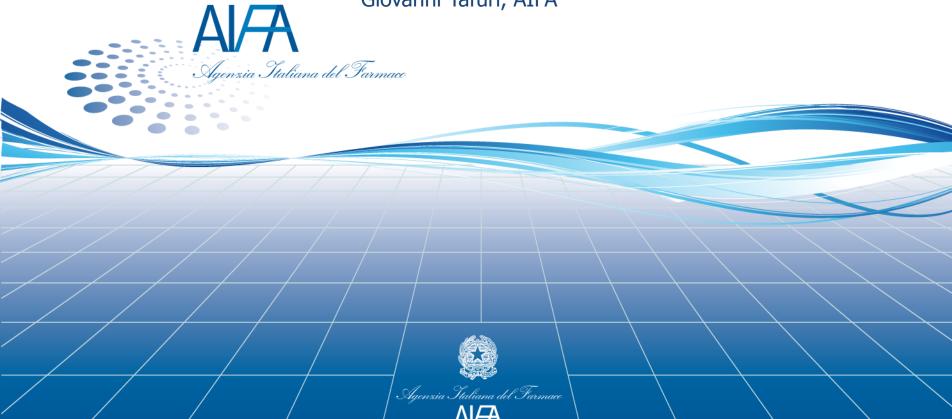
### **HTA Network Synergy Group**Update on progress and next steps

9 February 2018 Giovanni Tafuri, AIFA



#### **Background**

√10 November 2016: adoption of Reflection Paper on "Synergies between Regulatory and HTA issues on Pharmaceuticals" by the HTA Network

✓ Establishment of the Synergy Group, composed of similar numbers of HTA representatives (HTA Network and EUnetHTA JA3) and regulators (STAMP, HMA, EMA), chaired by AIFA.

✓26 June 2017: Kick-off meeting of the Synergy Group



#### **Objectives of the Synergy Group**

✓To map the activities - planned or ongoing - relevant to the collaboration areas identified in the Reflection Paper

✓ To provide an overview of the work carried out by various fora, avoiding duplication of efforts and facilitating synergies

✓To stimulate discussion on further collaborations/interactions amongst different bodies



#### **Data collection and analysis**

- •July-September 2017: agreement on a table template for the mapping exercise
- November 2017-January 2018: data collection
- •All Group members provided their contribution to the mapping exercise
- AIFA collected all inputs and discussed the contents with Group's Representatives to ensure consistency of the information



## Template for data collection as agreed by all participants of the Synergy Group

Collaboration	Participating	Activities	Ongoing	Start date	Expected	Potential challenges to the	Supportive/reference documents
area	organisations	related to	/Planne	and	deliverables	implementation of joint	available (e.g. website, links to the
identified in		the	d	expected		synergisticactivities	documents)
the Reflection		collabora	Please	end date			
Paper		tion area	specify:	(MM/YYY			
			O/P	Y)			



### The table aims to collect data on the activities related to collaboration areas identified in the Reflection Paper:

#### Pre-marketing:

- ✓ Early dialogues/scientific advice
- ✓ Definition of unmet medical need
- ✓ Definition of therapeutic innovation
- √ Horizon scanning
- ✓ Promotion of research and dialogue in therapeutic areas with unmet medical need
- ✓ Cooperation on research needs (such as novel study designs, validation of endpoints etc.)



# The table aims to collect data on the activities related to collaboration areas identified in the Reflection Paper (cont'd):

#### Market entry:

- ✓ Information exchange on eligible patient populations
- ✓ Early information exchange on novel pharmaceuticals
- ✓ Cooperation on regulatory assessment reports



# The table aims to collect data on the activities related to collaboration areas identified in the Reflection Paper (cont'd):

#### Post-marketing – RWE and safety:

- ✓ Initiatives on post-marketing studies (e.g. PASS, PAES)
- ✓ Development of late dialogues with manufacturers
- ✓ Collaboration on RWD (e.g. disease/product specific registries)



The table aims to collect data on the activities related to collaboration areas identified in the Reflection Paper (cont'd):

#### Other areas

- ✓ Initiatives on patients involvement
- √Other initiatives (ATMPs/personalised medicine/orphan drugs)



#### **Preliminary results**

- •Most collaboration areas identified in the Reflection paper seem to be covered (planned or ongoing) with the exception of "Promotion of research and dialogue in therapeutic areas with unmet medical need".
- •Overall, different Groups deal with similar activities, although they have different aims and remits
- In general, little duplication or replication of the activities related to regulatory and HTA synergies



#### Areas for possible collaboration

- ➤ General interest in the definition of unmet need/therapeutic innovation expressed by different participants
- > Real World Data is of interest to different fora
- ➤HTA Network Multiannual Work Programme 2016-2020, EMA/EUnetHTA work plan and HMA reported initiatives on patients involvement



#### **Conclusions and next steps**

- ➤ Information exchange on activities of common interest to different Groups is envisaged
- ➤ The table will be further discussed among the Synergy Group participants. Updates may be necessary.
- The final outcome of the mapping exercise will be presented during the next meeting of the HTA Network.



#### Thank you for your attention

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