The Dawn of a New Era: Cross-Border Collaborations—Regional, Pan-European, and Transcontinental—How Will They Shape the Future of Access?

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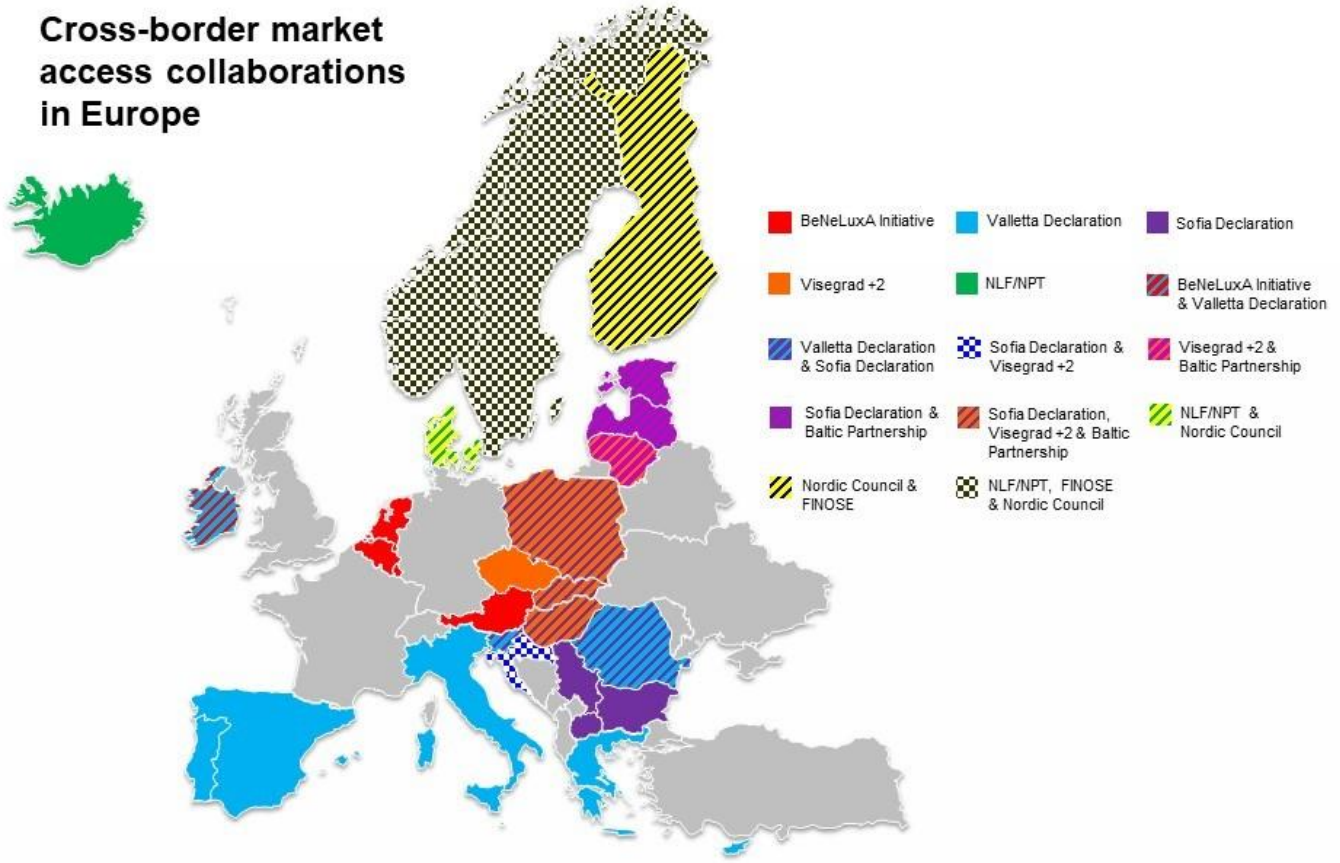
Approaches to cross-border collaboration

- Horizon scanning
- Sharing best practice
- Sharing pricing information
- HTA methodological development
- Joint HTA
- Joint pricing negotiation
- Joint tendering/procurement

Regional cross-border collaborations



- Beneluxa Initiative has focused largely on ATMPs. Belgium and the Netherlands have been the main users of outputs.
- Joint Nordic HTA Bodies (formerly FINOSE) and Nordic Pharmaceutical Forum work closely together and have regular interaction with Beneluxa. Working Group on Exchange of Information and Experience in the Medicines Area (WGEMA) has a more strategic focus.
- Valletta Declaration Group has kept a relatively low profile, serving as a platform for information exchange, but a “resurgence” of activity is expected.
- SUSTAIN-HTA will support the HTA Coordination Group and its Subgroup on Methodology and “aims to assist in the alignment of HTA methodologies.”
- Eight countries have expressed interest in voluntary cooperation on joint HTA.
- NICE has worked closely with the Danish Medicines Council. Spain and Portugal are also looking to collaborate.

Pan-European cross-border collaborations

- National Competent Authorities on Pricing and Reimbursement (NCAPR) has funding from EU4Health and the European Commission's backing to "exchange and share best practice regarding the implementation of cross-border access agreements and negotiations." Priorities include efficiency and affordability, transparency and innovative payment methods.
- EURIPID has data on drug prices and managed entry agreements for 28 European countries and has published guidance on international reference pricing.
- The Medicine Evaluation Committee (MEDEV) is a network of 23 national authorities from 19 countries that brings together all the institutions (national HTA agencies and social health insurers-payers) responsible for drug assessment and P&R.
- Critical Medicines Alliance will foster collaboration to "help unlock manufacturing, contractual or financing solutions to allow better strategic autonomy for critical medicines in the interest of European citizens."
- Mechanism of Coordinated Access to Orphan Medicinal Products (MoCA) seeks "to support more equitable access to authorised therapies for people living with rare diseases, rational prices for payers and more predictable market conditions for OMP developers."
- Novel Medicines Platform brings together 53 countries to share best practice and "pave the way for joint procurement outside the EU."

Transcontinental cross-border collaborations

Name	Participants	Key objectives
Project Orbis	Australia, Brazil, Canada, Israel, Singapore, Switzerland, UK, US	Accelerated regulatory approval of cancer therapies
Access Consortium	Australia, Canada, Singapore, Switzerland, UK	Accelerated regulatory approval of non-oncology drugs
UK Int'l Recognition Framework	UK, Australia, Canada, EU, Japan, Switzerland, Singapore and US*	UK recognition and lighter-touch evaluation of marketing authorisations of cutting-edge drugs from 7 other regulatory authorities
AUS-CAN-NZ-UK Collaboration	Australia, Canada, New Zealand, UK	8 "like-minded" HTA bodies will share information on best practice and conduct a pilot JCA
-	Canada, Belgium, Denmark, Iceland, Ireland, Netherlands, Norway, Portugal, Sweden	Canada will work with members of Beneluxa Initiative, Nordic Pharmaceutical Forum and Portugal to share experiences on dealing with lack of evidence and negotiating prices for high-priced drugs

* UK MHRA recognises decisions of other designated regulatory agencies

- Project Orbis approved 10 new cancer drugs and 8 new oncology indications from May 2021 to December 2023 and has shown "exceptional worth in clinical situations where time really does matter."
- Access Consortium "creates a market of some 160 million people" and will explore collaboration with HTA agencies.
- UK's new International Recognition Procedure will be "a very important tool in our regulatory toolbox": first drug—Amgen's Xgeva—was approved within 30 days.
- AUS-CAN-NZ-UK Collaboration Arrangement will conduct at least one pilot joint clinical assessment.
- NICE International is increasingly active, especially in APAC and Latin America (including a bilateral agreement with Taiwan).
- IQWiG believes its membership of the International Network of Agencies for Health Technology Assessment (INAHTA) will play a key role in fostering collaboration with agencies abroad
- Pan-American Health Organization (PAHO) participated in a recent meeting of the Novel Medicines Platform.