EDMA's reflection on the Council conclusions on personalised medicine for patients

EDMA welcomes the Council conclusions on personalised medicine for patients published on December 7, 2015. In vitro diagnostic (IVD) manufacturers appreciate the Council's increased recognition of the specific value of diagnostics in making personalised medicine an accessible and sustainable reality in Europe, empowering patients to make informed health choices. We also welcome that the Council has identified challenges for access to IVDs as a key point to be addressed by Member States. While the overall health care expenditure is a relevant issue to consider, challenges to access companion diagnostics in Europe should be sought beyond budget constraints, given that far less than 1 % of the total healthcare expenditure is invested in companion diagnostics.

We would like to propose concrete actions that Member States and the European Commission could focus on to effectively support patient access to personalised medicine. Diagnostic information can help to ensure personalised medicine is affordable for healthcare systems in Europe while further empowering patients and carers to make informed health decisions.

All Member States should develop adequate access mechanisms for IVDs.
A key focus should be given to set-up adequate patient access mechanisms for innovative companion diagnostics in all European health systems, in parallel to support the development of innovative diagnostics. This is of paramount importance to allow access to clinically effective, financially sustainable personalised medicine as stated in the Council conclusions.

The value of diagnostic information to make personalised medicine a sustainable reality for European patients needs to be recognised and rewarded by European health systems.
Companion diagnostics enable the delivery of high quality care while improving the efficiency of health systems. They help to redirect health care resources where they are most needed. Diagnostic information enables patients to make informed choices and health care professionals to select the most efficient pathways of care, facilitating savings in inpatient and outpatient care from unnecessary adverse events in non- responders, also reducing cost of treatment and care and time waste from non- effective medication strategies.

Europe needs to avoid creating new barriers for access to valuable diagnostic innovation limiting access to personalised medicine.
We welcome that the Council has put forward the need to develop specific procedures to evaluate the impact of personalised medicine, taking into account the added value from the patient's perspective. We strongly feel national HTA agencies and Joint European HTA should recognize the specificities needed to perform HTA on diagnostics such as companion diagnostics, to bring out the value of diagnostic information. Whenever HTA approaches are used they need to be coupled with adequate strategies to promote the uptake and recognition of the value of companion diagnostics by the health systems.

We welcome the Council's view that a specific focus on personalised medicine is needed, fostering cooperation between Member States and sharing of best practices. EDMA thinks this could be fully accomplished if the European Commission and Member States foster a

multi-stakeholder dialogue partnership specifically dedicated to medical technologies such as in vitro diagnostics. Patients, decision makers and Member States, health care professionals, IVD industry and possibly HTA agencies could seat around the table to define pragmatic ways for EU joint work to support access to valuable personalised medicine in a sustainable way. This is, in our view, a fundamental step to guide a truly patient centric EU Joint Action, and share best practices for the value assessment of personalised medicine, drawing from European and other leading international models such as Australia and the US in a pragmatic and useful way for Member States.

Conclusions:

We welcome the Council of the European Union recognition of the value diagnostic information provided by IVDs brings in the overall personalised medicine strategy, welcoming also the call to support the development of IVDs. In order to make personalised medicine a successful strategy, challenges around an effective market access to IVDs need to be addressed by most Member States.
EDMA has concrete proposals in order to facilitate the access to valuable companion diagnostics, thus enabling access to personalised medicine for European patients while addressing affordability challenges. We welcome the opportunity to continue the dialogue and collaboration at the EU level, with the European Commission and with individual Member States.