

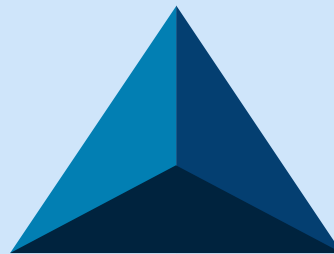
Drug Value & Market Access Optimization

*“Finding
New & Better
Avenues”*

From Drug Cost
to Payer Valuation
- **How to get the best value?** -

Excerpts

June 2016



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The complete report can be ordered at: jimpeny@smart-pharma.com (+33 6 11 96 33 78)

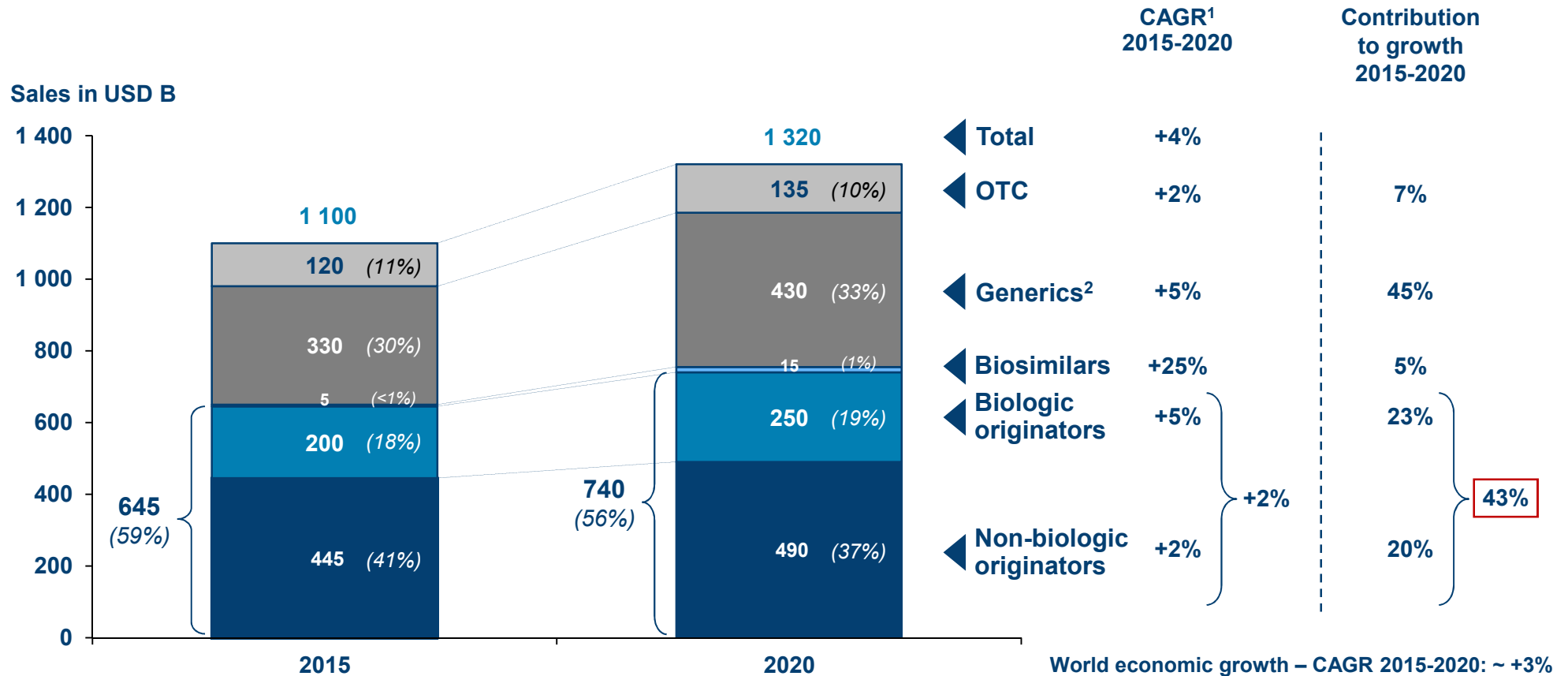
The purpose of this report is to provide key information and robust analyses to better optimize drug valuation, from the pharmaceutical companies perspective

Context & Objective

- To slowdown the increase of healthcare expenditure, governments and public or private payers implement a large array of cost-containment mechanisms
 - Drugs are particularly affected by these measures, which include:
 - Drug prices control and regulations to favor the prescription of cheaper products like generics and biosimilars
 - Capping of the prescribed volumes
 - Selective reimbursement of drugs (e.g. limitation to a subset of patients or to the most severe cases)
 - However, the way these measures are applied does not allow governments and payers to guarantee access to innovation to the largest number of patients
 - Thus, governments and payers have no choice but to increase their pressure on drug prices and “force” pharma companies to accept affordable prices
- In this context, the following questions must be raised:
 - What is the value of innovative drugs for the community?
 - What is a fair price for pharmaceutical companies?
 - This report reviews:
 - The economic and healthcare environment
 - The R&D cost of drugs
 - The drug pricing strategic approaches of pharma companies, governments and payers
 - The health economic evaluation methods
 - The market access processes in selected countries
 - The best practices in market access
 - The ways to leverage the corporate reputation of pharma companies
 - Smart Pharma Consulting proposes new thoughts likely to help pharma companies to optimize the valuation of their drugs

Sales of original drugs should keep on growing significantly by 2020, contributing to 43% of the global pharma market growth

Global pharmaceutical market growth by segment (2015 – 2020)



Sources: Nicholas Hall's OTC Yearbook 2015 – IMS World Review Executive 2015 – United Nations: World Economic Situation and Prospects 2016 – Smart Pharma consulting estimates

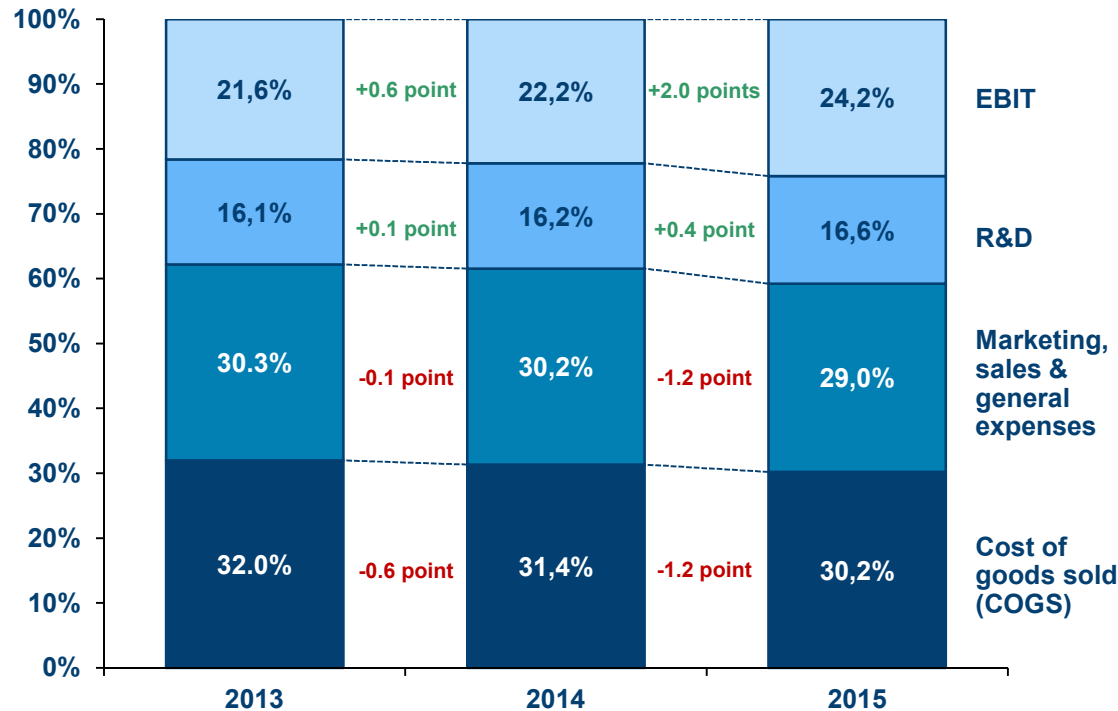
¹ Compound annual growth rate — ² Including branded and unbranded generics, excluding OTC

Among the top 30 pharma companies, the trend goes toward an increase of the EBIT and of the R&D expenses while sales and manufacturing costs are slightly decreasing

Evolution of the top 30 pharma cost structure (2013 – 2015)

Cost structure as a percentage of total revenues¹

Weighted average of total revenues



- The analysis of the top 30 pharmaceutical companies in the world shows that their average profitability has increased by 2.6 points between 2013 and 2015
- This improvement can be explained by the restructuring of their product portfolio in which the weight of high priced secondary care products has been increasing
- Besides, the marketing and sales investment for these specialist-driven secondary care products is much lower than for GP-driven primary care products
- Restructuring and streamlining initiatives have also contributed to improve the economic performance of these companies
- These good performances are the Achilles heel of pharmaceutical companies when negotiating price and reimbursement of their drugs with governments and payers

Note: panel of the 30 biggest pharma companies in terms of prescription sales as of 2014

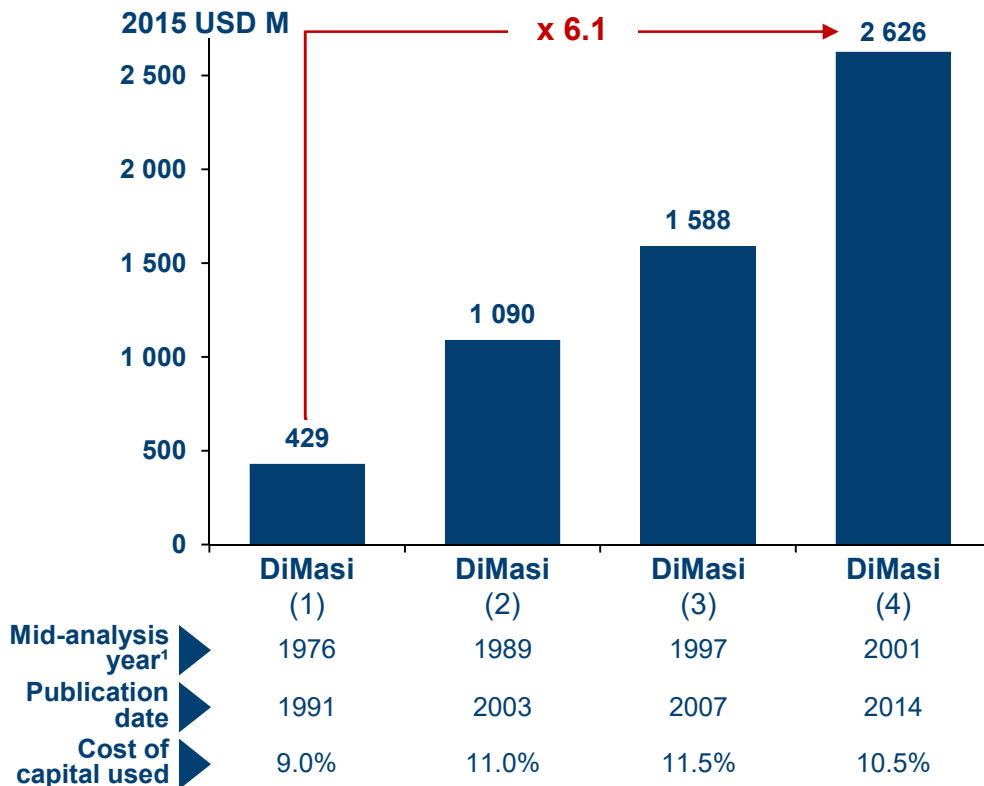
Sources: Companies annual reports – Federal Reserve annual exchange rates – Smart Pharma Consulting estimates

¹ Excluding Astellas, Daiichi Sankyo and Takeda for 2015, which have not published financial results at the moment of the study (due to their fiscal years ending in March) – Excluding for 2015 Actavis which merged with Allergan – Excluding Servier over the whole period for not publishing financial results and Boehringer Ingelheim for publishing non-standardized financial results

The analysis of four studies carried out with the same methodology, shows that the development cost of new drugs has more than sextupled over the last three decades

Evolution of R&D costs

Estimated capitalized cost per approved new drug (pre-tax)



- The evolution of the capitalized R&D costs per approved new drug, after neutralization of the inflation, can be mainly explained by:
 - The growth of the out-of-pocket costs, especially the growth of clinical trials spending: x10.8 between the 1991 and the 2014 estimates (vs. preclinical spending which grew less: x3.9)
 - The decrease of the success rates to reach approval from phase I, ranging from 23% in the first 1991 estimates to 12% in the 2014 estimates
 - The overall increase of the used cost of capital, even if, in the 2014 estimates a 10.5% cost of capital was used, in decrease of 1 point of percentage from the previous estimates. These assumptions of cost of capital seem overestimated compared to available data from NYU Stern School of Business for biotech products (9.2%, based on 411 firms) and for traditional pharma (7.7%, based on 157 firms)

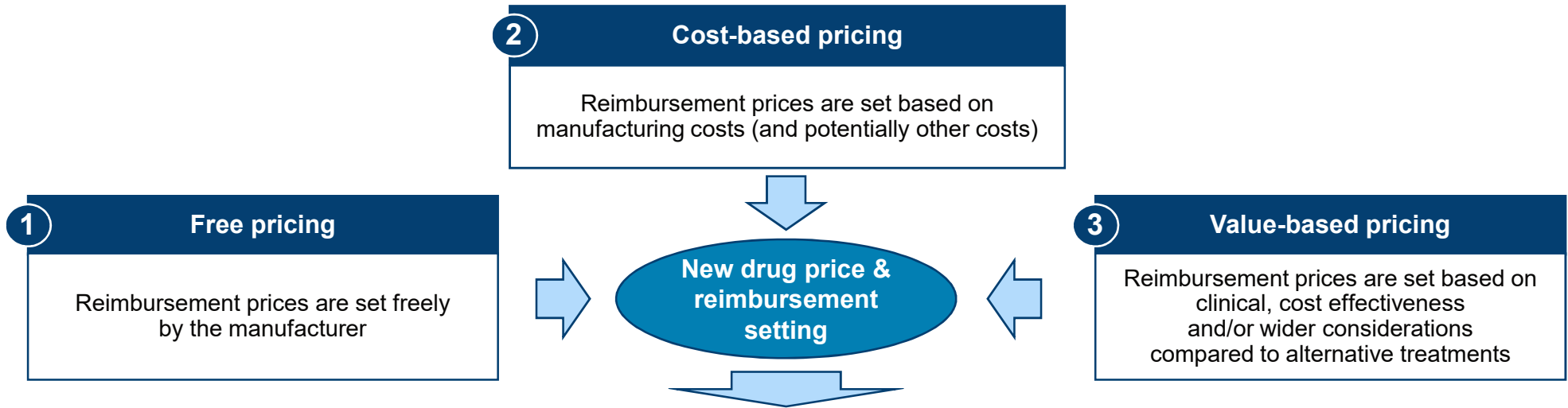
Note: For the sake of comparability, all values are adjusted to USD 2015 prices using data of the US GDP implicit price deflator from the US Bureau of Economic Analysis. The GDP implicit deflator shows the rate of price change in the economy as a whole, being the ratio of GDP in current local currency to GDP in constant local currency

Sources: DiMasi (1991) – DiMasi et al. (2003) – DiMasi, Grabowski (2007) – DiMasi (2014) – Cost of Capital - NYU Stern School of Business, January 2016 – Smart Pharma Consulting analysis

¹ Products with first testing in humans over the analyzed period

The price and reimbursement of drugs are set according to three basic principles and implemented through different mechanisms during all their life-cycle

Drug price setting approaches and life-cycle evolutions¹



Price & reimbursement setting mechanisms during the drugs life-cycle

Internal price referencing	International price referencing ²	Managed entry agreements	Price cuts	Paybacks	Tenders	Compulsory licensing	Voluntary licensing	Tiered pricing
Reimbursement prices are set compared to prices of drugs of the same class	Reimbursement prices are set compared to prices in other countries	Price / volume agreements, risk-sharing agreements, etc.	Post-marketing reimbursement prices reevaluations	<i>A posteriori</i> rebates to healthcare system (PPRS, safeguard clause, etc.)	Competition between similar products	Licensing imposed by a government to a third party w/o the consent of the patent holder	Out-licensing by a patent holder to a third party to produce and/or market an invention	Differential pricing reflecting the willingness to pay across countries

Sources: "Access to new medicines in Europe: technical review of policy initiatives and opportunities for collaboration and research", OECD – "Value-based pricing for pharmaceuticals: Implications of the shift from volume to value", Deloitte – Smart Pharma Consulting analysis

¹ Non-exhaustive list – ² Also called External price referencing

Value-based pricing aims to set drug prices based on multiple criteria to assess their general impact on the healthcare system or on the society, as a whole

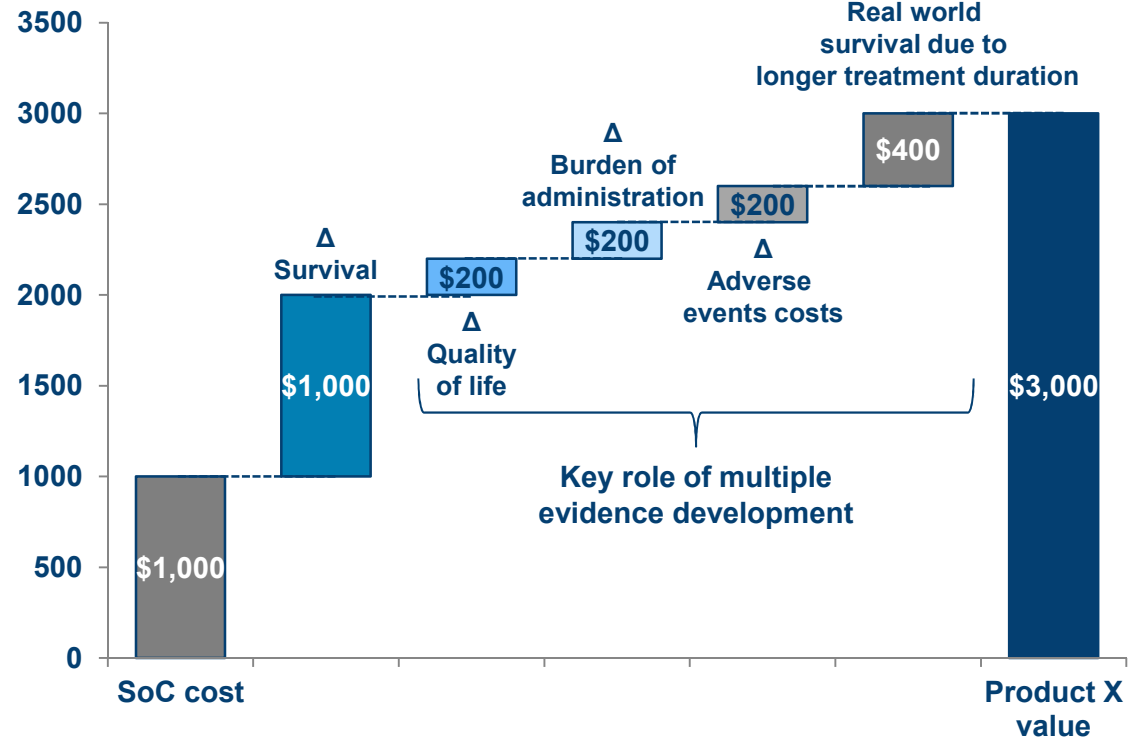
3 Value-based pricing – Approach

Definition & analysis

- Value-based pricing (VBP) sets prices based on a value assessment that takes into account several criteria such as clinical efficacy, cost-effectiveness, or a wider range of criteria including the burden and severity of the disease and the long-term benefits of the treatment
- VBP consists in negotiating prices for new pharmaceuticals based on their value for the society as assessed through Health Technology Assessments (HTA)
- By ensuring access to cost-effective drugs today and incentivizing manufacturers to invest in cost-effective products for the future, VBP seeks to provide a sustainable solution to pharmaceutical price regulation. But while it aims to reward innovation, establishing a clear relationship between the level of innovation and the price is not straightforward

Product X value vs. standard of care (SoC)

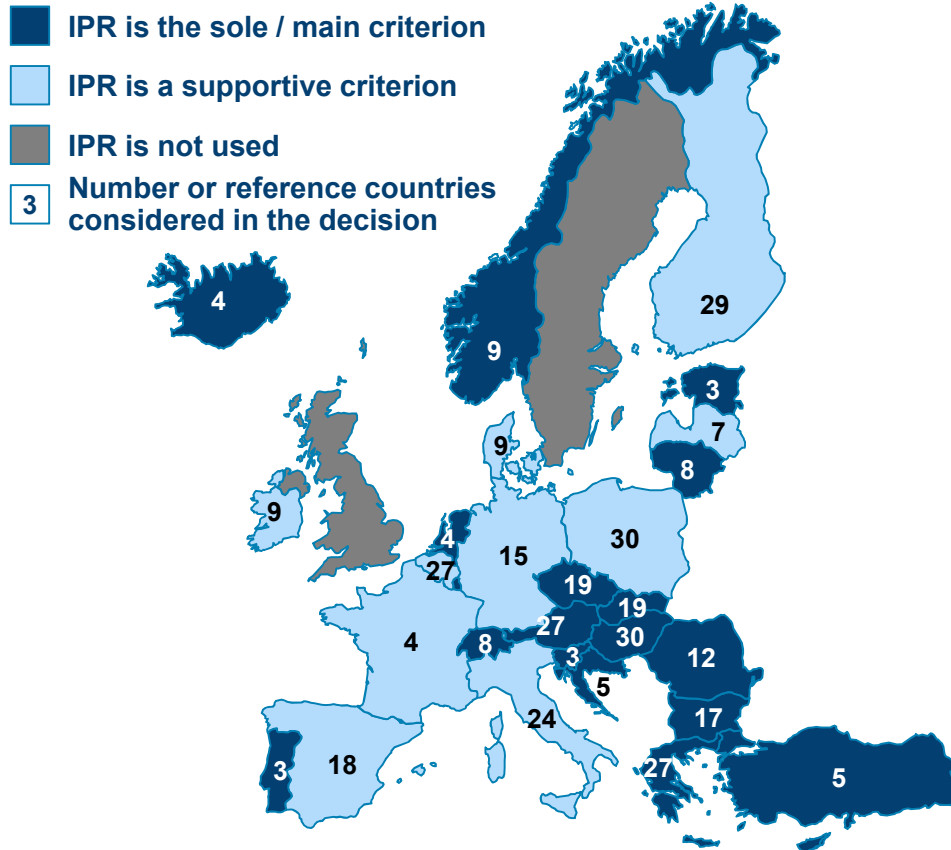
Drugs prices and incremental (Δ) value



Sources: "Future strategies for pricing and market access in oncology", Analysis Group, Oct. 2014 – "Access to new medicines in Europe: technical review of policy initiatives and opportunities for collaboration and research", OECD – Smart Pharma Consulting analysis

International Price Referencing (IPR) is used in most European countries to set drug prices but its scope may vary from one country to another

International price referencing



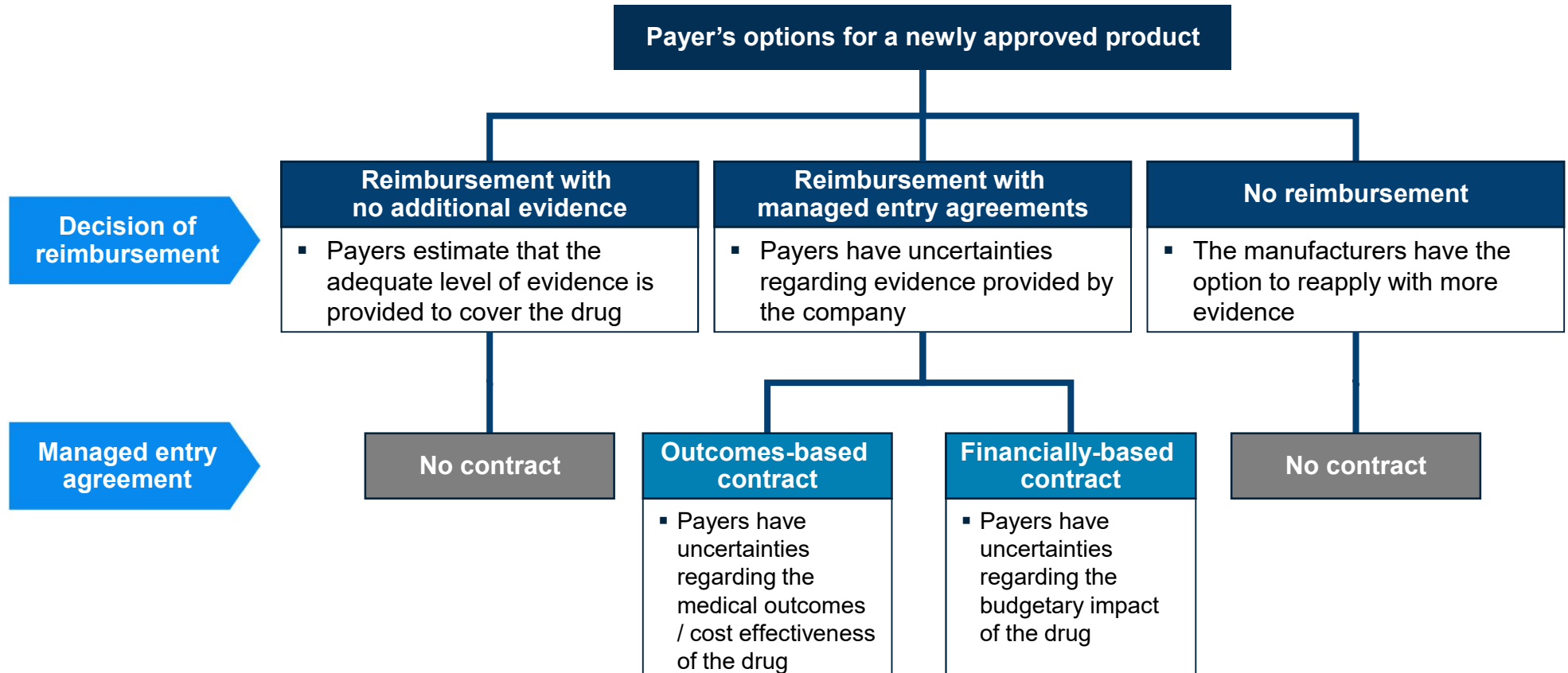
- If most European countries use the International Price Referencing to set the price of drugs, there are some disparities in its usage and calculation:
 - The scope of the use of IPR may depend on the country. For example, in Italy, all reimbursed medicines are concerned while in Spain only new reimbursed medicines with no comparator available are concerned
 - The calculation may also vary. In France, prices should be similar to those in the reference countries and should not be lower than the lowest price in one of the four reference countries while in Belgium prices are based on the average price in reference countries
 - The revision frequency might also depend on the country with bi-annual revisions in the Netherlands or annual revisions in Spain
 - Ex-factory prices are considered in most European countries but Norway, Denmark or the Netherlands consider pharmacy purchasing prices

Sources: "Study on enhanced cross-country coordination in the area of pharmaceutical product pricing", European Commission, Dec. 2015 – "External reference pricing of medicinal products: simulation based considerations for cross-country coordination", European Commission, 2014 – Smart Pharma Consulting analysis

Note: Germany should use the International Price Referencing to set drugs prices but it is not used in practice

Managed entry agreements may be considered by payers when the level of medical evidence is too low and/or the financial impact is too high

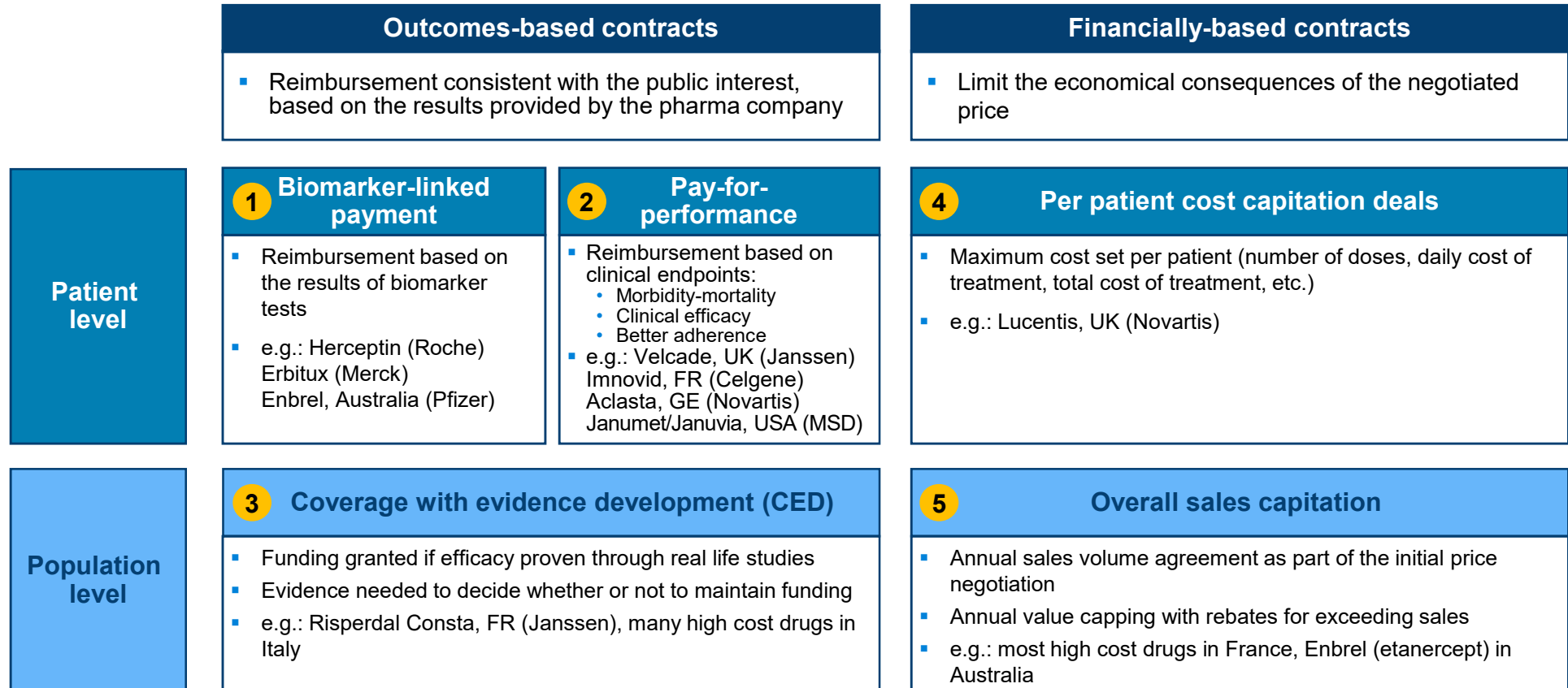
Payer's options for a newly approved product



Sources: "Can't Get No Satisfaction? Will Pay for Performance Help? Toward an Economic Framework for Understanding Performance-Based Risk-Sharing Agreements for Innovative Medical Products", Adrian Towse and Louis P. Garrison Jr, 2010 – Smart Pharma Consulting analysis

Managed entry agreements are expanding to reduce the risk for the payer (efficacy, safety, etc.) and/or to enable pharma companies to negotiate better prices

Classification of the managed entry agreements



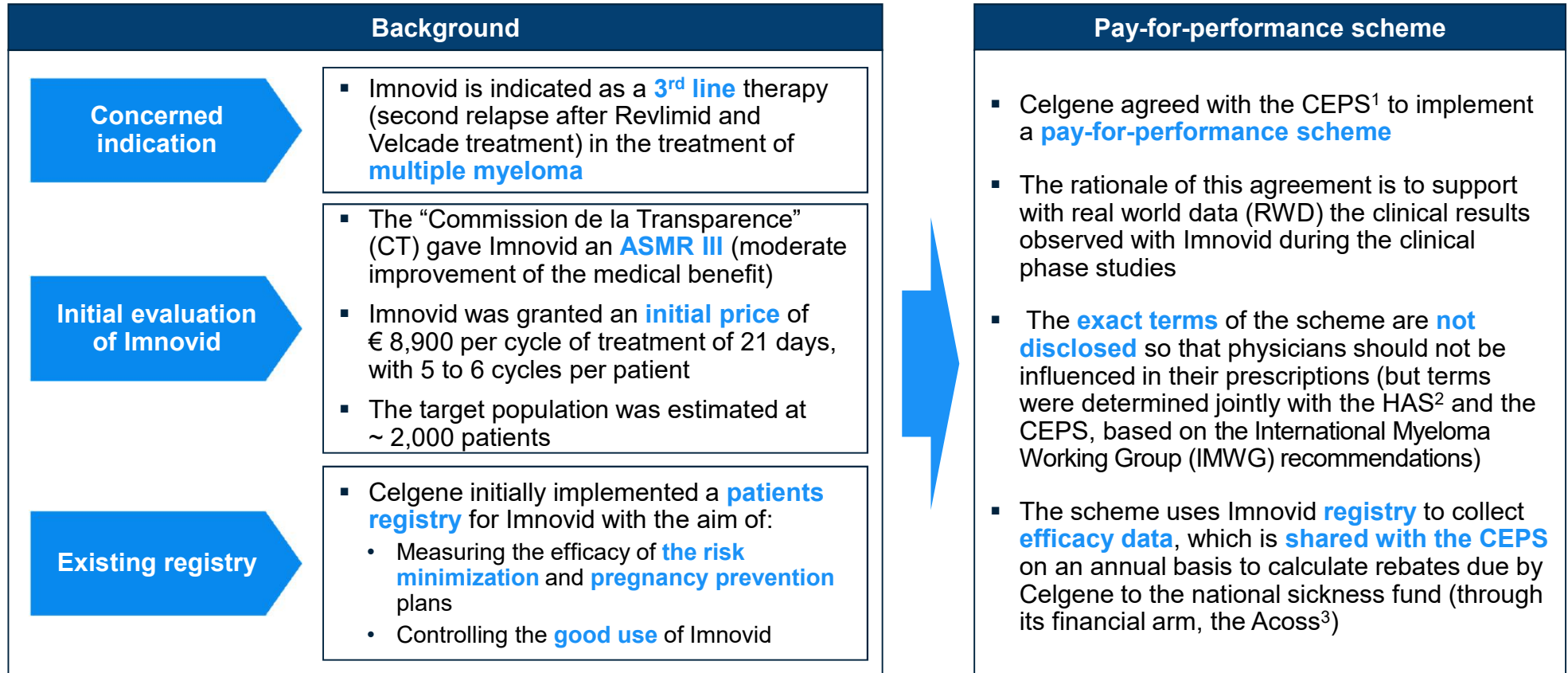
Sources: "Innovation et prix du médicament contrats d'accès au marché des médicaments remboursables : choix des schémas d'étude et des critères de jugement", Réseau d'Evaluation en Economie de la Santé, Jan. 2014 – "Unpacking Risk Sharing and Alternative Pricing Schemes"; Pharmaceutical Commerce, Feb. 2010 – "Mechanism Of Coordinated Access (MOCA) and transparent value framework, managed entry agreements", AIFA – Smart Pharma Consulting analysis

Celgene agreed to implement a pay-for-performance scheme based on an ad-hoc registry for Imnovid in France



2

Case study: Imnovid pay-for-performance scheme in France (2015)



Sources: "Médicaments : quand les laboratoires sont rémunérés à la performance", Les Echos – "Celgene a conclu un accord "efficace ou remboursé" avec le CEPS pour Imnovid"; APMnews

¹ Comité Economique des Produits de Santé → Economic Committee on Healthcare Products – ² Haute Autorité de Santé → National Authority for Health – ³ Agence Centrale des Organismes de Sécurité Sociale → Central Office for Social Security Organizations

Managed entry agreements enable an early access of patients to innovation while also facilitating reimbursement negotiations and limiting the budgetary risk for payers

Opportunity analysis

	Opportunities	Relative importance ¹
Payers	<ul style="list-style-type: none"> Potential to re-evaluate the effectiveness of the drugs at a later stage and re-negotiate the price based on real-world evidence and thus to move towards a value-based pricing system 	5
	<ul style="list-style-type: none"> Help address post-licensing uncertainty by offering flexibility in dealing with new and often expensive treatments 	5
	<ul style="list-style-type: none"> Improve the cost-effectiveness through a discount or a payback agreement for non-responders 	4
	<ul style="list-style-type: none"> Potential to create synergies with existing initiatives on registries in Europe: pulling evidence from different countries could allow to generate a large pool of data and increase the statistical significance of the results 	3
	<ul style="list-style-type: none"> Enable different types of schemes addressing different needs, both financial and non financial 	3
Manufacturers	<ul style="list-style-type: none"> Speed up reimbursement negotiations for drugs which were likely to be rejected by drug reimbursement agencies 	5
	<ul style="list-style-type: none"> Potential to benefit from a better corporate reputation as a result of the willingness to take responsibility for the use of the drug in real-life 	4
	<ul style="list-style-type: none"> Potential to reinforce the long-term collaboration between payers, health authorities and pharmaceutical companies 	4
	<ul style="list-style-type: none"> Enables discounts without impacting list prices 	4
Patients	<ul style="list-style-type: none"> Ability to gain faster access to innovative medicines 	5

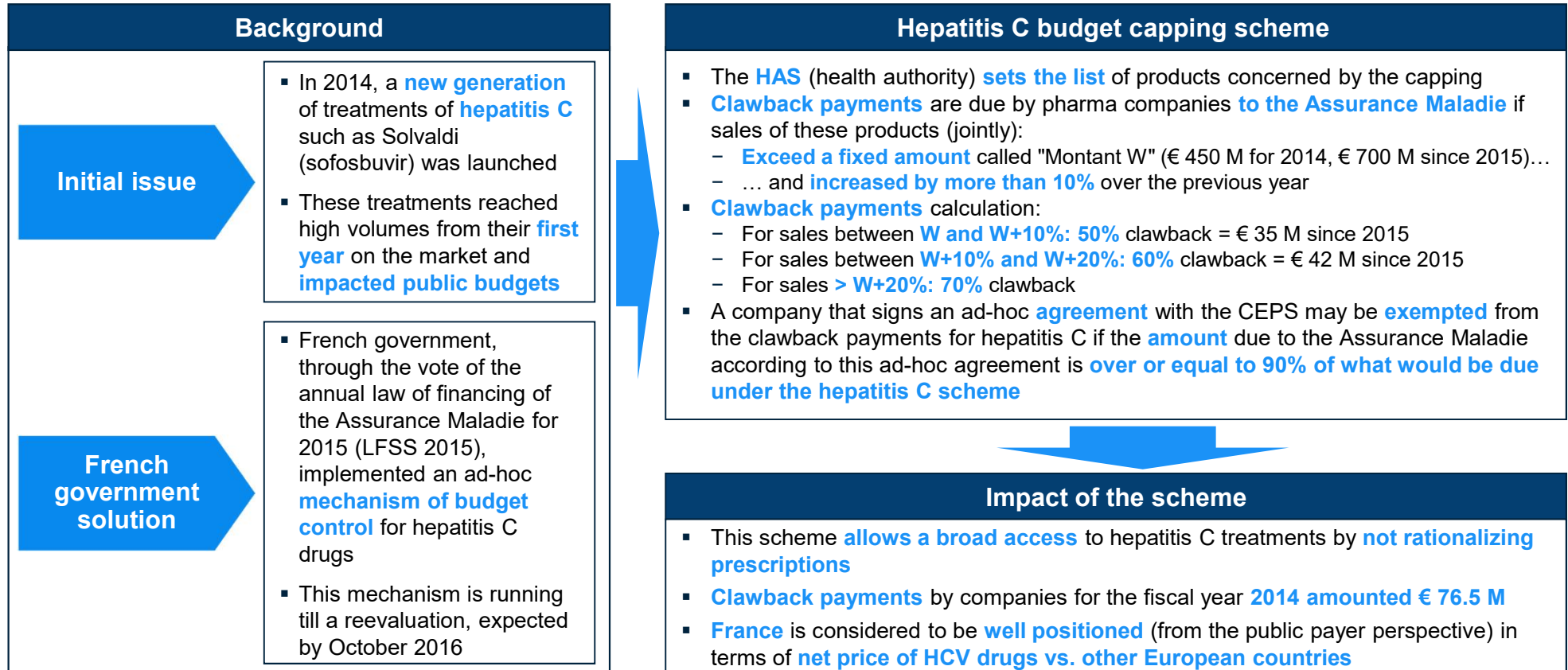
Sources: "Managed entry agreements for pharmaceuticals: the European experience", Alessandra Ferrario and Panos Kanavos, April 2013 – Smart Pharma Consulting analysis

¹ Rating from 5 = very important to 1 = limited importance

Due to their impact on public budgets, French authorities voted a budget capping for all innovative hepatitis C drugs sales



Case study: HCV budget capping in France



Sources: "Contribution au titre de médicaments destinés au traitement de l'hépatite C", URSSAF – LFSS 2015 et 2016 – "Produits de santé à l'heure des comptes", APICCS – CEPS 2014/2015 annual report – Smart Pharma Consulting analysis

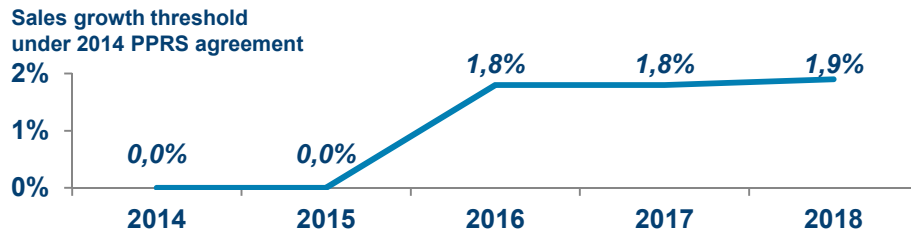
UK 2014 PPRS (Pharmaceutical Price Regulation Scheme) includes one total pharmaceutical sales capping and one profitability capping for the 2014-2018 period

Case study: UK 2014 PPRS

The 2014 PPRS is a voluntary agreement between the British Department of Health (DH) and the Association of British Pharmaceutical Industry (ABPI) which regulates the supply of branded medicines to the NHS¹ by 2018

Sales growth paybacks

- Due to the current state of the global economy and the **financial challenges** facing the NHS, the DH and the ABPI have agreed to introduce a **limit on the growth** of the **overall cost** of the branded medicines purchased by the NHS
- Payments are made by pharma companies on a quarterly basis of net sales to the NHS of **branded medicines**, i.e. after any other discounts already given
- Smaller companies** with sales to the NHS of less than £5m are exempt from payments and to stimulate innovation, **products with first sales after January 2014** are **not concerned** by this scheme either



Profitability paybacks

- The scheme provides a framework for determining **reasonable limits to the profits** to be made from the supply of branded medicines to the NHS
- There are two **profitability thresholds** that pharma companies choose to refer to (they are designed to be similar):
 - One level of **return on sales (ROS)** target: **6%**
 - One level of **return on capital (ROC)** targets: **21%**
- Within either limits**, companies are **allowed to set and change prices** in line with commercial considerations and NICE² appraisals
- If companies **reach the profit threshold**, they have to **pay 50% of the additional profit** to the NHS and are **not allowed to increase their prices**
- Companies must submit an **Annual Financial Return** to the DH for **control** purpose

Sources: "Understanding the 2014 PPRS"; ABPI – Smart Pharma Consulting analysis

¹ National Health Service – ² National Institute for Health and Care Excellence

An EU collaboration for Health Technologies Assessment exists since 2005 with the aim to set a better communication between HTA bodies and to standardize methodologies

Initiatives of assessment collaborations in Europe

About EUnetHTA

- EUnetHTA was established in 2005 to create an effective and sustainable network for HTAs (Health Technologies Assessments) across Europe
- EUnetHTA helps develop reliable, timely, transparent and transferable information to contribute to HTAs in European countries
- EUnetHTA supports collaboration between European HTA organizations at the European, national and regional level through:
 - Facilitating efficient use of resources available for HTA
 - Creating a sustainable system of HTA knowledge sharing
 - Promoting good practices in HTA methods and processes



EUnetHTA Joint Action 1 strategic objectives (2010-2012)

- To develop principles, methodological guidance and functional online tools and policies to:
 - Produce, publish, store and retrieve structured HTA information
 - Improve Relative Effectiveness Assessment (REA) by identifying areas where methodological guidance is needed and by providing it, suggesting ways to integrate REA of pharmaceuticals as a special version of the HTA Core Model (methodological framework for production and sharing of HTA information)
 - Structure exchanges and storage of information on evidence generation on new technologies (e.g. registries and trials)
- To test and implement:
 - A web-based toolkit for structured exchanges and storage of information on evidence generation on new technologies
 - The application of the HTA Core model in common production of at least 2 Core HTAs
 - A REA of (a group) of pharmaceuticals in line with the core HTA development
 - Real life support of information flow on new technologies prompting those where parallel assessments of same technologies are detected and alerting on opportunities for information sharing and closer collaboration
 - Provision of a contemporary information management system which supports collaborative HTA work and ensures rapid dissemination of HTA results

EUnetHTA Joint Action 2 strategic objectives (2012-2015)

- To strengthen the practical application of tools and approaches to cross-border HTA collaboration
- To aim at bringing collaboration to a higher level resulting in better understanding for the Commission and Member States (MS) of the ways to establish a sustainable structure for HTA in the EU
- To develop a general strategy, principles and an implementation proposal for a sustainable European HTA collaboration

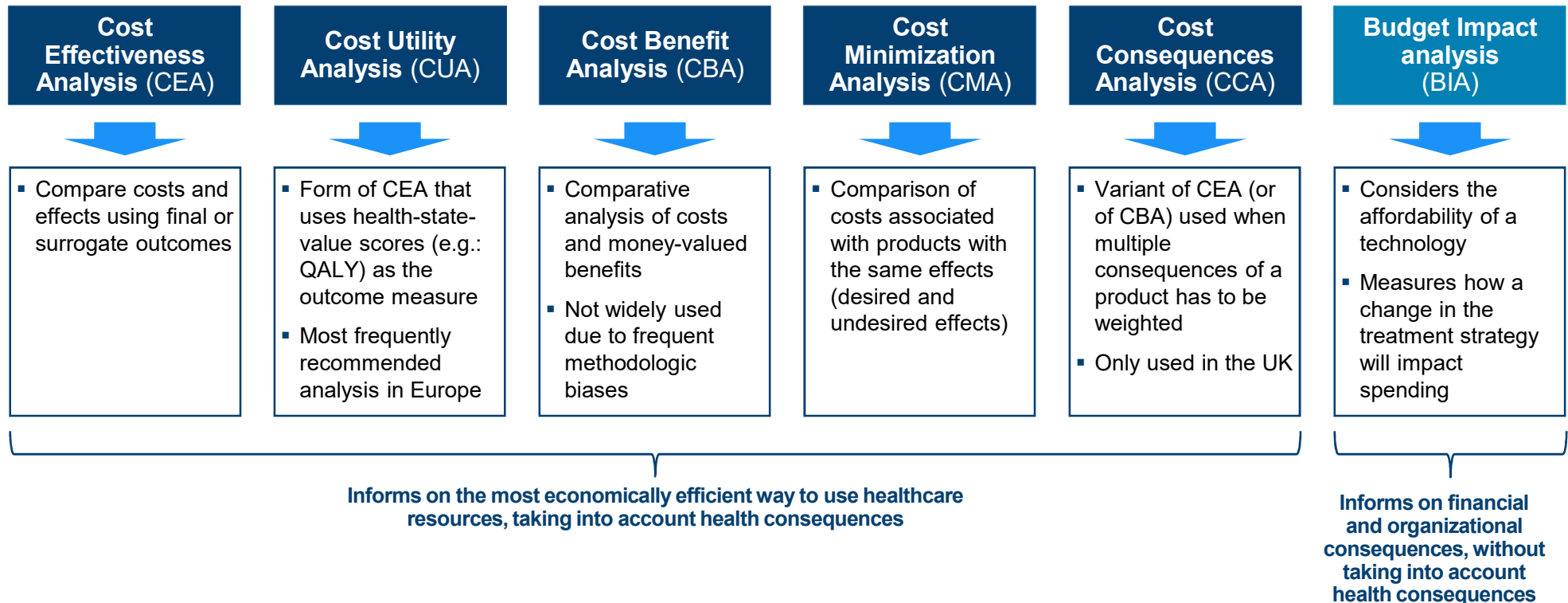
Sources: EUnetHTA website – Smart Pharma Consulting analysis

Note: Were implemented in Europe some other collaborative initiatives such as SEED (Shaping European Early Dialogues For Health Technologies), with the aim to implement early discussions between pharma companies and HTA bodies, to align product development with the future HTA requirements

Each type of evaluation compares alternative treatments from different perspectives

Types of health economic evaluations

Six types of evaluations used by regulatory agencies



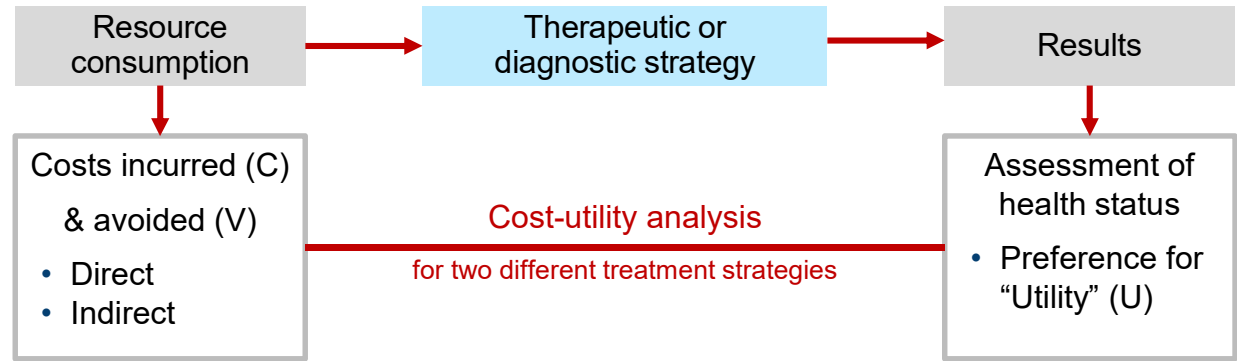
Sources: EUnetHTA 2015 – Smart Pharma Consulting analysis

The cost-utility analysis compares two treatment strategies based on their cost and their impact on a quality criterion aggregated with an efficacy criterion called QALY

Cost-utility analysis (CUA)

Definition

- The cost-utility analysis compares the costs associated with a medical strategy and its utility, which is a criterion combining the efficacy and the quality
- Thus, saving a life is important but not enough, the quality of life should also be considered
- The cost-utility analysis is a particular form of cost-effectiveness analysis for which results are measured by the number of years of life gained, adjusted with the quality of life, so called “quality-adjusted life year” (QALY)

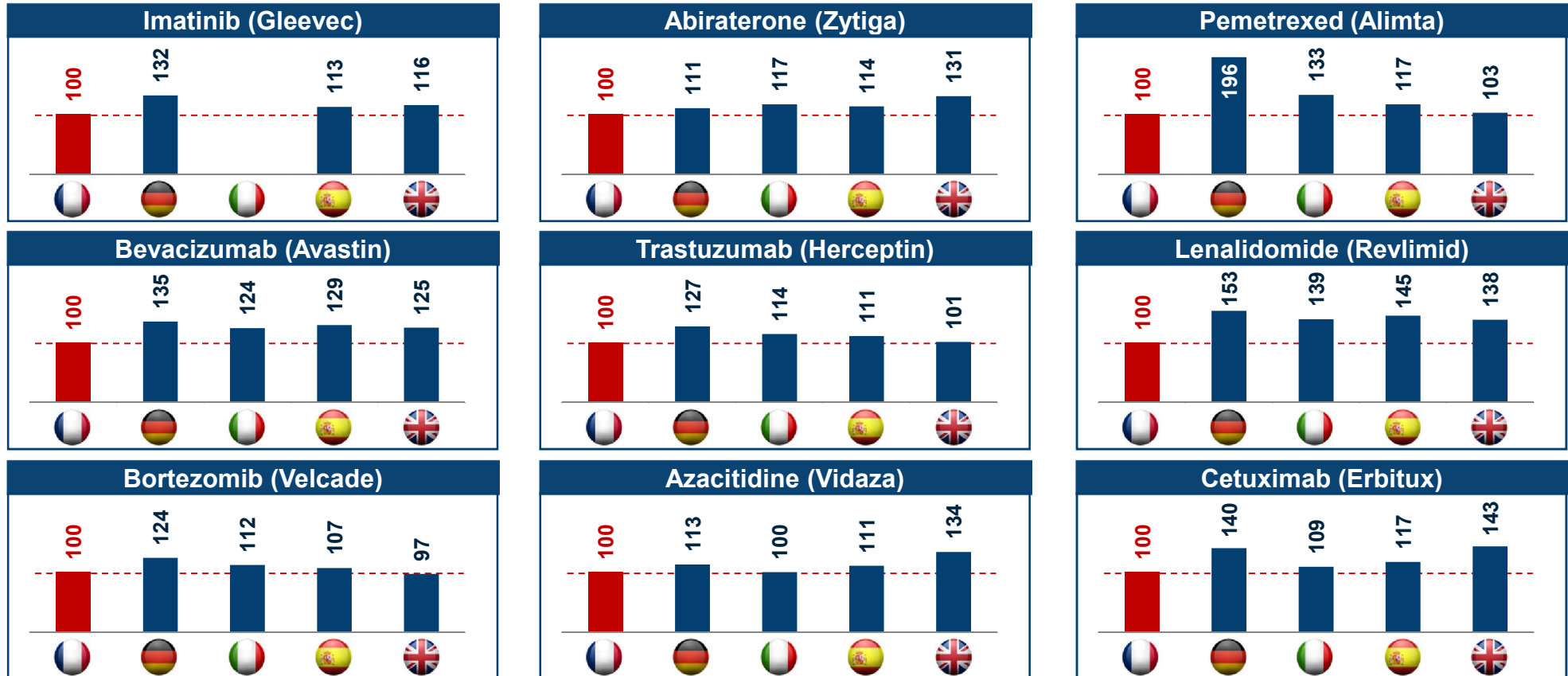


- “Utilities” of health states are generally expressed on a numerical scale ranging from 0 to 1 (0 represents the “utility” of the state “Dead” and 1 the utility of a state lived in “perfect health”)
- Thus, a year of healthy life accounts for 1 year of life and a year of lower health state accounts for a fraction of a year (<1). Some health states may be considered worse than death and have negative scores
- QALYs are used to compare protocols where the impact on quality of life is engaged
- This is the case for anticancer drugs comparisons which can improve response and/or survival time, and particularly living comfort; the results are then expressed using QALYs

Sources: Marie-Christine Woronoff-Lemsi, Georges Weil 2011 – HAS 2014 – EUnetHTA 2015 – Smart Pharma Consulting analysis

The analysis of a selection of onco-hematology treatments shows that prices are in general lower in France than in the other EU 5 countries

Oncology drugs price comparison in Europe

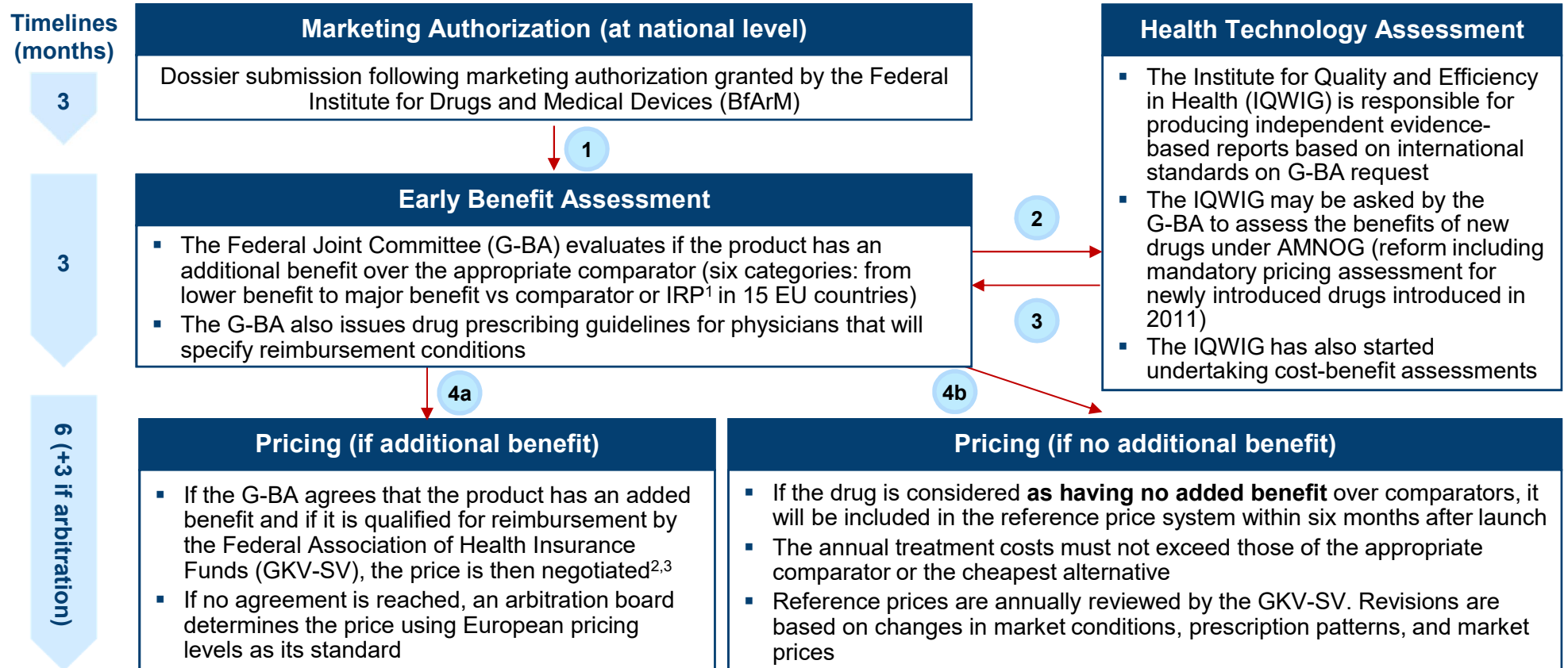


Sources: CEPS annual report 2014/2015 – Smart Pharma Consulting analysis

Note: Ex-factory prices, without rebates/discounts, based on HIS database as of July 2015

Drug reimbursement is automatic following marketing authorization* and price free up to 12 months, period during which an early benefit assessment (EBA)** is carried out

National market access considerations in Germany (1/3)



* Exceptions: non-prescription drugs, lifestyle drug

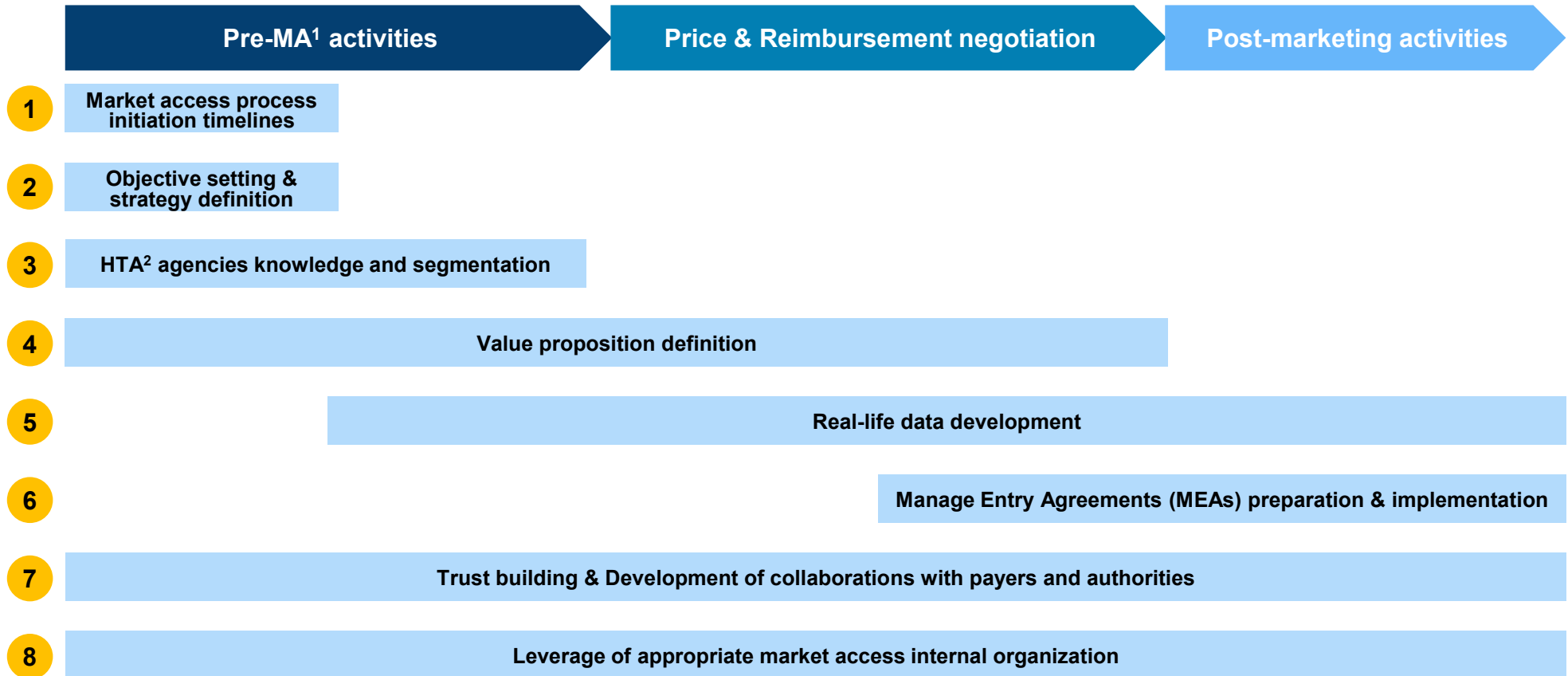
** Exemptions for non reimbursed drugs, hospital-only drugs and generics

Sources: FirstWord 2013 – IMS – GVK – “Reimbursement Systems for Pharmaceuticals in Europe Concept Mechanism and Perspective”, EMAUD – Smart Pharma Consulting analysis

¹ International Reference Price – ² Since June 2013, where there have been several appropriate comparators, price negotiation should be based on the cheapest comparator – ³ Since 2007, German health insurers are able to negotiate drug price contracts directly with pharma companies through a tendering process

The best practices related to the market access process are well identified from the pre- to the post-marketing authorization phases of products

Market access best practices

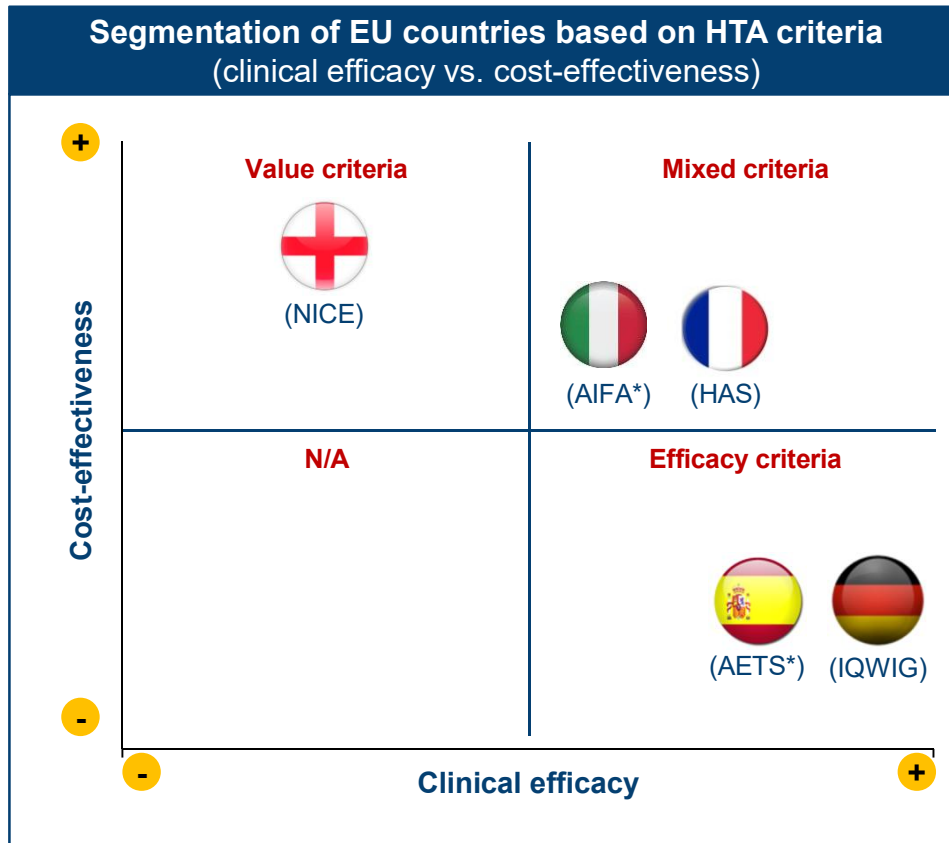


Sources: Smart Pharma Consulting analysis

¹ Marketing Authorization – ² Health Technology Assessment

Pharma companies may cluster HTA agencies according to the assessment criteria they value the most and then develop a specific value proposition for each of them

3 Payers knowledge and segmentation



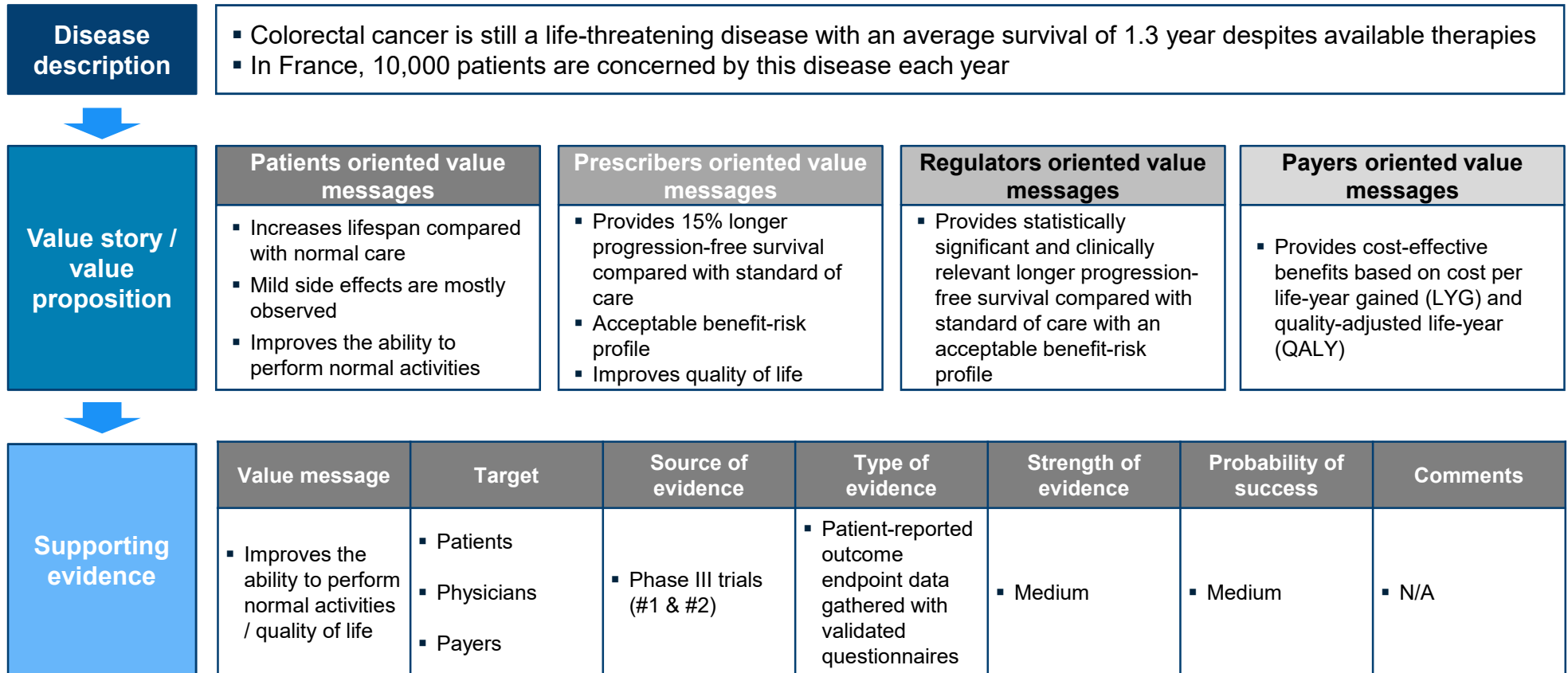
- The first step for market access activities planning is to understand **what will drive national HTA** (Health Technology Assessment) agencies **decisions** when it comes to drug evaluation
- A good understanding of their requirements will allow to define an **appropriate value proposition** for each of them
- The **"one fits all" strategy is no longer valid** since each country has different requirements
- **HTA agencies** can be **segmented** according to the importance they grant to the following **criteria**:
 - **Clinical efficacy** vs. **cost-effectiveness**
 - **Absolute¹** vs **relative therapeutic value²**
 - **Narrow** view vs. **holistic** view of the impact of the drug (Health Related Quality-of-Life, societal impact, etc.)
 - Importance of **subpopulations**

Sources: "Reimbursement Systems for Pharmaceuticals in Europe Concept Mechanism and Perspective", EMAUD – Smart Pharma Consulting analysis

* Note: In Spain and Italy, policies may differ from a region to another
¹ Disease severity and burden, unmet needs, efficacy/safety of the product –
² Incremental efficacy/safety versus available comparators

Value dossiers may help to develop targeted key messages for the different stakeholders

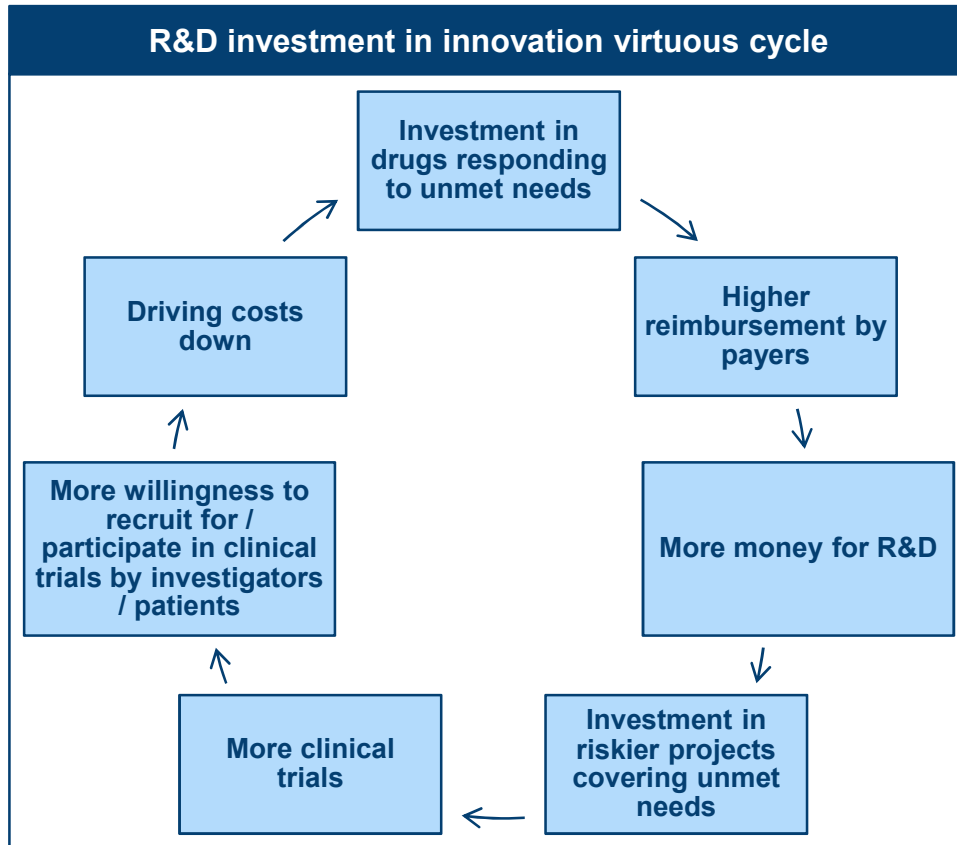
4 Value proposition definition – The value dossier: Example



Sources: ISPOR 14th annual meeting presentation, RTI Health – Smart Pharma Consulting analysis

Pharma companies corporate reputation is directly related to their research announcements responding to previously unmet needs

Corporate reputation building – Involvement in R&D



Patient-centric mindset for an improved corporate reputation

- A reputation benchmark performed by Alva showed that pharma companies **reputation peaked** when were announced **patient-driven breakthrough research initiatives**:
 - **AstraZeneca** reputation improved when was announced in 2014 a partnership with Eli Lilly for the development of **Alzheimer** treatments based on **genome-editing technology**. It also peaked when was announced its partnership with **PatientsLikeMe** in 2015
 - **Merck** reputation peaked in 2015 with the announcement of its partnership with Genea Biomedx and with Illumina for the development of **pioneering assisted reproductive treatments**
 - **GSK** reputation also peaked with the announcement of R&D innovations such as **Ebola vaccine** reaching phase II during late 2014 or **malaria vaccine** being approved by the EMA and soon to be used in Africa

Sources: "Pharma industry improves its tarnished reputation", CenterWatch News Online – "R&D innovation – a reputation differentiator for pharma", Alva – Smart Pharma Consulting analysis – Merck press release

The Pharma Corporate Reputation Audit developed by Smart Pharma Consulting facilitates the identification of key challenges to improve corporate reputation

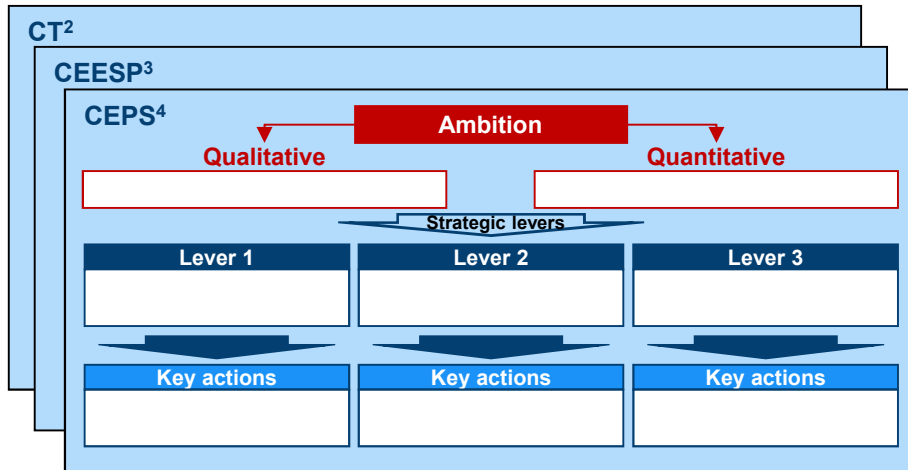
Corporate reputation strategy & tactics



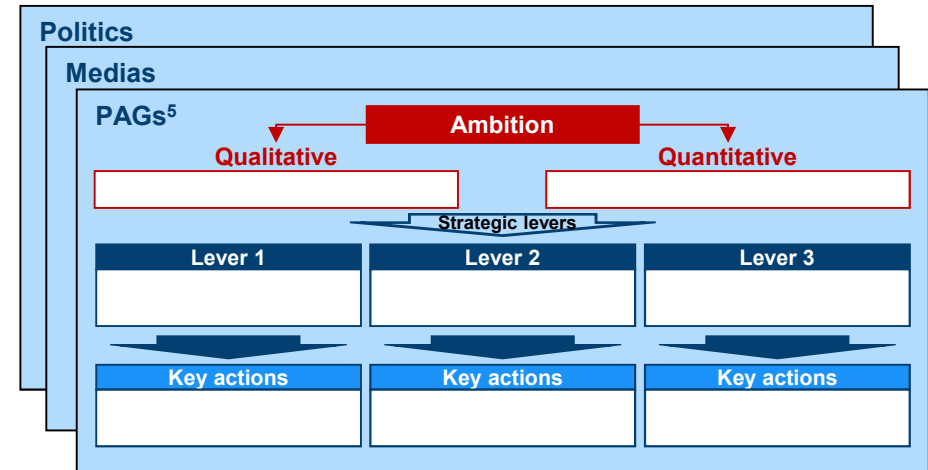
Illustrative – France

Pharma Reputation Strategy Card

HTA¹ / Pricing



Access environment



- Strategy and related actions aim at achieving the set ambition in terms of corporate reputation improvement
- The Pharma Reputation Strategy Card can be applied for one stakeholder group (i.e. HTA / Pricing, Access environment...) or sub-group (i.e. CT, CEESP, CEPS, Etc.), or even for one individual stakeholder (i.e. President of the CEPS)
- Strategic levers correspond to strengths on which the company should capitalize to create a competitive advantage or weaknesses to be corrected

Sources: Smart Pharma Consulting analysis

¹ Health Technology Assessment – ² Transparency Commission – ³ Health economic evaluation committee – ⁴ Drug pricing committee – ⁵ Patient Advocacy Groups

Market access strategy and corporate reputation play a key role to optimize drug price valuation and to take the advantage over competition...

Selected key takeaways

- Pressure of governments and payers on drug prices will keep on increasing but the impact within the same category of drugs will significantly differ, depending on market access strategy design and execution by pharma companies

DON'Ts

- Justify the price of innovation by the level of investment in R&D which is almost half the one invested in marketing, sales and general expenses
- Invoke the high level of risk, knowing that there is no case of bankruptcy amongst pharma companies
- Invest in sophisticated and expansive health economic studies which will be most likely criticized and not taken into consideration to grant you a better price
- Propose managed entry agreements for which the uncertainty associated with outcomes is high
- Underestimate the importance of corporate reputation

DOs

- Pharma companies should act in good faith and put themselves in governments and payers shoes
- Put forward evidence that are well-documented and articulated in a convincing argument to support the asking price
- Managed entry agreements should remain as simple as possible and generate a minimum of controlled associated costs
- Each pharma company should strengthen its corporate reputation to differentiate itself positively from others and thus get preferred (vs. competitors)

... knowing that pharma companies are not considered as all equal by governments and payers in the context of drug pricing & reimbursement

Core capabilities

1 Strategy

- **Assessing the attractiveness of markets** (Hospital / retail innovative products - Vaccines - OTC - Generics)
- **Growth strategy**
 - Optimization of marketing / sales investments
 - Development of a company in the hospital market Business
 - Valuation for acquisition
 - Portfolio / franchise assessment
- **Extension of product life cycle performance**
 - Improvement mature products performance
 - Adaptation of price strategy
- **Defense strategies vs. new entrants**
- **Competitive strategies in the hospital market**
- **Strategic partnerships companies / pharmacies**

2 Management

- **Facilitation and structuring of strategic thinking for multidisciplinary product teams**
 - Key challenges identification
 - Strategic options formalization
 - Resource allocation optimization program
- **Training of marketing and market research teams to sales forecast techniques (modeling and scenarios development)**
- **Development and implementation of a "coaching program" for area managers**
 - Sales reps coaching
 - Regional action plans roll-out
- **Development and implementation of a "sales techniques program" for sales forces (STAR¹)**

¹ Sales Techniques Application for Results (training course)



3 Organization

- **Rethink of operational units organization**
- **Improvement of sales force effectiveness**
- **Improvement of the distribution channels covering the hospital and retail markets**
- **Development of a strategic planning process**