Pilots of Multi-Stakeholder Consultations in Early-Stage Drug Development
Frequently Asked Questions

1. What is this initiative?
The pilots are an initiative of multiple European healthcare institutions to test multi-stakeholder consultations in early-stage drug development. The purpose of the consultations is to improve clarity and alignment among stakeholders regarding what constitutes a medicine’s value and the evidence required to demonstrate that value most effectively. Participating companies will seek early advice regarding a medicine in development initially in either breast cancer or type 2 diabetes. Currently three pilots are planned for the latter half of 2010 and early 2011, encompassing three different companies’ medicines in these disease areas.

2. What is the background of the initiative?
The pilots arose from the European Healthcare Innovation Leadership Network. The Network comprises healthcare leaders from across Europe. These leaders are committed to addressing the complementary goals of improving patient health outcomes and enhancing the climate for innovation under competing pressures to control healthcare costs. AstraZeneca, GlaxoSmithKline and Johnson & Johnson support and fund this initiative and are providing medicines from their pipelines for the pilots. The initiative is independently led by Tapestry Networks in accordance with established principles and guidelines for public-private networks.

3. What institutions have contributed to the pilots?
The following institutions have contributed to the thinking behind the pilots, many of them participating directly in this initiative:

- **France**: Agence Française de Sécurité Sanitaire des Produits de Santé (AFSSAPS); Comité Economique des Produits de Santé (CEPS); Haute autorité de santé (HAS); Transparency Commission
- **Germany**: Federal Joint Committee (G-BA); German Centre for Health Technology Assessment and Public Health, University of Erlangen-Nürnberg
- **Italy**: Agenzia Italiana del Farmaco (AIFA)
- **The Netherlands**: Dutch Healthcare Insurance Board (CVZ); Dutch Diabetes Association; Netherlands Breast Cancer Association (BVN); Menzis; UVIT
- **Sweden**: Swedish Medical Products Agency (MPA); Swedish Association of Local Authorities and Regions (SKL); Swedish Breast Cancer Association (BRO); Dental and Pharmaceutical Benefits Agency (TLV)
- **United Kingdom**: Medicines and Healthcare products Regulatory Agency (MHRA); National Institute for Health and Clinical Excellence (NICE); National Health Service Primary Care Trusts (Derbyshire County, Redcar & Cleveland, Stockton-on-Tees)
4. Who is participating in the pilots?
The pilot initiative involves clinicians, health technology assessed (HTAs), patient representatives, payers, regulators and drug developers from France, Germany, Italy, the Netherlands, Sweden, the United Kingdom and the European Medicines Agency. The agreed consultation process will engage all participants on issues of a medicine’s therapeutic value and a narrower group of HTAs and payers on questions of economic value deriving from therapeutic benefits.

5. What are the objectives behind the pilots?
The primary objective behind the pilots is to improve clarity and alignment across stakeholders regarding what constitutes a medicine’s value and what evidence is required to demonstrate that value most effectively. The pilots provide a novel platform for early advice given to a company to impact clinical development plans and ultimately provide better medicines substantiated with better data to meet European health systems’ requirements. The pilots also are designed to provide a proof-of-concept opportunity on which subsequent pilots and broader initiatives for early consultation may be based.

6. What is the relationship of the pilots to other early advice processes?
The pilots will not replace existing channels for regulatory and reimbursement approval. Consultation recommendations will be non-binding and will not supersede existing advice processes.

7. Who designed the pilots?
The pilots are the result of a collaborative design effort involving all participants and coordinated by Tapestry Networks. Experience gained from other existing early advice process, including the UK’s NICE early advice, Sweden’s TLV-MPA national experiment and European Medicines Agency’s and US FDA’s early scientific advice processes informed the design.

8. What principles are reflected in the pilot design?
Key among design principles agreed by participants is the equal standing among all institutions to encourage open dialogue and mutual learning. The pilot consultations focus on the methodology of value assessment and identifying areas where alignment is possible among participating stakeholders regarding the data required to demonstrate value. Pricing questions presently are not within the scope of pilot consultations, given that these decisions fall under national mandates.

Following the pilots, published communications will support transparency in the pilot process, but also maintain the confidentiality of advice related to a specific medicine. Participants anticipate that this experimental initiative could help shape subsequent pilots and broader initiatives for early consultation.
9. What is the source of the recommendation to test multi-stakeholder consultations in early-stage drug development?

Through its deliberations, the Network has focused on understanding, assessing, capturing and rewarding the therapeutic and economic value delivered by different medicines. To add clarity and specificity to this discussion, Network members and Tapestry Networks identified two initial focus areas, chosen for their high unmet needs and impact on healthcare systems: type 2 diabetes and breast cancer. Tapestry Networks convened Working Groups focused on these two therapeutic areas in 2009, comprising leading medical experts, regulators, payers, reimbursement authorities, patients and industry representatives from across Europe.

Working together over the course of 2009, Working Group participants established a shared value framework – an agreed set of attributes, therapeutic endpoints and economic inputs – for evaluating new medicines for these focal illnesses. Participants also identified a number of difficulties in the drug development process that limit the ability of health systems to deliver the right medicines to the right patients at the right time. These difficulties include the high cost of bringing innovative new medicines to market, the limited additional benefit over existing treatments that many new medicines provide, and problems getting newly developed medicines that promise significant improvement in health outcomes to patients in a timely manner. Working Group participants recommended multi-stakeholder consultations in early-stage drug development to help address these problems. The pilots test these recommendations.

10. What is Tapestry Networks?

Tapestry Networks is a professional services firm that brings together public- and private-sector leaders to solve complex problems through exclusive, trust-based networks. The Networks that Tapestry convenes are independently led in accordance with public-private principles. The European Healthcare Innovation Leadership Network is such a network. Please refer to the Tapestry Networks Pilot Website for further information and to track updates regarding the pilot initiative.