer - the price for analogue (as regards their international non-proprietary name, dosage form and dosing) medicinal agents which are in civil circulation on the territory of the Russian Federation.

Duly registered maximum manufacturer's prices for medicines included into the Essential Drug List are indicated in the respective state register. Sale of medicines included into the Essential Drug List without above-mentioned state registration of their maximum manufacturer's price is prohibited.

- (b) Establishing maximum wholesale and retail trade margins applied to the prices of medicines (which is effected at the regional level):

Under the Law on Circulation of Medicines, Resolution No. 865 and Resolution of the Russian Government "On Measures for Improvement of the State Regulation of Prices (Tariffs)" No. 239 dated 7 March 1995, as amended, the maximum wholesale and retail trade margins for medicines included in the Essential Drug List are established by regional governmental authori-



ties according to the methodology approved by the Government of the Russian Federation.

Wholesalers and/or pharmacy organizations, individual entrepreneurs having a pharmaceutical activity license shall sell medicines included into the Essential Drug List at prices not exceeding the actual manufacturer's selling price (which shall not exceed the registered maximum manufacturer's price) and the amount of respective wholesale and retail trade margins established by regional governmental authorities.

Prices for other medicines, which are not included into the Essential Drug List, and medical devices are not regulated by the state.

### 3. PROVISION OF MEDICINAL PRODUCTS AND MEDICAL DEVICES TO PATIENTS

#### 3.1 Out-patients

The out-patient provision of medicines and medical devices is based on different state-run programs, the main of which are, in particular, the following:

- (a) Additional medicinal supply program, according to which certain categories of citizens specified by law (e.g. veterans, participants of World War II, disabled persons, etc.) receives certain medicines and medical devices free of charge.
- (b) Seven nosologies program, which is set up to supply expensive medicines for treatment of certain diseases (haemophilia, mucoviscidosis, hypophys-eal nanism, Gaucher's disease, malignant neoplasms in lymphoid, haematogenic tissues and other related tissues, disseminated sclerosis, and after-transplantation conditions). The current list of such medicines was adopted by the Russian Government Resolution No. 2053-r dated 31 December 2008.

#### 3.2 In-patients

Within the State Program in hospital settings the patients are guaranteed to receive free of charge medical aid; medicines included into the Essential Drug List; medical devices, blood components, aliment, including specialized aliment, based on medical indications according to the applicable standards of medical aid. It is also possible to receive medicines not included into the Essential Drug List in case of medical indications in order to substitute a medicine included into the Essential Drug List due to individual intolerance, on vital indications.

#### 3.3 Off-label use

Russian healthcare legislation does not provide for regulation of off-label use and regulates the supply of medicines in accordance with their approved indications.

#### 3.4 Measures Used to Control Healthcare Expenses

The main instrument controlling the expenses of the state (municipal) budget for purchases of medicines and medical devices is the Russian budget system, according to which all the purchases should be made within the budget provided.

Other instrument ensuring control is the contractual system in the sphere of state and municipal purchases. The state and municipal purchases of medicines and medical devices are performed in accordance with the Federal Law No. 44-FZ dated 5 April 2013 "On Contractual System of Purchases of Goods and Services for State and Municipal Needs" (the "**Law on Contractual System**"). The purchases of medicines are usually performed by their INN and in the form of open auctions in electronic form, where the bid with the lowest proposed price wins the auction.

The state regulation of prices also helps in controlling the healthcare expenses. Though the prices of medicines purchased in accordance with the Law on Contractual System are not specifically regulated, the general price regulation rules (please see section 2.6 above) applies for medicines purchased within the state/ municipal procurement as well (i.e. for the medicines included into the Essential Drug List purchased within the contractual system).

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## United Kingdom

### 1. SUMMARY OF THE PRICING AND REIMBURSEMENT SYSTEM IN THE UK

- Generally speaking, manufacturers enjoy freedom of pricing in respect of medicines and medical devices in the UK; however, there are numerous factors that will inevitably influence the price set by a manufacturer.
- Those factors include consideration of the "value" that will be attributed to a new product by the National Institute for Health and Care Excellence ("**NICE**"), the main Healthcare Technology Assessment ("**HTA**") body in the UK.
- The majority of medicines and medical devices are sold in the UK through the National Health Service ("**NHS**"), the State healthcare provider. Manufacturers typically sell medicines and medical devices to wholesalers, who sell the products on to pharmacists or hospitals; or products are sold directly to those pharmacists and hospitals by the manufacturer.
- Under the UK healthcare model, services and medicines are – subject to limited exceptions such as the prescription charge (explained below) – provided free to patients at the point of use.
- Another salient feature of the UK healthcare system is the limit on the total spends of the NHS on branded, prescription medicines via two schemes: one voluntary and one statutory. Where that spend is exceeded, manufacturers must pay a percentage rebate against their total sales.
- Those schemes also regulate the price at which certain medicines can be sold, as well as restricting the profits that can be made on sales to the NHS by pharmaceutical companies.
- Pharmacists receive a payment from the NHS as reimbursement for products dispensed to patients. The price paid by the NHS is governed by a number of factors, such as the nature of the medicine, and is either set out in the Drug Tariff (explained below) or is based on the price determined by the manufacturer on launch.

- Providers of secondary care (e.g. hospitals) may procure medicines either individually or through collaborative processes.
- For medical devices, freedom of pricing in primary care depends upon whether the device in question is listed in the Drug Tariff, and this will affect the price that is reimbursed to dispensers.
- As with medicines, the pricing of medical devices in secondary care is a matter of negotiation with manufacturers and/or wholesalers.

### 2. OVERVIEW OF THE UK HEALTHCARE SYSTEM

The UK healthcare market is one of the largest markets in the European Union ("EU") and worldwide. This section provides a brief overview of the key features of the UK healthcare system.

#### 2.1 The National Health Service<sup>1</sup>

Over 90% of healthcare in the UK is provided by the NHS, which is almost entirely funded from taxation and provides most services free at the point of use. In 2012/13, the budget for the NHS was around £108.9 billion.

Over 90% of medicines dispensed in the UK are paid for by the NHS, although patients in England are, subject to some exemptions, required to make a contribution towards the cost of their medicines.<sup>2</sup>

Alongside NHS services, nearly seven million people have private health insurance; however, these policies

<sup>1</sup> The provision of healthcare in the UK is devolved to the governments of the constituent nations of the UK, namely Northern Ireland (through Health and Social Care in Northern Ireland); Scotland (NHS Scotland); and Wales (NHS Wales). The UK Government has responsibility for the English NHS. References in this note are to the NHS in England unless otherwise specified or where specific mention of the other nations of the UK is made. There are differences in the other jurisdictions that are not addressed in this chapter.

<sup>2</sup> As at 1 April 2013, this payment (called the "prescription charge") was set at £7.85 per prescribed item. There are, however, exemptions for certain patients, such as those suffering from cancer or those in receipt of specified state benefits. There are separate arrangements in place for the rest of the UK.

provide only healthcare benefits (normally in secondary care) and do not typically cater for pharmaceutical or device benefits. Whilst a small number of prescriptions are written and dispensed privately, the details set out below apply only to those medicines dispensed under the NHS, except where otherwise indicated.

The NHS is undergoing major changes in its structure in England pursuant to the Health and Social Care Act 2012, with the majority of those reforms having taken effect on 1 April 2013. These changes are intended to result in NHS services opening up to competition from providers that meet NHS standards on price, quality and safety. Providers will be regulated by a new regulator called Monitor (charged with regulating providers of health and adult social care with the aim of promoting competition, regulating prices and ensuring continuity of services). In addition, local authorities will take on a bigger role, assuming responsibility for budgets for public health.

The basic division between primary care providers (ie general practitioners ("**GPs**"), pharmacies and related services that patients can access directly) and secondary care providers (i.e. hospitals, specialists and others, which patients can generally only access indirectly by referral from a primary care provider) will remain. Set out below is an overview of the principal bodies, and their roles, under the new system.

#### **(a) The Secretary of State for Health and the Department of Health ("DoH")**

The Secretary of State has ultimate responsibility for the provision of health services in England. The duty to ensure the promotion of a comprehensive health service in England is enshrined in primary legislation (see section 1(1) of the National Health Service Act 2006). The DoH oversees health and social care systems, for example by setting national policy, securing resources and managing relationships throughout the health and care system. In the context of medicines, responsibilities include the negotiation with the pharmaceutical industry of the Pharmaceutical Price Regulation Scheme ("**PPRS**") (as to which, see below) and the setting of prices for certain generic medicines and medical devices (and related services) under the Drug Tariff (explained below). The DoH also has strategic responsibility for the NHS Commissioning Board (see below), Monitor and the Care Quality Commission ("**CQC**") (the independent regulator of health and social care services in England).

#### **(b) The NHS Commissioning Board (known as NHS England)**

NHS England has overall responsibility for, amongst other things, commissioning primary care services. It has direct responsibility for commissioning pharmaceutical services (the dispensing of drugs and appliances and related "specialised services", which cater for adults and children who suffer from very rare conditions, covering, for example, orphan and ultra-orphan drugs) from pharmacies and dispensing appliance contractors ("**DACs**"). It also oversees and supports commissioning of secondary care services by clinical commissioning groups ("**CCGs**").

#### **(c) CCGs**

CCGs replace organisations such as primary care trusts ("**PCTs**") and strategic health authorities, which were primarily responsible for ensuring adequate primary and secondary healthcare provision, but have now been abolished. CCGs have taken on many of the functions of PCTs, as well as some functions previously carried out by the DoH in respect of commissioning secondary care services. Each GP belongs (together with other health professionals, such as nurses) to a CCG. CCGs can commission any service provider that meets NHS standards and costs. These can be NHS hospitals (operated by NHS Foundation Trusts – see below), social enterprises, charities, or private sector providers. However, they must be assured of the quality of services they commission, taking into account both the guidelines of NICE, and the CQC data about service providers.

#### **(d) NHS Foundation Trusts**

These are independent legal entities, created with the purpose of devolving decision-making from central government. They are responsible for providing and developing healthcare in local communities (including hospital services) and have freedom to set their own strategy, including by retaining their surpluses and borrowing and investing in new services. Local people can become members and governors of Foundation Trusts. According to NHS England, it is expected that all NHS trusts will become Foundation Trusts by 2014.

#### **(e) NICE**

NICE is the UK's principal HTA body (although, strictly speaking, its remit only extends to England and Wales). NICE was founded in 1999 with the intention of providing guidance to the NHS on the correct adoption of health technologies (medicines and devices) and also to provide guidance on clinical practice (treatment for patients with specified conditions and diseases). Since 2005, NICE has also had responsibility for certain public health functions previously exercised by the Health

Development Agency and, since April 2013, NICE has been responsible for providing guidance for those working in social care. Pharmaceutical and device companies are principally interested in NICE's technology appraisals and clinical guidance functions. Details of NICE's technology appraisals and how these affect pricing are discussed below.

## 2.2 Distribution and dispensing of medicines and devices

The market for the distribution of pharmaceuticals and devices is highly concentrated: the three leading wholesaling distributor chains in the UK have a combined market share of approximately 90%. Generic medicines account for approximately 29% of the market for pharmaceutical and biotech products, measured by value.

In the primary care setting, medicines and medical devices are dispensed in the community through approximately 12,600 pharmacies and 5,800 dispensing doctors, as well as a small number of DACs, who may only dispense certain medical devices. Whilst each dispensing pharmacy is a stand-alone provider, approximately 61% of pharmacies in the UK are part of local, regional or national chains.

As explained further below, secondary care providers may procure medicines and devices independently, collectively or through the Commercial Medicines Unit (the "CMU") (part of the Medicine, Pharmacy and Industry Group of the DoH). Those products may then be dispensed to patients by secondary care providers as appropriate.

## 2.3 Key legislative provisions

The legislation governing medicines in the UK includes the Medicines Act 1968, which has been amended several times, most notably in response to Directive 2001/83/EC (as amended), and the Human Medicines Regulations 2012. Medicines are divided into three categories<sup>3</sup>:

- prescription-only medicines, which must be prescribed by GPs or other suitably qualified healthcare professionals;
- pharmacy medicines (available without a prescription, but under the supervision of a pharmacist); and
- general sales list (GSL) medicines, sometimes referred to as "over-the-counter" ("OTC") medicines.

<sup>3</sup> See, e.g., reg. 5 of the Human Medicines Regulations 2012.

Medical devices are principally governed by the Medical Device Regulations 2002 (as amended).

There are numerous other regulations governing such matters as the advertising, wholesale distribution and retail sale of medicinal products.

The National Health Service Act 2006 (as amended) and the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 regulate the commissioning by NHS England of pharmacies, dispensing doctors and DACs to provide pharmaceutical services. Those Regulations also prescribe the terms of service for those organisations and establish the Drug Tariff, which sets out the reimbursement and remuneration to be paid to pharmacies, dispensing doctors and DACs that dispense certain medicines and medical devices.

One of the key features of pharmaceutical regulation in the UK is profit control of companies that supply branded medicines to the NHS. These restrictions are embodied in the statutory Health Service Branded Medicines (Control of Prices and Supply of Information) (No 2) Regulations 2008 (as amended). However, those regulations do not apply to manufacturers who participate in the voluntary PPRS<sup>4</sup> (and it is, in fact, the PPRS that covers the majority of branded medicines). New versions of both these schemes – which are explained in detail below – apply from 1 January 2014 inclusive.

## 3. PROVISION, PRICING AND REIMBURSEMENT OF PHARMACEUTICAL PRODUCTS

Broadly speaking, following the granting of market authorisation<sup>5</sup>, manufacturers enjoy freedom of pricing for their products (although the level at which that price is set will be shaped by other factors such as, in the case of generic medicines, the Drug Tariff, as well as by NICE's assessments and parallel imports<sup>6</sup>). Medicines are sold by manufacturers either to wholesalers or directly to pharmacists and secondary care providers, which then dispense medicines to patients.

Primary care providers such as pharmacists receive a payment from the NHS as reimbursement for the product dispensed, together with remuneration for any related services provided. As explained further below, the

<sup>4</sup> See sections 262(2) and 263(7) of the National Health Service Act 2006, and reg 2(3) of the Health Service Branded Medicines (Control of Prices and Supply of Information) (No 2) Regulations 2008.

<sup>5</sup> Marketing authorisation can be granted by the national body, the Medicines and Healthcare Products Regulatory Authority, for use in the UK, or through the European Medicines Agency (under the "centralised procedure") for use in the EU.

<sup>6</sup> The UK Parallel Import Licensing Scheme allows medicinal products authorised in other EU Member States to be marketed in the UK, provided the imported products have no therapeutic difference from their UK equivalent.

price paid by the NHS depends upon the nature of the medicines dispensed (e.g. branded or generic). For example, for generic medicines, the price paid by the NHS to prescribers is generally determined by the Secretary of State and set out in the Drug Tariff. For products not listed in the Drug Tariff, such as proprietary medicines, the price paid to dispensers is based on the "list price", that is, the price of the product as determined by the manufacturer.

Secondary care providers such as hospitals can be supported by the CMU or act independently or collectively in the procurement of both branded and generic medicines for use in secondary care.

### 3.1 Branded prescription medicines<sup>7</sup> in primary care

The manufacturer generally has the freedom to set any price for the product; this is the price that will be reimbursed to the pharmacist (or dispensing doctor) by the NHS.

Under the traditional wholesale model, manufacturers sell prescription medicines to wholesalers at the list price less 12.5%; this is intended to provide the wholesaler with a reasonable distribution margin. Wholesalers then compete on price to become a pharmacy's main supplier of medicines.

The Office of Fair Trading (the UK's consumer and competition authority) found, in its 2007 report on the distribution of medicines in the UK<sup>8</sup>, that wholesalers retain an average distribution margin of 2% (i.e. selling to pharmacies at a 10% discount from the list price).

There also exists a "clawback" mechanism, which allows the NHS to share the profits made when pharmacies purchase medicines at a price below that which they are reimbursed by the NHS. It is understood that, for 2013, the level of permitted profit that independent pharmacies can make nationally is set at £500m. Clawback operates where this cap is exceeded, and, as a result, the NHS can effectively pay less than the list price for branded medicines. Clawback can also apply to branded generics and generic medicines. The DoH works in consultation with the Pharmaceutical Services Negotiating Committee (PSNC) to measure the discounts obtained by conducting a survey of a sample of pharmacies.

<sup>7</sup> I.e., medicines bearing the name given to them by the manufacturer that developed them and available only upon prescription by a doctor or other healthcare professional.

<sup>8</sup> [http://www.offt.gov.uk/shared\\_offt/reports/comp\\_policy/oft967.pdf](http://www.offt.gov.uk/shared_offt/reports/comp_policy/oft967.pdf)

In recent years, there have been a number of significant derogations from the traditional wholesaling model, with some companies only selling to a limited number of wholesalers and other manufacturers adopting a "direct to pharmacy" ("DTP") model. Under DTP schemes, manufacturers sell direct to pharmacies and appoint one or more logistic service providers ("LSPs"), which are paid a fee to deliver medicines to pharmacies. Wholesalers then compete to become a manufacturer's appointed LSP.

A relatively small number of GP practices (dispensing practices), almost exclusively in rural areas, are authorised to dispense prescription medicines to their patients as well as prescribe them. Sales of prescription medicines by manufacturers to dispensing practices are made at the NHS price, although it is common for manufacturers to offer significant (usually individually negotiated) discounts to such dispensing practices.

### 3.2 The role of the Pharmaceutical Price Regulation Scheme

The PPRS is a voluntary scheme agreed between the Government (through the DoH) and the pharmaceutical industry (through the Association of the British Pharmaceutical Industry ("ABPI")). The PPRS applies to all branded, licensed medicines available on the NHS. The new PPRS scheme (the "2014 PPRS") applies from 1 January 2014 until 31 December 2018 (inclusive). There is an alternative statutory scheme – the Health Service Branded Medicines (Control of Prices and Supply of Information) (No 2) Regulations 2008 (as amended) – that governs those manufacturers that choose not to participate in the PPRS. An amended version of the statutory scheme enters into force on 1 January 2014.

The key aim of the 2014 PPRS is to keep the NHS total spend on branded drugs flat until the end of 2015, with subsequent comparatively small increases until 2018.

The main features of the 2014 PPRS are set out below.

#### (a) The rebate (known as the "PPRS Payment Mechanism")

One of the stated purposes of the 2014 PPRS is to "provide Government with surety on the level of NHS expenditure on branded health service medicines purchased by the NHS from members of the [PPRS]"<sup>9</sup>. Thus, whereas under the previous scheme (the "2009 PPRS") there was no upper limit on NHS expenditure on branded medicines, the 2014 PPRS provides that the growth rate of NHS spending on branded medicines will be capped as follows:

<sup>9</sup> See paragraph 6.1 of the 2014 PPRS.

- The permitted increase in expenditure on branded medicines as compared to the previous year (the so-called "Allowed Growth Rate of Measured Spend") will be set at 0% for the first two years, increasing to just under 2% for years three to five.
- The actual NHS expenditure on branded medicines at current prices is forecast to increase year-on-year by between 2.14% and 3.87% over the lifetime of the 2014 PPRS.
- To compensate for the difference between the allowed growth rate and the actual growth rate, participants in the scheme will, subject to certain exemptions, be required to make quarterly payments (called "**PPRS payments**") in arrears to the DoH. The first payment is set at 3.74% of net sales, with this percentage to increase to an estimated 7.13% for year two and 9.92% for years three to five, although these percentages will be adjusted based on the actual spend in each year.

Companies with sales of less than £5 million in the previous year will be exempt from these payments. Sales of new products (that is, products introduced to the market after 31 December 2013 after receiving marketing authorisation) will be excluded from the sales used to calculate the PPRS payments owed by each company.

#### **(b) New products: pricing and the role of NICE**

Upon the launch of a new product, companies remain free under the 2014 PPRS to set the list price at their discretion. However, "*[i]t is assumed that prices at launch will be set at a level that is close to [the product's] expected value as assessed by [NICE]*"<sup>10</sup>.

NICE's assessments occur through "technology appraisals", which are recommendations on the use of new and existing medicines and treatments within the NHS in England and Wales. These cover both medicines and medical devices. The recommendation is based on:

- clinical evidence (how well the medicine or treatment in question works); and
- *economic* evidence (how well the medicine or treatment works in relation to how much it costs the NHS).

NICE conducts "single technology appraisals" (covering a single technology for a single "indication"<sup>11</sup>) and "multiple technology appraisals" (covering more than one technology, or one technology for more than one indication), as well as "highly specialised technologies" (HST)

evaluations, which consider treatments for very rare conditions. The manufacturer or sponsor of the technology is invited to provide evidence as part of these processes. NICE also invites all non-manufacturer consultants to submit a statement on the potential clinical and cost-effectiveness of a treatment.

The results of those appraisals are key to manufacturers: they are not merely highly influential both in the UK and internationally, but the NHS is under legal obligations to fund and resource medicines and treatments recommended by NICE for use by the NHS (although the precise scope and strength of the so-called "right to drugs" is somewhat uncertain).

Contrary to the Government's previously stated expectation, NICE will not play a role in the setting of prices. NICE will, however, "*undertake all elements of assessment for a broader definition of value*" in line with a system of "value-based pricing" (VPB).

It is understood that NICE's "broader" assessment of value will encompass an analysis of wider societal benefits (WSBs) and burden of illness (BoI) in the assessment of quality adjusted life years (QALYs), the method currently used by NICE to produce its technology appraisals. Manufacturers will need to take this into account when setting prices in order to secure a NICE recommendation, which is, in practice, critical to the success of drugs.

While the Government has issued broad terms of reference on the conduct of such assessments, NICE is expected to carry out a full public consultation prior to implementing methods for implementing the terms of reference in autumn 2014.

#### **(c) Fixed, yet flexible, pricing for existing products**

The principle of "flexible pricing", introduced in the 2009 PPRS, will continue to apply<sup>12</sup>. Companies will be free to increase or decrease the original list price of products where either:

- there is significant new evidence that changes the value of an existing indication; or
- a major new indication is proposed.

This will only apply, however, to medicines subject to a NICE appraisal, and NICE will conduct a review to determine whether the proposed new price provides value

<sup>10</sup> See paragraph 7.14 of the 2014 PPRS.

<sup>11</sup> I.e., the purpose for which the medicine is used.

<sup>12</sup> That said, it is highlighted in the 2014 PPRS that no applications were received under the flexible pricing mechanism within the 2009 PPRS and it is noted that, in light of this, the proposals contained in the 2014 PPRS may need to be reviewed in the future if, for example, there are no applications under the 2014 flexible pricing provisions.

to the NHS (as above, how "value" is actually assessed is not yet certain).

Subject to the DoH's agreement, companies will also be able to "modulate" prices; that is, increase the list price of certain products provided there is an equivalent decrease across the wider portfolio, and on the condition that there is no overall impact on the NHS (taking appropriate account of the discounts often applied in the secondary care setting).

Manufacturers will still be able to agree Patient Access Schemes with the DoH (with input from NICE) in order to improve the cost-effectiveness of a particular drug with the aim of enabling a positive NICE recommendation where this may not yet have been forthcoming based on available evidence.

#### (d) Profit controls

The profit controls, introduced by the 2009 PPRS will, with some adjustments, remain in place. In particular, the allowable "Return on Capital" ("**ROC**") and "Return on Sales" ("**ROS**") targets<sup>13</sup> will be capped and associated with "margins of tolerance" (to be increased from 40% to 50%). This means that, if the scheme member's assessed profit exceeds the ROS or ROC target by more than 50%, it will be required to repay the excess or reduce prices by an equivalent amount.

The limits on profit are also linked to pricing outside the flexible pricing regime described above. If a scheme member's profit is more than 50% below the ROC or ROS target, then it will be entitled to apply for a price increase. Conversely, no price increase will be granted unless the scheme member's estimated and forecast profits for the current and following financial years are below the 50% ROS or ROC target.

### 3.3 The statutory scheme

Companies that do not participate in the PPRS are governed by the statutory scheme under the auspices of the Health Service Branded Medicines (Control of Prices and Supply of Information) (No 2) Regulations 2008 (as amended), which is understood to apply to around 10% of branded medicines. Like the PPRS, an amended statutory scheme applies from 1 January 2014<sup>14</sup>. The amended scheme introduces a 15% price cut on branded medicines sold by companies governed by that scheme, removes the exemption on price ad-

justment in relation to products costing no more than £450,000 in a calendar year, and sets an exemption from the provision of information and from price adjustments for companies whose sales of branded medicines are less than £5 million in a given year.

### 3.4 Generic medicines in primary care

The reimbursement price for generic medicines (as well as for those drugs which are not readily available as generic, in which case the price will be based on a particular proprietary product) is determined by the Secretary of State and published in the Drug Tariff. The prices are set out in one of three categories in part VIIIA of the Drug Tariff. Of those categories, two – categories A and M – govern the prices of commonly prescribed generics; Category C covers drugs which are not readily available as generics.

Part VIIB of the Drug Tariff sets out the prices of "special and imported unlicensed medicines".

The manner in which the price set out in the Drug Tariff is calculated depends on the category/Part under which the medicine is listed. For example, for category A in Part VIIIA, the price is determined based on the weighted average of the price of four particular manufacturers for the pack size listed in the Drug Tariff. For category M, the price is based on "information submitted by manufacturers".

### 3.5 OTC medicines in primary care

OTC medicines can be sold by pharmacies, supermarkets and other retail outlets without the supervision of a pharmacist. They are sold to retailers at a price agreed between the manufacturer (or wholesaler) and the retailer, and prices can vary widely (the minimum price of OTC products was previously set by manufacturers under the Retail Price Maintenance scheme; however, this was abolished, for OTC medicines, in 2001).

### 3.6 Unlicensed medicines

The general freedom of prescribers to prescribe any product in the UK extends to unlicensed medicines<sup>15</sup> (which prescribers can prescribe, although they do so at their own personal risk). Restrictions do apply, however, in the case of products which appear on the so-called "Blacklist" or the "Selected List Scheme".

- (a) The Blacklist is officially those drugs, medicines or other substances found in Schedule 1 to the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc) Regulations

<sup>13</sup> Which target applies to the scheme member depends on the extent to which its sales exceed the capital employed (see paragraph 8.12 of the 2014 PPRS). As at December 2013, the ROS target is set at 6% of sales per year, with the ROC target being set at 21% per year.

<sup>14</sup> The changes will be implemented through the Health Service Medicines (Control of Prices and Supply of Information) (Amendment) Regulations 2013.

<sup>15</sup> I.e., medicines that are used outside the terms of their UK licence or which have no licence/marketing authorisation for use in the UK.

2004 (which also features as a list published in Part XVIII A of the Drug Tariff). Products that appear on the Blacklist cannot be prescribed on NHS prescriptions. If such a prescription is dispensed, then NHS Prescription Services will refuse to refund the cost to the dispensing pharmacy. Certain branded medicines on the Blacklist can be dispensed against prescriptions for generic drugs, if the approved generic name is not itself on the Blacklist.

- (b) The Selected List Scheme is found in Schedule 2 to the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc) Regulations 2004 (see also Part XVIII B of the Drug tariff) and relates to drugs and medicines that may only be ordered in certain circumstances and for certain conditions. Prescriptions must be marked "SLS" by the prescriber.

### 3.7 Provision of medicines in secondary care

As set out above, providers of secondary care can purchase medicines in a number of ways, including in co-operation with the CMU. In this context, orders can be placed direct with suppliers and many medicines are received direct from the manufacturer.

The PPRS is also relevant in the secondary care context in that the profit restrictions set out therein apply to all sales of branded medicines to the NHS (i.e. covering primary and secondary care sales). Where price modulation is implemented by scheme members, the DoH will monitor that company's modulations to ensure that the required price neutrality is delivered across both primary and secondary care.

## 4. REGULATION OF MEDICAL DEVICES

The freedom of manufacturers to set prices of medical devices carrying a CE mark in the UK is dependent upon whether the device in question is listed in Part IX of the Drug Tariff. Where the device is listed, the reimbursement price is set out in the Drug Tariff; otherwise, the manufacturer is free to set the price at its discretion. For certain medical devices covered by the Drug Tariff, reimbursement amounts will be determined by the NHS Prescription Services Authority.

Part IX of the Drug Tariff covers medical devices falling into four classes:

- A: dressings, bandages and certain other devices;
- B: incontinence devices;
- C: stoma devices; and
- R: chemical reagents.

If a manufacturer wishes a product falling within the Part IX categories to be included in the Drug Tariff, an application must be made to NHS Prescription Services. If accepted, the "entry price" for that product will be determined by NHS Prescription Services, primarily on the basis of the price of other similar products, although the manufacturer is entitled to make representations as to why the price should be different. The manufacturer may also apply annually for a price increase. The NHS has published detailed guidance on the application process.

Products falling within the four classes set out in the Drug Tariff classes must meet any relevant technical specification set out in Part IX. Demand for any device not fulfilling the relevant specification, or costing more than the mandated price, will be virtually nil as the patient would need to pay for it privately.

Such medical devices may be dispensed on prescription by pharmacies, dispensing doctors or DACs. The price at which those "retailers" purchase products from manufacturers (or wholesalers) is a matter of negotiation between those parties, although is significantly influenced by the reimbursement price set out in the Drug Tariff. In practice, many DACs in the UK are associated with a particular manufacturer of medical devices.

The Drug Tariff also sets out the remuneration to be paid to pharmacies, dispensing doctors and DACs in respect of the dispensing of prescriptions, as well as other services related to the appliances in question.

Secondary care providers may source medical devices from manufacturers, wholesalers, or the NHS Supply Chain (a joint operation between the NHS and DHL Logistics). Prices for supply of relevant products will be a matter of negotiation, although secondary care providers may need to take account of laws relating to procurement in certain circumstances.

### Other Medical Devices

In principle, the sale of any device not falling under the Drug Tariff is a contractual matter between the seller and the NHS Trust in question; however, a good deal of guidance is available to NHS Trusts regarding procurement in the NHS and it would be normal for such Trusts to follow this guidance. In addition, purchase of items whose cost exceeds a certain threshold (currently £113,057) fall within the EU requirements for Public Procurement (most notably usually involving a competitive tender process) and companies selling high value items should be aware of these requirements.



## 5. FUTURE DEVELOPMENTS

The full impact of both the 2014 PPRS and the statutory scheme on pharmaceutical manufacturers remains to be seen.

Perhaps of greater long-term significance, however, will be NICE's consultation on its value assessment. In particular, much will depend on how exactly that mechanism functions, and whether this truly allows issues such as wider societal benefit to form part of the assessment of new and existing products. Indeed, manufacturers will perhaps see the upcoming NICE consultation as a real chance to shape the meaning of "value" in the UK healthcare market.

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