What is Influencing Pricing and Reimbursement in 2016?
Policy Trends Identified by Payers

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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 rest of 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 identified by the PRPC that they feel will have the greatest impact in 2016.

ONCOLOGY | **Immuno-Oncology** (primary area of concern) | Combination Treatments (secondary area of concern)

Segments of Payer Concerns	Trend Examples (Non-exclusive and may apply to other conditions)
P&R Process Changes / Adjustments	• CDF (Cancer Drugs Fund)[1] and Highly Specialized Technology (HST) evaluations[2] • Opening the debate on process changes in orphan drug assessment • Accelerated access review and adaptive pathways • Reducing time of pricing negotiations
Cost Concerns	• New contracting arrangements • Price per indication/ patients • Increased portfolio contracting • New contracting arrangements "package deals" • Specific focus on claw-back clauses and utilization of performance contracts and real-world evidence (RWE) to reassess prices
Methodological Concerns	• Long-term efficacy benefits and uncertainty of data in early access • Quality of Life (QoL) data: missing values • Adverse Events (AE) data: survival analyses, "progression related" events, AE selection itself (e.g., special events for assessment) • Added benefit based on lesser harm – request for non-inferiority in benefit

Selected countries of PRPC (5 EU and U.S.) *Almost all countries of PRPC (5 EU and U.S.)*

ORPHAN	New molecules / new indications (primary area of concern)	Number of available molecules in one indication (secondary area of concern)

Segments of Payer Concerns	Trend Examples (Non-exclusive and may apply to other conditions)
P&R Process Changes / Adjustments	• Highly Specialized Technology (HST) evaluations[2] • Opening the debate on process changes in orphan drug assessment • Accelerated access review and adaptive pathways • Different reimbursement routes for indication extensions
Cost Concerns	• Increased contracting and risk sharing • Pre-defined budget by indication – multiple drugs share available budget
Methodological Concerns	• Uncertainty of data in early access and expression of patient benefit • Endpoints and statistically relevant demonstration • QoL data: missing values

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CHRONIC INDICATIONS	New disease states (e.g., nonalcoholic steatohepatitis – NASH) (primary area of concern)	New molecules in low cost environment (e.g., PCSK9 for cholesterol) (secondary area of concern)

Segments of Payer Concerns	Trend Examples (Non-exclusive and may apply to other conditions)
P&R Process Changes / Adjustments	• Assessment of older drugs already on the market (recurring trend) • Exploration of limiting prescriptions in markets where specialist prescribing is currently not an option
Cost Concerns	• Chronic diseases and their "business case" – hurdle of generic standard therapies as price reference (e.g., diabetes, hypertension) • Increased contracting and risk sharing • Agreed final price retroactively valid from market entry (or defined period of time) • Making information on final prices available
Methodological Concerns	• Missing long-term data at market entry • Measuring progression-related events

Selected countries of PRPC (5 EU and U.S.) *Almost all countries of PRPC (5 EU and U.S.)*

BIOSIMILARS	Economic case for biosimilars and change of prices for branded products	What may be the budget impact if switching is an option?

Trend Examples (Non-exclusive and may apply to other conditions)
Extension / introduction of Rx quotes
Management of formulation changes of branded products
Continuous evaluation against branded reference products

■ *Selected countries of PRPC (5 EU and U.S.)* ■ *Almost all countries of PRPC (5 EU and U.S.)*

Most Dominating* Trends across All Markets and Indications

1 Contracting and new ways to price drugs

2 Changes in assessment and pricing of orphan drugs (process and methods)

3 Methodological adjustments including route or access (early/regular) and indication (including patient benefit demonstration, long-term morbidity/mortality, data uncertainty, progression related AEs, role of RWE, etc.)

** Most frequently mentioned by the PRPC between January – March 2016, across all six participating countries (Germany, Italy, Spain, England, France, and U.S.)*

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 welcome, and updates will continue to be made available.

REFERENCES

[1] Cancer Research UK. Cancer Drugs Fund. Available at: http://www.cancerresearchuk.org/about-cancer/cancers-in-general/cancer-questions/cancer-drugs-fund. Accessed March 24, 2016.

[2] National Institute for Health and Care Excellence (NICE). NICE Highly Specialised Technologies Guidance. Available at: https://www.nice.org.uk/About/What-we-do/Our-Programmes/NICE-guidance/NICE-highly-specialised-technologies-guidance. Access March 24, 2106.