Pricing and Reimbursement Policy Trends in Europe

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Market access is the ultimate goal for healthcare treatments, however, priorities and decision processes can vary from country to country and can change quite often. To gain insight into what factors affect a product's access in various markets, Evidera has established a Pricing and Reimbursement Policy Council (PRPC) composed of current and former payers from six countries, including Germany, Italy, Spain, England, France, and the U.S. This council meets on a quarterly basis, in addition to debates and discussions via blog throughout the year, to identify changes in policy trends across the markets that may affect and influence changes in pricing and reimbursement (P&R).

Below is an overview of the trends affecting Europe as identified by the PRPC at their September 2016 meeting. (Note the U.S. payers are not included in this update.)

POLICY TRENDS	IMPLICATIONS FOR MARKET ACCESS

Key Trends in Germany

A change to the current law proposed on 22 July 2016 is under consultation.[1] Ratification of the law is expected by the end of 2016/beginning of 2017 invoking several changes to Germany's pharmaceutical market.

- Limited reimbursement for patient groups with no additional benefits
- Price freezes will continue until 2022
- Introduction of a turnover threshold for new drugs with an annual threshold of 250M Euros – if this threshold is reached in any month of the first 13 months on the market, the agreed price with the GKV (statutory health insurance funds) will be applied retroactively from the month the threshold was met.
- Details of pricing and drug rebates will not be made public
- Benefit assessment for drugs launched pre-AMNOG. Drugs that launched before 2011 cannot (since 2014) be considered for G-BA (Gemeinsamer Bundesausschuss – The Federal Joint Committee) assessment. However, in the future and in exceptional cases, an assessment may be possible if the active ingredient, launched before 2011, is intending to extend its use and launch in a different line of therapy or indication.

The storm ahead: German reform proposals will allow limits on reimbursement and potentially limits on free pricing.

New restrictions and hurdles

In the past, G-BA was not in a position to exclude sub-populations with no "incremental benefit" from reimbursement, hence all populations went forward to price negotiations and reimbursement. This is likely to change and G-BA may recommend to exclude "no incremental benefit populations" from reimbursement.

This would provide an opportunity for manufacturers to obtain a high price (at lower volume). This requires careful preparation of the GKV dossier only after the G-BA makes its final incremental value verdict.

Protect your price

The reform presents an opportunity to assess medications launched prior to 2011 for their incremental value.

It can well be expected that price negotiations will follow the benefit assessment and will be used to negotiate price, though for drugs launched prior to 2011 free pricing applies. This requires careful consideration in launching a line or indication extension in Germany and what effect this may have on the price of the molecule.

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Key Trends in Germany (continued) • Evidence Transfer. For patient groups or part-indications that are included in a label, but no separate evidence and studies were submitted to the G-BA, the G-BA can consider an incremental benefit assessment if "evidence transfer" would allow this. What will constitute an "evidence transfer" will need to be defined by the G-BA. This clause was mainly included to allow innovative drugs to be used in paediatric setting (note: label inclusion is required).	**Protect your price (continued)** While GKV negotiations and any additional rebates were not actively published, in the future the price, any rebates, or contracts beyond legal rebates will be treated as strictly confidential. This is likely to protect price referencing and will push international referencing to the published German list price. In addition, price freezes will continue. The introduction of the turnover threshold limits the "free pricing" period during the first 12 months on the German market. Hence careful assessment of use/demand/volume/time and expected negotiated price (or fixed price reference group price) is needed to determine when the threshold may be reached.

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Key Trends in Spain • The Ministry of Health (MOH) set the Informe de Posicionamento Terapeutico, i.e. Therapeutic Positioning Report (IPT), in 2013 with the aim to allow for restrictions and potential non-reimbursement on national listings if a new product is more expensive than therapeutic alternatives and does not provide an incremental benefit (Inform Posicionamiento Terapeutico – Therapeutic Positioning Report: http://www.aemps.gob.es/medicamentosUsoHumano/ informesPublicos/home.htm). • Hospital-initiated specialist drugs can have continued prescribing and dispensing in ambulatory setting and community pharmacy. http://www.diariomedico.com/2016/09/07/area-profesional/sanidad/sanidad-farmacos-de-diagnostico-hospitalario-pueden-deben-ir-a-la-farmacia. • Stronger biosimilars promotion at national and autonomous community level is anticipated. • DRG (diagnosis related group) payments in Cataluña are being deferred to hospitals negotiating directly with manufacturers over pricing – leading to DRG aligned pricing. This will be initially initiated for auto-immune conditions; oncology was initially included but withdrawn for implementation.	**Align price of new pharmaceuticals to available budgets** Excluding reimbursement if price exceeds therapeutic alternative The effect, and if the MOH would be committed to exclude national reimbursement listing, remains to be seen. The implication may be that access is via autonomous regions. A space to watch. Aligning DRGS to price- and indication-based pricing Indication-based pricing is a concept in which payers in many markets are interested. It is important to evaluate the first DRG aligned prices. However some indications may be more sensitive to price disadvantages depending on budgets in the current DRGs. For the pilot project in Cataluña, we certainly will watch the group of auto-immune conditions.

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Key Trends in France

- In August 2016, the Government released new policy guidelines[2] to the CEPS (Comité économique des produits de santé) providing general guidance on the increased support for the use of budget impact and stronger use of price/volume or outcomes-related pricing and contracting.
- Beyond traditional price volume agreements, the French government is supporting CEPS to explore new types of agreements. While the guidance is vague, it includes indication-based pricing and control of budgets by indication.
- The increased emphasis to outcomes-based contracting includes, in particular, the intention to use real-world evidence.
- Incentivising competition between biosimilars and branded products is especially highlighted within the guidance document.

Getting tough on pricing – opening the doors to indication-based pricing

Some of the suggested measures are already known to manufactures, such as volume-based contracting. Other aspects, such as considering budget impact in price negotiations, need to be made more explicit (e.g., to what degree will budget impact be considered in pricing).

However, the French government also provides the CEPS with the mandate to consider completely new schemes, such as indication-based pricing. This is an opportunity for manufactures to collaborate with the CEPs and shape the approach of a new pricing and access model.

Key Trends in Italy

The push for biosimilar switching is a first in the EU. Other measures are aimed to allow increased contracting and tendering.

- Pharmaceutical governance for Italy likely to change in the 2017 budget, but no drafts have been released yet.
- As part of that process, in April 2016, the regions proposed to promote increased volume/discount agreements. These agreements should potentially include portfolio pricing and discounts and duration of treatment with a specific drug.
- In addition, regions propose a) to extend the therapeutic equivalence among different drugs belonging to the same therapeutic class in order to favour tendering; and, b) to promote the competition between biologics and their biosimilars by supporting switching patients from branded to biosimilars.[3]

Oncology pricing and reimbursement

- The Italian association of oncology (Associazione Italiana di Oncologia Medica - AIOM) has proposed to establish a national fund dedicated to innovative cancer drugs independent from the National Health Fund (Fondo Sanitario Nazionale, FSN). This proposal has been officially endorsed by the AIFA (Agenxia Italiana del Farmaco – Italian Medicines Agency).

Moreover, the AIOM has made the following proposal: a) promoting price-volume agreements; b) establishing treatment cost per patient independently from its length (parity price); and, c) improving the implementation of registries and managed entry agreements (MEAs).

First mover in Europe to give wide support to biosimilars switching

Very likely that the abilities of regions to administer new contracts and tendering will vary significantly. Hence budget control and compliance to new contracting measures is unlikely to be homogenous across Italy – and requires even more attention to local requirements of Health Regions.

However, the move to recommend switching patients from branded to biosimilars is a daring one and may require further endorsement. Monitoring is needed as the current decision is carefully phrased, but nevertheless requires planning ahead and considerations on how to maintain market share, such as by additional service offerings or local service contracts with Health Regions, to protect market share.

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Key Trends in the UK

- All cancer drugs/indications expecting to receive a marketing authorisation (license) will now be appraised by National Institute for Health and Care Excellence (NICE).
- Early funding option available, through new interim funding arrangements, for those drugs given either a NICE draft recommendation for routine commissioning use, or a NICE draft recommendation for use within the Cancer Drugs Fund (CDF).
- Clear entry and exit points for drugs in the CDF.
- Managed Access Agreements between National Health Service (NHS) England and pharmaceutical companies, setting out the terms of a drug's entry into the CDF and the means by which data will be collected to resolve any uncertainty relating to a drug's clinical and cost-effectiveness.
- All eligible patients to receive CDF drugs, not just the number of patients needed to resolve uncertainty.
- Expenditure control mechanism to reduce risk of overspend and ensure the fund never needs to close to new entrants.
- A new, joint NHS England/NICE CDF Investment Group to manage the overall CDF budget.
- Similar opportunities for off-label drugs to gain access to CDF funds, if deemed to show clinical promise.

A new fast-track system, including an accelerated NICE appraisal process

- Earlier funding, from the point of marketing authorisation, for the most promising drugs through new interim funding arrangements.
- A managed access approach to rapidly support and resolve any areas of uncertainty for drugs showing clinical promise.
- Each drug/indication looked at on an individual basis with bespoke data collection and **commercial access arrangements** – no "one size fits all" approach - managed by a joint NHS England/NICE CDF Investment Group.
- **Investment Group** will oversee budget management (expected to be fixed £340M budget in year one); expenditure control mechanism to reduce the risk of overspend; closer working with the pharmaceutical industry to encourage the responsible pricing of cancer drugs, driving stronger value for money in drug expenditure.

If you have questions or would like to share the trends you have identified (confidentially), please contact marketaccess@evidera.com. Questions and comments are encouraged and welcomed and updates will continue to be made available in future issues of this newsletter.

REFERENCES

[1] Referentenentwurf, des Bundesministeriums für Gesundheit Stand: 22. Juli 2016, Entwurf eines Gesetzes zur Stärkung der Arzneimittelversorgung in der GKV; (GKV-Arzneimittelversorgungsstärkungsgesetz – AM-VSG)

[2] http://social-sante.gouv.fr/IMG/pdf/la_lettre_d_orientation_des_ministres_du_17_aout_2016-2.pdf

[3] http://www.agenziafarmaco.gov.it/sites/default/files/Secondo_Concept_Paper_AIFA_BIOSIMILARI.pdf