Accessibility

Accessibility refers to physical access to the products, or where the products can be delivered to people. It involves the overall organisation of the health system and especially, its procurement, supply and dispensing systems. In order to embrace the notion of access to treatment, accessibility in this publication is also understood as encompassing factors such as access to prescribers and proper education and information about the products.

Affordability

Affordability refers to a product's cost vs. the ability and willingness of people (as well as health systems and third-party payers) to pay for it. Affordability entails a product's price components (manufacturing, supply, taxes, mark-ups), as well as policies and other factors that affect these components – such as pricing and reimbursement policies, intellectual property and competition laws, regulatory standards and requirements.

Availability

Availability is defined as the presence in a country of products that meet the population's health needs. It refers to the range of products marketed in a country; which of them are selected by the health system; and how and according to which indications and guidelines they should be prescribed and delivered.

Chronic disease

Chronic diseases are health conditions of long duration and generally slow progression, such as diabetes, cardio-vascular and respiratory diseases or cancer. They are the leading cause of mortality worldwide.

Co-payment

Type of cost-containment mechanism where the cost of healthcare is shared between the health system and the patient. The co-payment amount is set by the insurance or health system and is paid by the patient each time a medical service is accessed. It can be defined either as a fixed amount or as a proportion of the cost per service. Apart from its financial implications, the implementation of co-payment has a regulatory effect on demand for healthcare.

Coverage

Coverage refers to the financial protection offered by the health system to the population through the financing of certain health services or products.

Diabetes education

An inclusive process involving people with diabetes, their carers and families, that aims to provide the tools, skills and knowledge they need to adapt behaviour and effectively self-manage their condition(s). Good self-management improves people with diabetes' health status and quality of life - reducing the need for healthcare interventions.

EU laws on medical devices

Medical devices, like all other goods, are subject to EU competition and trade rules under the single market. The EU has set harmonised standards for intellectual protection of medical device innovation. In order to bring a medical device onto the EU internal market, a set of rules and standards must be followed, which are defined at the EU level, regarding the quality and safety of the device. These standards and rules vary according to the risk classification of the device. However, the implementation of these rules and the certification of individual devices depend on Member States – through designated national institutions in charge of monitoring compliance and enforcing these rules - and to a lesser extent, on manufacturers themselves. This has resulted in uneven implementation of EU standards and rules. To improve safety and surveillance, and level the implementation of EU norms, the EU legislative texts which regulate the standards and certfication of safety, quality and efficiency of medical devices (i.e. Medical Devices Directives and Regulation) are currently being revised.

Source: personal communication with EUCOMED, (European medical technology industry professional organisation). EUCOMED 2013.

EU laws on medicines

Although healthcare remains the competence of EU Member States, a number of aspects of pharmaceutical policies depend on EU laws. The EU has set harmonised standards for intellectual protection of innovations in all sectors including pharmaceuticals; and discussions are on-going to foster cooperation in this field. Marketing authorisation for specific categories of medicines – such as diabetes drugs – is centralised in the hands of the European Medicines Agency; which assesses the safety, efficacy and quality of medicines. The Agency is also responsible for a number of safety-monitoring activities on marketed medicines. Although pricing and reimbursement policy is a national competence, national legislation and procedures have to comply with the EU Transparency Directive, which aims to ensure transparent national decision-making in this field to prevent disruptions in the single market. The supply of medicines must comply with the regulatory, quality and control criteria defined in the EU Directive on medicinal products for human use.

Sources: "Central authorization of medicines", 2013; Vogler, S. et al., 2011, Southern Med Review; Personal communication with professional organisations: EFPIA (European Federation of Pharmaceutical Industries and Associations), 2013; GIRP (European Association of Pharmaceutical Wholesalers), 2013

European Economic Area (EEA) Agreement

This agreement brings together the EU Member States and three countries of the European Free Trade Association (Iceland, Norway and Liechtenstein) in a single market, referred to as the 'internal market'. All EU legislation relating to medicines and medical devices is covered under the EEA Agreement. As such, all Member States of the European Economic Area have harmonised their regulatory frameworks and authorisation procedure for medicines and medical devices.

Health Technology Assessment (HTA)

This process evaluates the medical, social, economic and ethical issues related to the use of a health technology, to provide objective evidence to health policy-making.

Household Net Adjusted Disposable Income

This indicator developed by the OECD represents the amount of money a household earns - and can spend on goods and services - per year minus taxes. For further information about this indicator, visit the OECD Better Life Index. http://www.oecdbetterlifeindex.org/

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Mandatory Health Insurance

This is a type of health system where healthcare costs are covered by health insurance schemes. Enrolment and contribution to such a scheme or schemes is compulsory for the population. Mandatory health insurance systems are generally characterised by the separation of healthcare provision and healthcare financing functions: health insurance schemes act as purchasers of health services from public and/or private providers.

Mutual recognition agreements

Bilateral agreements between the EU and a third country that aim at facilitating market access through preferential access to conformity assessment and certification.

National Health System/Services

This type of health system is generally characterised by public provision of health services to the whole population, mostly free-of-charge at the point of care and financed by government general revenue (mainly taxes).

Non-branded products

In this publication, non-branded products refer to products that share similar characteristics with a product already on the market (the original or branded product) and so, may be to some extent, substitute it. It includes generics, biosimilars or "me-too" products.

Out-of-Pocket Expenditure

Health-related payment made by a person on its own resources - i.e. an expenditure which is not covered or reimbursed by a third party payer like a health insurance.

Parallel Trade

Form of trade where goods and products are traded from one market to another without the consent of the original manufacturer or supplier. It is lawful in the EU under the principle of free movement of goods in the single market. Barriers or restrictions on such a trade are prohibited by EU treaties. However, some restrictions may be justified and authorised under EU law to protect health and life.

Pharmacoeconomic Analysis or Pharmacoeconomics

The description and comparative analysis of the value of a health product based on its cost versus its effects or benefits to healthcare systems and society.

Prevalence (national/comparative)

This is the proportion of people affected by a certain condition at a given time in a population. In this publication we make a distinction between national diabetes prevalence (also called current prevalence) and comparative diabetes prevalence (or age-standardised prevalence). National diabetes prevalence represents the share of the population that has diabetes in each country. Comparative diabetes prevalence assumes that all countries in the region share the same age profile for a better comparability of the data. All national and comparative prevalence estimates were retrieved from *IDF Diabetes Atlas, 5th Ed*.

Private Health Expenditure

This type of expenditure covers all health spending from private entities, such as private voluntary insurance corporations, the voluntary sector or households (i.e. out-of-pocket payments).

Procurement

The process of acquiring or purchasing services or goods from an external source. In the current publication, it concerns the purchasing of medical products from manufacturers or suppliers. Public procurement is the procurement of goods and services on behalf of a public authority, such as a government agency. To prevent fraud, the law of most countries regulates government procurement more or less closely.

Public Health Expenditure / Government Health expenditure

This type of expenditure covers all health spending from public bodies, i.e.government, regional or local authorities, national health insurance funds or social security schemes.

Quality Issues Reporting System

The structure, frameworks, procedures and resources that aims at identifying, reporting and addressing medical products that fail to meet national and/or regional standards.

Reference pricing (external/internal)

Reference pricing is a price setting tool mostly applied to medicines. Two types of reference pricing can be distinguished. External reference pricing consists in setting the price of a specific medical product according to the price of that same product in other countries. Internal reference pricing sets the price or maximum reimbursement level of a medical product according to those applied to products classified in the same category or considered similar. Both types of reference pricing may be combined or used separately. Additionally, they can be both implemented using a range of different methodologies (including median, average, or lowest price....).

Regressive mark-up scheme

Regressive mark-up schemes are a way to regulate the charges, costs and profits suppliers and retailers add to the price of medical products. Under such a scheme, mark-ups are capped according to a regressive scale: the higher the price, the lower the mark-up.

Rural

In the context of this publication, rural is defined according to the distance to a healthcare professional; any person with diabetes living over 5 km from a practicing doctor and/or pharmacy is considered here as rural.

Substitution

Replacement of a product by another one classified as equivalent. However, equivalence criteria used in such a classification may vary from one health authority to another.

Tender

Tenders are a type of procurement procedure where suppliers are selected based on the quotations they submitted to the competent authority, further to its call for bids. Supply contracts are awarded to the applicant or applicants who submitted the offer that respond best to the criteria set by the authority.

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