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Europe's Biggest Multi-Country Access Alliance Picks Up The Pace

by Francesca Bruce

The Valletta Group says that cancer drugs, treatments for autoimmune diseases, orphan medicines and biosimilars are among the products it is targeting in its joint procurement efforts.

Europe's biggest cross-country coalition for improving sustainable access to medicines, the Valletta Group, will use lessons learned from the coronavirus pandemic in different EU member states to work on a plan for joint negotiations and procurement relating to medicines.

The Valletta Group is one of several European alliances and includes Portugal as well as two of Europe's biggest markets, Spain and Italy. It held a meeting at the end of June at which, according to the organizer, Portuguese medicines agency Infarmed, members agreed to deepen cooperation and knowledge sharing and identify and assess processes for joint negotiation and procurement to "facilitate and streamline the negotiation and sustainability procedures for medicines acquisitions".

Strategy options to be considered will be based on experience gained during the pandemic and from best practices.

Oncology medicines, treatments for autoimmune diseases, orphan drugs, biosimilars and products that will have a big budget impact are of most interest to the group. Information sharing is also a priority. Infarmed said that countries also "shared and debated lessons learned regarding their experiences related to dealing with advanced therapies."

The other members of the Valletta Group are Ireland, Malta, Cyprus, Greece, Slovenia, Croatia and Romania; France has observer status. It has the largest population of all the existing cross-country alliances, which means that any agreement on pricing or procurement would have major consequences for pharmaceutical companies. (See interactive map below detailing the Valletta



Group and other key alliances.)

Lessons From BeNeLuxA?

Joint negotiations and joint health technology appraisals are an important priority for the BeNeLuxA (Belgium, the Netherlands, Luxembourg, Austria and Ireland) initiative, Europe's most advanced cross-country initiative. Ireland is a member of both the Valletta Group and BeNeLuxA.

BeNeLuxA certainly has more tangible experience of negotiating with companies. Under the BeNeLuxA banner, Belgium and the Netherlands failed to reach an agreement with Vertex for its cystic fibrosis drug Orkambi (lumacaftor/ivacaftor) following a joint health technology appraisal. (Also see "Where Europe's 'BeNeLuxA' Joint Pricing Pilot May Have Gone Wrong" - Pink Sheet, 30 Jun, 2017.) The same countries subsequently struck a deal with Biogen over its SMA treatment Spinraza (nusinersen) following a joint HTA. (Also see "BeNeLuxA Makes First Positive" Reimbursement Decision On Biogen's Spinraza " - Pink Sheet, 19 Jul, 2018.)

Most recently, Ireland, Belgium and the Netherlands undertook a joint HTA of Novartis's gene therapy Zolgensma and discussions on possible joint negotiations are underway. (Also see "European Countries Should Join Forces To Lower Prices of Zolgensma & Kaftrio" - Pink Sheet, 19 May, 2021.)

Picking up the Pace

Some commentators noted that during the COVID-19 pandemic, cross-country collaborations on medicines access took a back seat as countries tried to respond to the crisis. (Also see "The <u>COVID-19 Economic Crisis – Fallout And Opportunities</u>" - In Vivo, 2 Dec, 2020.) However, it has also been suggested that the pandemic could revitalize these initiatives as pressure on public spending grows and the sustainability issue becomes ever more pressing, particularly in view of the slew of high priced drugs, including for advanced therapies, that are set to come to market.

Another issue that may gain momentum among Valletta Group members is transparency. Before the pandemic, the group said a "paradigm shift" in its approach to sharing information on drug pricing was necessary and agreed to take further action on information sharing. (Also see "EU <u>Valletta Alliance Ups The Ante On Drug Pricing Transparency</u>" - Pink Sheet, 24 Jul, 2019.)

Other cross-country alliances include the Nordic Pharmaceuticals Forum and the Visegrad Group.

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