Prospective Workshop

Essec Santé – Centrale Santé

"Will the Pharma « bubble » collapse within 3 years?"

Why payers' reimbursement strategies should have a significant impact on the Pharma research paradigm?

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Pricing and market access
Why does it suddenly matter?

$ = Volume x Price x Access

Before WW2

3 variables: volume, price, access

- Commercial success driven by **sales rep** = product sold to anyone, anywhere, for anything

1945-1990

2 variables: volume, price

- Access through national healthcare systems
- Commercial success driven by **marketing** = product approved by health authorities and used as much as possible in each indication

1990+

1 variable: price

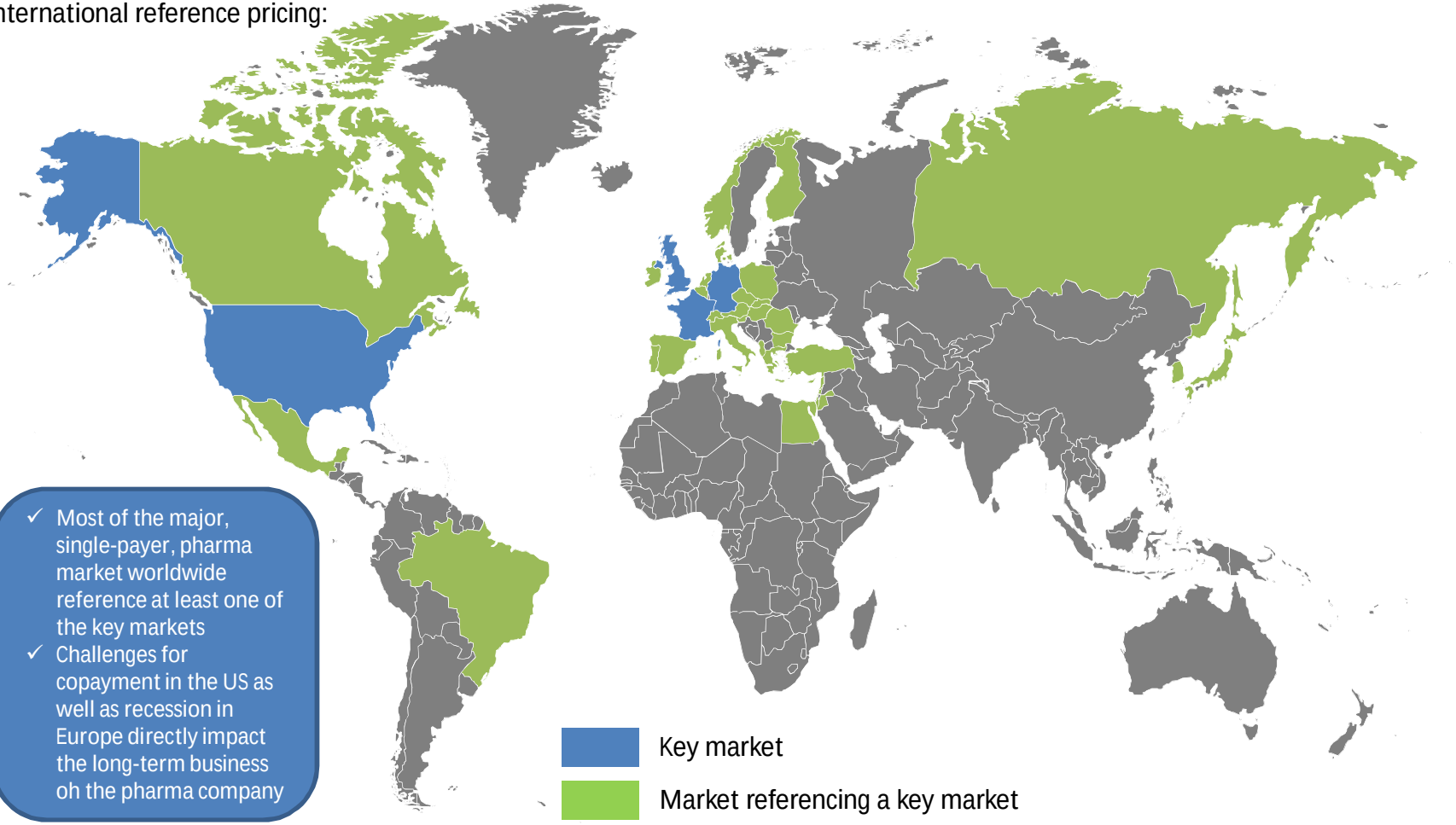
- Volume is limited by the indication of the drug
- Commercial success driven by **market access** = product launched in an indication optimising its pricing potential

Pricing and market access

Why the economic downturn in the USA and in Europe impact the entire 'pricing business'?

Classic international launch sequence:

International reference pricing:



- ✓ Most of the major, single-payer, pharma market worldwide reference at least one of the key markets
- ✓ Challenges for copayment in the US as well as recession in Europe directly impact the long-term business oh the pharma company

Source: Data on file

RoW = Rest of the world

Rewarding innovation: analysis of the case of the United States

The United States, from pure liberalism to a structured, national approach to pricing

Key dates	
1965	• Creation of Medicare and Medicaid programmes [1]
2010+	• Steady implementation of "Obamacare" to limit the growth of private healthcare [2] • It is estimated that about 60 percent of all personal bankruptcies in the USA are related to medical bills [3]
2013	• The bill "United States National Health Care Act" known as "Medicare-for-all" bill supporting a single-payer system reintroduced at the Senate [4]

Case study: Zaltrap (aflibercept)

Indication	Metastatic colorectal cancer Adjunctive therapy to FOLFIRI
Key efficacy results from pivotal trial	Median OS with FOLFIRI = 12.06 months Median OS with Zaltrap + FOLFIRI = 13.05 months HR = 0.758 (0.714-0.935); p = 0.00007 [5]
Proposed price	$11,000+ / month (duration of treatment ~1 year) [6]

FOLFIRI = FOL-folinic acid, F-fluorouracil, IRI-irinotecan; OS = Overall survival

- **In October 2012, the Memorial Sloan-Kettering Cancer Center published a tribune in the New York Times to explain why they will not list Zaltrap in their hospital [6]**
- **3 weeks later, Sanofi offered discounts of 50% on Zaltrap's official price [7]**

"In most industries something that offers no advantage over its competitors and yet sells for twice the price would never even get on the market"

Innovation evaluation in the USA

- **If the USA remains as it is today, the need for copayment and the inability of most of the Americans to do so will mechanically limit the pricing potential of "me-too-innovative" drug**
  - **One in 10 cancer patients now reports spending more than $18,000 out of pocket on care – who can afford that for more than 1 year? [6]**
- **If it becomes a single-payer market, it is likely that only essential medicines will be provided through the healthcare system**

Source: [1] Social Security amendments, 1965 (link, accessed June 2013); [2] Patient Protection and Affordable Care Act (link, accessed June 2013); [3] Obama Care Factsdispelling the myths (link, accessed June 2013); [4] House Reps Introduce Medicare-for-All Bill (link, accessed June 2013); [5] Zaltrap (aflibercept) Summary of product characteristics (link, accessed June 2013); [6] In Cancer Care, Cost Matters, New York Times, October 2012 (link, access June 2013); [7] Sanofi Halves Price of Cancer Drug Zaltrap After Sloan-Kettering Rejection, New York Times, November 2012 (link, accessed June 2013)

Rewarding innovation: analysis of the top European markets

The United Kingdom, setting trends in pharmacoeconomics since its creation

Key dates	
1948-1969	• Creation of the NHS (National healthcare system) England and Northern Ireland, NHS Wales and NHS Scotland respectively managed by the NICE (National institute for health and care excellence), the AWMSG (All Wales medicines strategy group) and the SMC (Scottish medicines consortium) [1]
1970-2013 From pure economics…	• In England and Northern Ireland, NICE evaluates selected drugs* and recommends them for use at the NHS if they are deemed cost-effective against standard of care
2014+ *… to clinical evaluation*	• Implementation of the VBP (value-based pricing) system framework to evaluate innovative drugs

* NICE focus on oncology, maternity-related diseases, paediatrics, vascular conditions, long term conditions, mental health, public health, general and acute conditions [2] ; SMC evaluate every single new drug coming to the market

Market access, pricing and reimbursement process

Market authorisation | Health technology assessment | Price and access

EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH

MHRA Regulating Medicines and Medical Devices

MHRA = Medicines and Healthcare products Regulatory Agency

NICE National Institute for Health and Care Excellence

Scottish Medicines Consortium

All Wales Medicines Strategy Group
Grŵp Strategaeth Meddyginiaethau Cymru Gyfan

- **As off 2013, a significant number of drugs haven't made it through the NICE assessment:**
  - **The number of cancer drugs being rejected by NICE raised by 50% between 2010 and 2012 [3]**
  - **Some new drug coming to the UK market have been evaluated in clinical trials against an approved SOC… that has never been reimbursed by the NHS**
- **To fix the 'broken' model, the UK is replacing the cost-effectiveness rationale by the VBP… Looking at the evolution of the French and German (HTA) health technology assessments outcomes, what can we anticipate?**

Innovation evaluation in the UNITED KINGDOM

- **Former system was not evaluating incremental benefit against SOC but was rather performing an economic analysis of the hard outcomes of a treatment**
- **New VBP system getting closer to the French ASMR and German AMNOG approach cannot be expected to reconcile public payer concerns and need for return on investment on new drugs**

Source: [1] The NHS: what can we learn from history? Historyextra.com (link, accessed June 2013); [2] Topic Selection Programme, NICE (link, accessed June 2013); [3] Number of cancer drugs being rejected by health watchdog rises 50% in two years (link, accessed June 2013)

Rewarding innovation: analysis of the top European markets
Germany, from free pricing to a highly payer-regulated market

Key dates

Before 2011

- Germany is the third largest pharmaceutical market in the world and the largest in Europe
- It is one of the few mature countries where pharma companies are free to set prices [1]

January 2011

- Implementation of the AMNOG (Arzneimittelmarktneuordnungsgesetz) reform, ending the free-pricing era and opening the 'comparative pricing' age [2]

October 2011

- Linagliptin, developed and marketed by Boehringer Ingelheim, a privately owned German company, is granted 'no additional benefit', leading to price parity against generics [3]
- Boehringer Ingelheim decides not to launch on its domestic market [4]

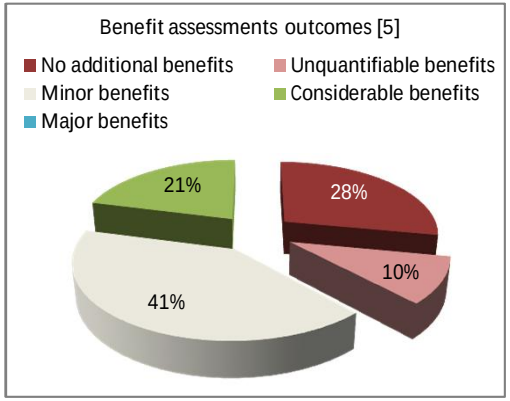
Market access, pricing and reimbursement process

Market authorisation	Health technology assessment	Price and access
EMA, BfArM, Paul-Ehrlich-Institut	IQWiG Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen; Gemeinsamer Bundesausschuss	Benefit assessment → GKV Spitzenverband

BfArM = Bundesinstitut für Arzneimittel und Medizinprodukte

IQWIG = Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen; G-BA = Gemeinsame Bundesausschuss

GKV = Gesetzlichen Krankenversicherung



- **From the implementation of the AMNOG to April 2013 (n = 28), only 21% of the assessments allowed pharma companies to negotiate a premium over SOC**
- **Some innovative drugs are now reimbursed in the so-called emerging markets, but not in Germany**

Innovation evaluation in GERMANY

- **Comparative evaluation has started only 2 years ago in Germany and has been perceived from the very first assessments as a real threat to the pharma industry business**
- **Limited incremental benefit over SOC does not allow for premium significant enough to fuel the R&D as it is being performed today**

Source: [1] Eurohealth Vol 17 No 1 (link, accessed June 2013); [2] Gesetz zur Neuordnung des Arzneimittelmarktes in der gesetzlichen Krankenversicherung (Arzneimittelmarktneuordnungsgesetz - AMNOG) vom 22. Dezember 2010 (link, accessed June 2013); [3] Bundesministerium für Gesundheit Bekanntmachung eines Beschlusses des Gemeinsamen Bundesausschusses über eine Änderung der Arzneimittel-Richtlinie (AM-RL): Anlage XII – Beschlüsse über die Nutzenbewertung von Arzneimitteln mit neuen Wirkstoffen nach § 35a des Fünften Buches Sozialgesetzbuch (SGB V) Linagliptin Vom 29. März 2012 (link, accessed June 2013); [4] Kein Linagliptin für Deutschland, Ärzte Zeitung, 26.04.2012 (link, accessed June 2013); [5] Value in Health, Volume 16, Issue 3 , Page A257, May 2013. (link, accessed June 2013)

Rewarding innovation: analysis of the top European markets
France, from clinical effectiveness to clinical & cost-effectiveness

Key dates	
December 2004	• Creation of the ASMR (Amelioration du service medical rendu), measuring the incremental innovation provided by a health technology [1]
Year 2011	• Only 1 new health technology out of 251 granted with an ASMR superior to IV by the HAS (Haute autorite de sante)[2]
December 2011	• Pharmaceutical companies required to provide head-to-head data to have their assets eligible for reimbursement in France [3]
October 2012	• Economic evaluation required for any innovative health technology expected to have a significant budget impact [4]

Market access, pricing and reimbursement process

Market authorisation → Health technology assessment → Price and access

EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH
ansm Agence nationale de sécurité du médicament et des produits de santé

HAS HAUTE AUTORITÉ DE SANTÉ

SMR
ASMR
CEM

UNCAM

Ansm = Agence nationale de securite du medicament et des produits de sante

SMR = Service medical rendu
CEM = Cost-effectiveness model

UNCAM = Union nationale des caisses d'assurance maladie

- **ASMR is a scoring tool used by the HAS to measure the degree of innovation of a health technology**
  - **ASMR I, II, III rewarding 'innovation' and affording price notification to the CEPS (Comite economique des produits de sante)**
- **ASMR scores are indication specific and vary over time**
- **From 2000 to 2006, 80%+ of the monoclonal antibodies (mAbs) have been granted an ASMR from I to III; from 2006 to 2012, 70% of the mAbs were granted with an ASMR IV or V [5]**

Innovation evaluation in FRANCE

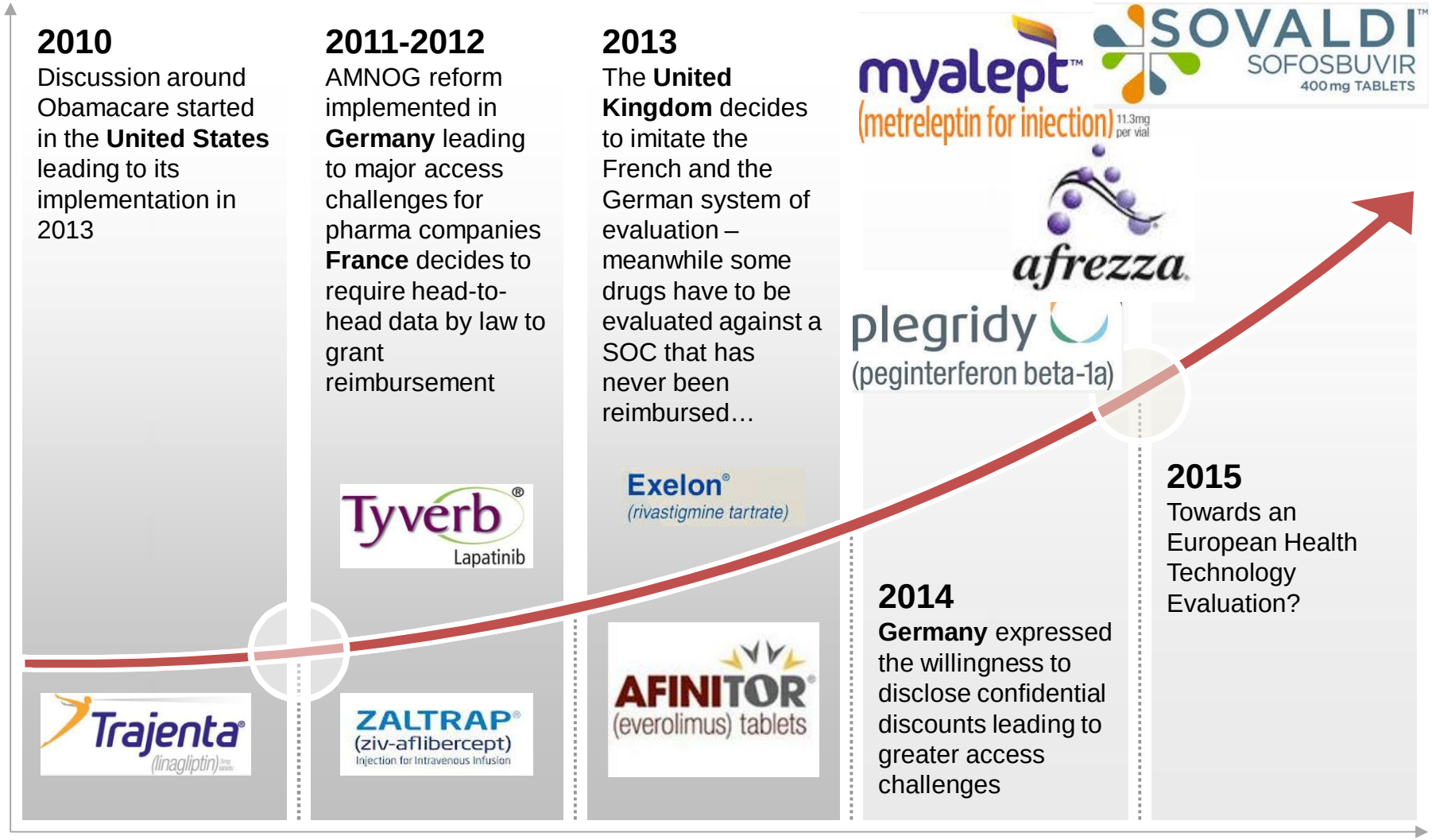
- **With the latest reforms, pharmaceutical companies are *theoretically* required to provide head-to-head data as well as a cost-effectiveness model to be reimbursed at a premium price over SOC (Standard of care)**
- **Evident inadequacy between investment required in R&D (Research and development) to demonstrate clinical/statistical superiority over SOC and the need for cost-effective treatments with current me-too approach**

Source: [1] Décret n° 2004-1398 du 23 décembre 2004 relatif aux médicaments remboursables par l'assurance maladie et modifiant le code de la sécurité sociale (deuxième partie : Décrets en Conseil d'Etat) (link, accessed June 2013); [2] HAS Rapport annuel d'activité 2011 (link, accessed June 2013); [3] LOI n° 2011-2012 du 29 décembre 2011 relative au renforcement de la sécurité sanitaire du médicament et des produits de santé (1) (link, accessed June 2013); [4] Décret n° 2012-1116 du 2 octobre 2012 relatif aux missions médico-économiques de la Haute Autorité de santé (link, accessed June 2013); HAS transparency commission reports (link, accessed June 2013)

In a nutshell…

What may happen in the coming 3 years

New drugs coming to the market have faced significant access challenges – are these artefacts or signals? We will see in no time



Key learnings & perspective

European payers are the new market gatekeeper

- Innovative assets needs marketing authorisation, reimbursement and price premium to be a **commercial success**
- No reimbursement / price premium in Europe → little hope for the rest of the world

The trend is to disclose any commercial in confidence discount

- Because of the threshold of NICE/SMC, **any patient access schemes agreed for the UK will impact the rest of the markets**
- Germany is looking forward to disclosing publically commercial in confidence discounts

Any other questions? Confidential market access challenges?

- Please contact me:

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