Key Trends in the European Market Access
Sample Extract

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Neil Grubert
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Table 11: Key generics policies in the European Economic Area countries (plus Switzerland)
The pros and cons of AP for pharmaceutical manufacturers are summarized in the figure below.

![Figure 1: Pros and cons of adaptive pathways for pharmaceutical manufacturers](source: Datamonitor Healthcare)

<table>
<thead>
<tr>
<th>Pros</th>
<th>Cons</th>
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<tr>
<td>- Earlier market access</td>
<td>- Greater uncertainty regarding total evidence that will need to be produced over the product’s lifecycle</td>
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<td>- Aligned with current shift towards patient stratification and precision medicine</td>
<td>- Regional or local payers are reluctant/not ready to approve use of products with additional uncertainties amid already constrained budgets</td>
</tr>
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<td>- Drives development of registries and other tools that are needed for RWE data collection and analysis</td>
<td>- Increases risk of multiple countries requiring own data</td>
</tr>
<tr>
<td>- Facilitates acceptance of RWE and pragmatic trial design among decision-makers</td>
<td>- Immature systems for data collection required for postmarketing analysis</td>
</tr>
<tr>
<td>- Route for early engagement with regulators and multiple payers/HTA bodies, allowing better selection of evidence required for access</td>
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HTA = health technology assessment; RWE = real-world evidence

THE EMA DEFINES THE MODELS AND CRITERIA FOR APS

The EMA launched a pilot project in March 2014 under the term “adaptive licensing,” but changed the name of this program to “adaptive pathways” in October 2014 “to emphasize the fact that its aim is to foster and facilitate the pathway of product development to potentially achieve earlier access to medicines through an early dialogue involving all stakeholders. The term ‘licensing’ has generated confusion about the scope of this project, which is not establishing a new regulatory tool” (European Medicines Agency, 2014). Drugs will still receive a full, conditional, or under exceptional circumstances marketing authorization, to be determined on a case-by-case basis.

The EMA has described two models for APs (European Medicines Agency, 2014):

In the first model, the manufacturer secures approval in a well-defined subpopulation with a high level of unmet clinical need, before expanding the indication to a larger population.

In the second model, the manufacturer secures an early marketing authorization, possibly on the basis of surrogate endpoints, subject to a commitment to reduce uncertainty by gathering
<table>
<thead>
<tr>
<th>Project/initiative</th>
<th>Objectives</th>
<th>Activities</th>
</tr>
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<tbody>
<tr>
<td>EUnetHTA’s multi-HTA early dialogues</td>
<td>Explore routes to providing manufacturers with timely guidance on HTA</td>
<td>Conducted 10 early-dialogue pilot projects between manufacturers and multiple HTA agencies in 2012 and 2013. The dialogues involved nine manufacturers and 12 HTA agencies, with the EMA present as an observer. Three more pilot projects were conducted in 2015: one on an orphan drug and two on medical devices.</td>
</tr>
<tr>
<td>SEED</td>
<td>Explore routes to providing manufacturers with timely guidance on HTA</td>
<td>Early dialogues between HTA bodies (a consortium of 14 HTA agencies led by France’s HAS) and manufacturers of pharmaceuticals and medical devices. Carried out 10 early dialogues (seven on medicines and three on medical devices). Three of the early dialogues on medicines were to include parallel scientific advice from the EMA. Compared to EUnetHTA early dialogues, SEED process has longer timelines and involves patient representatives.</td>
</tr>
<tr>
<td>Parallel scientific advice</td>
<td>Provide manufacturers with scientific advice from both regulators and HTA</td>
<td>The EMA and leading HTA agencies in Europe launched a parallel scientific advice pilot project in July 2010. By the end of 2014, they had provided such advice on 35 drugs; one-third of these assignments were conducted in 2014.</td>
</tr>
<tr>
<td>EUnetHTA's HTA Core Model</td>
<td>Provide a framework for generating and sharing HTA information in a</td>
<td>Developed nine domains along which new health technologies can be assessed. Four domains are applicable to rapid REAs, while all nine domains are applicable to full HTAs.</td>
</tr>
<tr>
<td></td>
<td>structured format in order to facilitate the re-use of this information for national or regional HTA processes</td>
<td></td>
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</table>
### Table 4: Recent national HTA and reimbursement policies in Europe

<table>
<thead>
<tr>
<th>Measure/change</th>
<th>Details</th>
<th>Potential impact</th>
</tr>
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<tbody>
<tr>
<td><strong>France</strong></td>
<td><strong>Compulsory economic evaluation of certain innovative medicines</strong>&lt;br&gt;Since October 2013, if a manufacturer is hoping to receive an ASMR rating of I, II, or III, and if the product is projected to have annual expenditure of €20.0m ($26.6m) or more after two years on the market, the drug will undergo an economic evaluation by the CEESP.</td>
<td>Limited impact so far as only a minority of drugs qualify for economic evaluation. There is no cost-effectiveness threshold and the CEESP remains in an advisory rather than decision-making role. However, results of economic evaluations do impact pricing negotiations so drugs with lower ICERs may be at an advantage.</td>
</tr>
<tr>
<td><strong>Germany</strong></td>
<td><strong>Contracting by sickness funds</strong>&lt;br&gt;The Act to Strengthen Provision in the Statutory Health Insurance System, enacted in June 2015, will allow the country's 16 states to replace indicative prescribing amounts with alternative methods of monitoring economical prescribing from 2017 onward.</td>
<td>The law will make it easier for sickness funds to conduct tenders for on-patent drugs, putting pressure on less differentiated brands in competitive markets. Manufacturers will need to offer discounts of up to 50% to ensure listing as a preferred agent, which physicians will be incentivized to prescribe.</td>
</tr>
<tr>
<td></td>
<td><strong>Potential AMNOG reforms</strong>&lt;br&gt;The mixed price negotiation may be replaced by consideration of patient subpopulations where added benefit is proven with concomitant G-BA guidelines restricting prescribing to those patients only.</td>
<td>Manufacturers will be able to negotiate higher prices but with stronger regulations preventing wider prescribing. The need to provide evidence in relevant patient subpopulations against relevant comparators will only intensify.</td>
</tr>
<tr>
<td><strong>Italy</strong></td>
<td><strong>The government and regional administrations signed the Health Pact 2014–16, re-affirming the role of HTA</strong>&lt;br&gt;Re-enforces commitment to and support of HTA in all regions and across a drug's lifecycle.</td>
<td>Increased use of economic evaluation in all regions and potential for re-evaluation will increase the burden for manufacturers. Desired effect of reduction in regional and local variation in access may be harder to achieve in practice.</td>
</tr>
<tr>
<td><strong>Spain</strong></td>
<td><strong>National IPTs were introduced in 2012</strong>&lt;br&gt;All new drugs are reviewed with the publication of an IPT assessing the drug's value, available evidence, and likely use in the treatment pathway with the aim of reducing regional and local re-evaluations.</td>
<td>IPTs are published with a significant delay, are often inconclusive, and payers and physicians continue to rely on regional and local assessments.</td>
</tr>
<tr>
<td><strong>UK</strong></td>
<td></td>
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Italy: national and regional governments re-affirm commitment to HTA

In July 2014, the Italian government and regional administrations signed the Health Pact (Patto per la Salute) 2014–16. This wide-ranging agreement on healthcare policy includes plans to create an HTA system for medical devices and a re-affirmation of the importance of HTA in the Italian pharmaceutical market. The document recognizes the role of the AIFA in promoting equitable and uniform access to innovative medicines and in guaranteeing the “efficient and cost-effective use of available resources” (Conferenze Stato Regioni ed Unificata, 2014). The figure below summarizes the pact’s key measures and their potential impact on the pharmaceutical industry in Italy.

Progress on implementing the pact’s objectives with regard to HTA appears to be quite limited to date, although the Ministry of Health (Ministero della Salute) has recently announced the formation of a control center. The pact’s inclusion of statements on HTA is a clear indication that national and regional governments agree that HTA should play an increasingly important role in ensuring equitable access to innovative medicines throughout Italy. It is particularly interesting that the agreement
prospects for many cancer therapies in the country, with drugs such as Avastin (bevacizumab; Genentech/Roche/Chugai) and Revlimid (lenalidomide; Celgene) no longer available for several previously covered indications. The move to delist drugs is symptomatic of changes to the CDF’s previously relatively low scrutiny of a drug’s price and formerly generous provisions, and has highlighted that the fund is not sustainable in the long term. Although the fund will continue to exist after the changes discussed below, the delistings indicate that manufacturers will need to offer steep discounts in order to secure market access through the CDF in future.

**OVERHAUL OF THE CDF WILL LIMIT COVERAGE TO DRUGS THAT HAVE A REASONABLE PROSPECT OF GAINING APPROVAL BY NICE**

The CDF has been seen by some as undermining NICE; the Independent Cancer Taskforce (ICT) suggests that the fund has “enabled some pharmaceutical companies to bypass NICE cost-effectiveness assessments.” The ICT therefore recommends that “NHS England should work with NICE, the Government, the pharmaceutical industry, and cancer charities to define a sustainable solution for access to new cancer drugs. This updated process should enable NHS England to confirm clinical utility, whilst managing within a defined budget, and should be aligned with NICE appraisal processes” (ICT, 2015).

In July 2015, the board of NHS England expressed its support for the ICT’s recommendation and announced plans to overhaul the CDF. The board envisages that the CDF should become a “managed access” fund for new cancer therapies, subject to clear entry and exit criteria. Funding would be provided for drugs that are promising, but have insufficient evidence at launch for NICE to recommend routine commissioning. Instead of simply rejecting such a drug, NICE could grant a “conditional approval” for CDF funding for a defined period. At the end of this period, the drug would undergo an abbreviated NICE appraisal based on real-world data and the price offered by the manufacturer. If NICE then recommended the drug, it would be transferred from the CDF to mainstream commissioning. On the other hand, if NICE rejected the agent, it would be removed from the CDF and would be available only through individual patient referral. New cost-containment measures would be needed to ensure spending remained within budget (NHS England, 2015a).

At present, the CDF offers manufacturers of many high-priced oncology drugs a means to circumvent rejection by NICE. Under the new system, however, funding would be available only for drugs that have a reasonable prospect of gaining approval by NICE on the strength of real-world data.

The NHS England board believes the proposed changes to the CDF will benefit patients, the NHS, and drug manufacturers. Patients will gain access to therapies that initially lack data sufficient to justify their routine use, and the NHS will be able to provide early access to promising oncology drugs and gather additional data to determine whether routine commissioning would be justified. The board’s proposal also states that “pharmaceutical companies will benefit from a transparent and contestable process, with NICE involvement, which will make clear the basis on which their products will be selected for use in the NHS, including the circumstances in which they may be eligible for time-limited access to funding through the CDF” (NHS England, 2015a).
negotiating such deals with manufacturers. To date, Velcade (bortezomib; Takeda/Johnson & Johnson) is the only drug to have been the subject of an outcomes-based PAS in the UK. However, Andy Stainthorpe, the director of PASLU, believes there is potential for outcomes-based schemes in the future: “Schemes need to use outcomes that already have systems in place to measure them, and companies need to find imaginative ways of fitting into what the NHS is already doing” (Scrip Intelligence, 2014).

FRANCE: OUTCOMES-BASED MEAS ARE NOT WIDELY USED

The authorities in France generally favor financially based MEAs over outcomes-based agreements. Innovative medicines are generally subject to price-volume agreements that require manufacturers to make refunds if sales of a drug exceed specified levels. In addition, some new drugs may face price cuts if any specified limits on the daily cost of treatment are exceeded. The Transparency Committee (Commission de la Transparence) or the Health Products Economic Committee (CEPS; Comité Économique des Produits de Santé) may require manufacturers to conduct postmarketing research as a condition of reimbursement. In 2013, the CEPS required 11 postmarketing studies, including four related to outcomes-based MEAs (CEPS, 2014).

Outcomes-based risk-sharing agreements are typically applied to medicines that receive an improvement in actual benefit (amélioration du service medical rendu) rating of V (ie no improvement), but for which the manufacturer claims a clear advantage over established therapies that can only be proven in the real world. Risk-sharing agreements are concluded on the understanding that the manufacturer will bear the full financial risk if postmarketing studies do not prove the drug’s superiority. One success story was Novartis’s Xolair (omalizumab): postmarketing research enabled the company to maintain its launch price (Ignjatovic and Hedden, 2014).

GERMANY: REBATES ARE NOW THE NORM FOR NEW DRUGS, BUT OUTCOMES-BASED MEAS ARE RARE

To date, outcomes-based MEAs remain rare in Germany, but rebates are now required for most new medicines. Historically, the government’s cost-containment strategy focused primarily on maximizing the use of generics. In 2003, the German government passed legislation permitting health insurance funds to negotiate voluntary rebate contracts, which may include volume-based payback arrangements. Most voluntary rebate contracts relate to generic drugs. More recent reforms have sought to control the net prices of new medicines. The Pharmaceutical Restructuring Act (Arzneimittelneuordnungsgesetz) introduced a requirement for manufacturers of most innovative new medicines launched after 31 December 2010 to negotiate rebates with the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband).

The Federal Joint Committee (G-BA; Gemeinsamer Bundesausschuss) has made some use of coverage with evidence development (CED) deals to overcome uncertainty at the time of launch. The committee has set time limits for manufacturers to gather additional post-authorization data and to re-apply for assessment; as of the end of 2014, the G-BA had imposed such restrictions, ranging from 1–5 years, in 23 instances (Wörmann, 2015).
cost-effective and recommended its use in most patient cohorts. Surprisingly, the institute did not demand a patient access scheme (PAS) from Gilead, but National Health Service (NHS) England apparently intends to control prices by conducting competitive tendering for DAAs.

In common with Italy and Spain, the UK has pledged dedicated funding to ensure that Sovaldi and other DAAs are widely available. Such a provision should help to tackle the problem of regional variations in access to these medicines, a major concern for national healthcare policymakers. However, many stakeholders question whether the levels of funding promised by national governments will be adequate to cover all eligible patients. Skeptics believe healthcare systems will be able to treat only a modest proportion of the total diagnosed population with DAAs, a situation that will blight the lives of patients who do not qualify for reimbursement, and could potentially impede this opportunity to eradicate HCV.

DELAYS IN ACCESS TO NEW HCV MEDICINES CONTRIBUTE TO WIDE VARIATIONS IN THE UPTAKE OF THESE DRUGS

In most countries, healthcare providers and patient organizations are frustrated at the delays they have experienced in evaluating Sovaldi and other DAAs, and in settling pricing and reimbursement terms. The additional factor of regional and/or local reimbursement decision-making merely compounds the challenges involved and increases delays in patient access to medications that can transform patients’ lives. A recent analysis by IMS Health found enormous variations in the uptake of Sovaldi across the five major EU markets. In the 12-month period ending 31 March 2015, the number of defined daily doses (DDDs) of the product dispensed in France exceeded 1,400 per 100,000 inhabitants, and consumption in Germany was greater than 800 DDDs per 100,000 inhabitants. By comparison, consumption was less than 200 DDDs per 100,000 inhabitants in the UK, less than 100 DDDs per 100,000 inhabitants in Spain, and less than 50 DDDs per 100,000 inhabitants in Italy (IMS Health, 2015).

DESPITE EVIDENCE OF CLINICAL EFFECTIVENESS AND COST-EFFECTIVENESS, BUDGET IMPACT IS A MAJOR BARRIER TO ACCESS TO NEW HCV THERAPIES

Payers are generally aware that Sovaldi and other DAAs are both clinically effective and cost-effective. They also recognize that these drugs have broad social benefits and can significantly reduce overall healthcare costs. Faced with increasing budgetary constraints, however, payers feel they have to make a choice between the long-term savings from providing access to these therapies, and the short-term costs of paying for the medications. Until they find truly effective ways of managing access, it is likely that budget impact will continue to trump cost-effectiveness.

FRANCE: LEGISLATION IMPOSES A NEW LIABILITY ON MANUFACTURERS OF HCV THERAPIES

In November 2012, Sovaldi first became available to 31 patients in France through a named-patient temporary authorization for use (ATU nominative; autorisation temporaire d’utilisation nominative). A cohort ATU (ATU de cohort) was granted in September 2013, which enabled a further 126 patients to receive treatment with the drug prior to marketing authorization in France (ANSM, 2015).
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