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LIFE SCIENCES GROWTH SERIES - EU PRICING AND REIMBURSEMENT AND NICE

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Background

- Medicines and devices pricing and reimbursement have become a major concern in the EU for both new and established products
- Influence of reference pricing
- Globally, the perceived need to control healthcare product budgets has led to evidential demands to show value
- Focus of presentation
  - EU level controls
  - Cost-containment efforts and mechanisms
  - Developments in demonstrating value for new and mature products
  - Risk-sharing arrangements being used with payers to address cost and payment concerns

EU Pricing and Reimbursement Controls

- TFEU Article 168 - Price setting/reimbursement a national competence
- Transparency Laws –Constraints on Governments
- Competition Laws – Constraints on Industry
- Off-label and unlicensed product cost-containment
- HTA and EU Harmonisation

Constraints on Governments

Directive 89/105

- Price approvals, increase approvals, price freezes, profit controls, product coverage
- Timelines, decision criteria and remedies
- Price cutting and reimbursement controls have moved on
- Proposed 2013 revision of the Directive abandoned in 2015

Competition Law – Constraints on Industry

- Article 34 TFEU - Free movement of goods
  - Parallel trade cannot be impeded under exhaustion of rights principles
- Article 101 - Restrictive agreements
  - Agreements which restrict, prevent or distort competition
- Article 102 - Abuse of a dominant position in a market
  - "Abuse", "Dominant", "Market"
- 2008 Sector Inquiry
  - Focus on slow generic entry

Cost-containment through Unlicensed/Off-label Use

- Unlicensed medicines
  - Article 5(1) MA exemption for special need exemption or named patient supply
  - *C-185/10 European Commission v Republic of Poland* - cost grounds
- Off-label use
  - Avastin and Lucentis
  - Industry complaints of inconsistency with EU MA regime in France and Italy allowing off label use even if licensed alternative
    - 2/2015 – Italy
    - 9/2015 - RTUs in France allowing temporary off label use

Diverse pricing and reimbursement controls - Supply

- Price controls
  - Statutory pricing and price freezes/reductions
  - Reference pricing
  - Cost-effectiveness assessment
- Expenditure control
  - Discounts and rebates
  - Patient access schemes,
  - Paybacks
  - Price-volume/outcomes/risk share agreements
- Profit control
  - UK PPRS

Diverse pricing and reimbursement controls - Demand

- Pricing and reimbursement
- Physician behaviour
  - Clinical practice guidelines
  - Prescription monitoring/quotas
- Aimed at patients
  - Forms of cost-sharing
- Aimed at pharmacies
  - Generic substitution
  - Claw-backs
- Reference pricing
- Economic evaluation (HTA)

Due to national competency: national methodologies differ significantly

Country	Price Changes (since 2008)					Drug Lists		Contracting Arrangements				HTA requirements (formal like NICE or as part of contract)			
	One off price cuts / extraordinary price reviews	Changes in VAT rates (+/-)	Reduction in marks ups for distributors	Intro of external reference pricing / changed method	Effective generic pressure e.g. incentives to prescribe	Positive	Negative / delisting	Price-volume	Managed entry schemes	Outcomes based schemes	Cost / Risk Sharing	Clinical Effectiveness, Safety, Budget Impact	ICER (cost / QALY)	Cost Minimisation Analysis	Health Economic Simulation
Germany			*			✘	✔	✔		✔	✔	✔	✘	Rarely	Rarely
France	✔				✔	✔	✘	✔		✔	✔	✔	✘	✔	✔
UK	✔				✔	✘	✔	✔	✔	✔	✔	✔	✔	Rarely	✔
Italy	✔				✔	✔	✘	✔	✔	✔	✔	✔	✘	✔	Rarely
Spain	✔		✔	✔	✔	✘	✔	✔				✔	✔	✔	✔
Austria	✔	✔			✔	✔	✔				✔	✔	✘	✔	✔
Belgium	✔					✔	✘					✔	✘	Rarely	✘
Czech Republic	✔	✔	✔			✔	✘	✘			✔	✔	✔	✔	✔
Denmark						✔	✘	✔				✔			
Finland						✘	✔					✔			
Greece	✔	✔	✔	✔	✔	✘	✔	✔				✔			
Hungary			✔		✔	✔	✔	✔		✔	✔	✔	✔	✔	Possible
Ireland	✔		✔			✔	✘	✔		✔	✔	✔	✔	✔	✔
Netherlands						✔	✔	✔		✔	✔	✔	✔	✔	✔
Norway						✔		✔				✔			
Poland						✔	✘	✔			✔	✔	✔	✔	✔
Portugal	✔	✔	✔	✔	✔	✔	✔	✔		✔	✔	✔	✔	✔	✔
Sweden						✔	✔	✔				✔	✔	✔	✔
Switzerland	✔					✔	✘	✔		✔	✔	✔	✘	✘	✘

*Germany also increased rebates to distributors

Ref: OECD/DELSA HEA (2015) and MAP BioPharma Limited (http://www.mapbiopharma.com/europe)

Nearly 100 HTA evaluation bodies

HTA Harmonisation Moves

- HTA-based evaluations used in many Member States - whether or not a drug offers an additional benefit determines its price – assessment and appraisal
- Directive 2011/24/EU on patients' rights in cross-border healthcare
  - Art 15 – EU to support cooperation between HTA bodies
  - EUnetHTA - facilitates cooperation and scientific information exchange among MS
  - Development of a HTA Core Model® that defines the key content required information sharing
  - HTA Network
- Proposal for an HTA Regulation
  - Aims to abolish obstacles to market access of medicinal products and medical devices
  - Formation of a coordination group
  - Joint clinical assessment reports and Joint Scientific Consultations
  - Legally binding?
  - Appealable by MS?

Some Key HTA Organisations

- France – Haute Autorité de Santé (HAS)
- Germany – appraisal component and decision-making Gemeinsamer Bundesausschuss (GBA) and evaluation component - IQWIG (Institute for Quality and Efficiency in Health Care)
- Italy - Agency for Regional Healthcare
- Spain - Agencia de Evaluación de Tecnologías Sanitarias (Instituto de Salud Carlos III) (AETS)
- France and Scotland review all medicines
- 39% of medicines reviewed - only review medicines of significant impact
- German G-BA 30% due to the implementation of the new AMNOG requirements

NICE

- National Institute for Health and Care Excellence - established 1999
- Applies in England and Wales (SMC in Scotland)
- Response to perceived ‘postcode lottery’
- The use of health technologies within the NHS (such as the use of new and existing medicines, treatments and procedures)
- Clinical practice (guidance on the appropriate treatment and care of people with specific diseases and conditions)
- Broader health guidance

NICE Processes

- Technology appraisals take one of three forms:
- A **single technology appraisal (STA)** which covers a single technology for a single indication.
- A **fast track appraisal (FTA)** which also covers a single technology for a single indication but with a shorter process time to speed up access to the most cost-effective new treatments.
- A **multiple technology appraisal (MTA)** which normally covers more than one technology, or one technology for more than one indication.
- NHS legally obliged to provide funding for medicines and treatments recommended by NICE's

NICE Processes

- Advisory Committee on Topic Selection draws up a list of potential topics
- NICE then invites consultee and commentator organisations to take part in the appraisal including patient groups, health care professionals to submit evidence and the manufacturers to comment
- An independent academic centre prepares an assessment report for comment
- Comments to assessment report result in an evaluation report
- Independent Appraisal Committee hears spoken testimony from stakeholders and produce the 'appraisal consultation document' (ACD)
- ACD sent to all consultees and commentators for further comments leading to the 'final appraisal determination'. The FAD is submitted to NICE for approval

NICE Processes

- NICE assesses the cost–effectiveness of the proposed treatment relative to the current best treatment
- Quality-adjusted life years (QALY) used as the primary outcome for quantifying the expected health benefits associated with a given treatment regime.
- Comparison of the present value of expected QALY flows with/without treatment relative to another treatment to derive the net/relative health benefit.
- When combined with the relative cost of treatment this is used to estimate an incremental cost-effectiveness ratio (ICER)
- NICE accepts as cost-effective those interventions with an incremental cost-effectiveness ratio of less than £20,000 per QALY/£30,000 per QALY
- End-of-life drugs, Orphans/Ultra Orphans
- Patient access schemes
- Since 2000, 576 Technology Appraisals, 892 product approvals, 82% positive

NICE Process – Cancer Drug Fund

- The Cancer Drugs Fund (CDF) aims to make promising cancer drugs available to patients before they are fully approved for use in the NHS.
- The CDF now part of NICE. as a managed-access fund.
- Drugs with clinical potential can be provided temporarily using the CDF, in cases where either NICE is yet to issue final Guidance, or where there is insufficient evidence for a proper assessment.
- The decision to provide any CDF funding is taken by NICE (+ NHS England), CDF funding is granted, where appropriate, at the conclusion of NICE HTA so now funding an HTA outcome rather than an HTA process.
- Data collection and commercial agreement as part of managed access agreement
- 264 Technology Appraisals, 327 products approved – 73% approved

Influence of NICE and the post-Brexit world

- NICE has since acquired a high reputation internationally as a role model for the development of clinical guidelines
- NICE International, established in May 2008 to help cultivate links with foreign governments
- Many agencies outside the UK adopt similar methodologies to NICE
- Of the recommendations given by the selected 13 HTA bodies, 60% echoed the NICE outcome and 40% provided a different recommendation
- Role and influence post-Brexit – limited EU-level controls
- UK slow adopter of new technologies
- Delayed access to new medicines and how UK might respond

Risk Sharing

- Financial based
  - Total patient population – capping and payback and volume and price reduction
  - Individual patients – maximum doses or treatment cost
- Outcome based
  - Outcome guarantees – payment only for responding patients
  - Coverage with evidence development – e.g. adaptive licensing allowing earlier collection of real world data
  - Conditional treatment continuation – defined level or response required.
- Patient access schemes – headline price for reference pricing and 'confidential' discounted price
- Pricing by indication
- Pricing Combinations

Trends

- Growth in drug spend is lower than commentators and governments expected e.g. UK PPRS
- The system of 28 different P&R schemes will remain largely unchanged for legal reasons and due to their different approach to health care
- However more cooperation in pricing and reimbursement matters between Member States, supported by the Commission and patient organisations

Biography

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- Paul Ranson is a consultant who focuses on the regulatory and commercial needs of the pharmaceutical, biotechnology, and medical devices sectors. Paul's regulatory expertise covers both marketing authorization-related matters and market access, pricing, and reimbursement issues. His commercial work is concentrated on transactions with a high degree of industry specificity including collaborations and outsourcing transactions.
- Paul is the legal adviser to the UK trade association for smaller and medium-sized companies (Ethical Medicines Industry Group) and the principal author of the legal module of an MSc on pharmaceutical licensing. He has also been a non-executive director of a specialty pharmaceutical company for some 10 years and was a member of an independent ethics committee for some 5 years.
- As a result of his expertise Paul is a frequent speaker at conferences on a variety of topics including licensing, health technology assessment and various regulatory topics including during 2015 the EU Pharmaceutical Law Forum in Europe and BIO and ISPOR in the United States. He has written some 10 reports on pharmaceutical and medical device regulatory issues and has authored/co-authored numerous journal articles.

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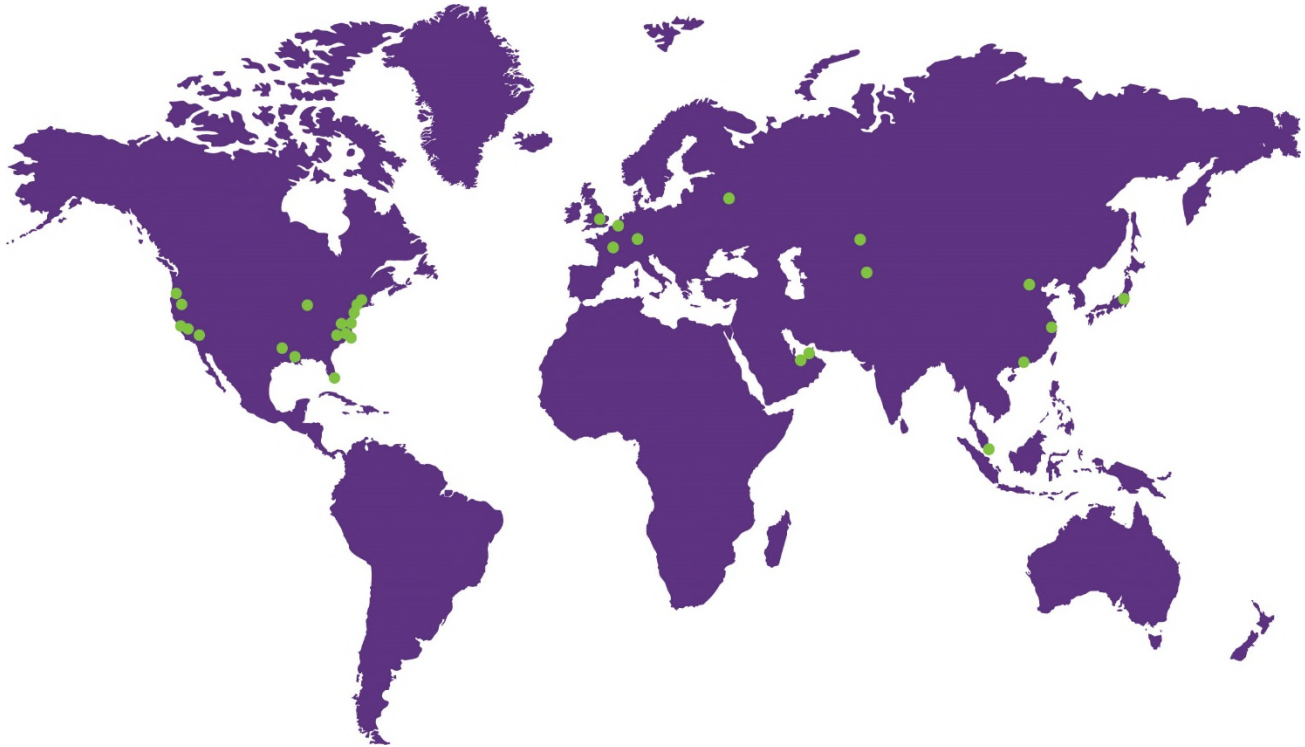

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