ISPOR 19th Annual European Congress
Vienna, October 29th | November 2nd 2016

ITALIAN TIMINGS IN NEW DRUGS APPROVAL: AN UP-TO-DATE ANALYSIS

Lanati EP, Lidonnici D, Ronco V
MA Provider, Milano, Italy

Objectives: The present study analyses the timings of recently approved new drugs in Italy, pointing out the whole national process duration, from submission to price and reimbursement decision published on the Italian Official Journal.

Methods: We screened all reports published on the Italian Medicines Agency website regarding the monthly decisional meetings of the two commissions in charge of discussing the pricing and reimbursement requests presented by pharma companies (Technical Scientific Committee and Price and Reimbursement Committee). The public reports have been analyzed since January 2015 to the end of September 2016, focusing on new drugs approved by EMA with centralized procedure, and integrated with information taken from the Italian Official Journal. In case of drugs approved in 2015, we analyzed 2014 reports. This was the basis for the creation of a database that will be monthly updated. For each drug analyzed, a number of standard checkpoint have been highlighted in order to measure the minimum, average and maximum timing for price and reimbursement approval.

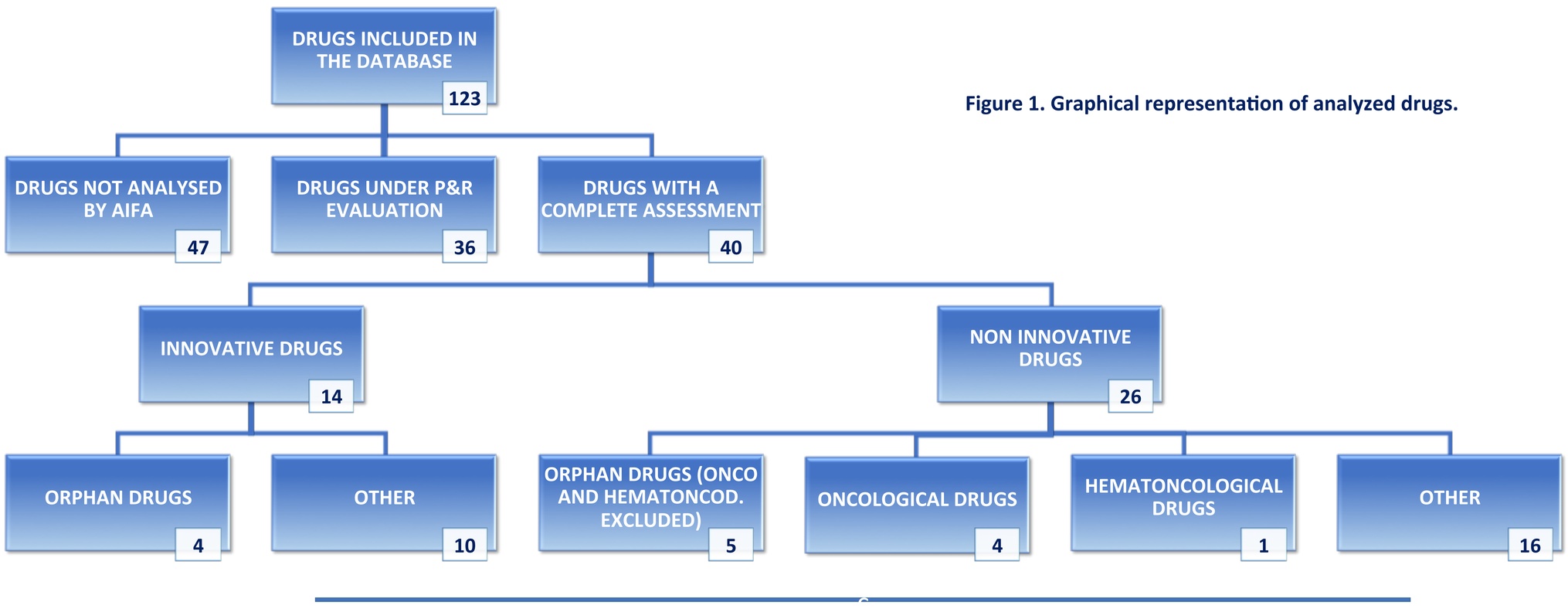
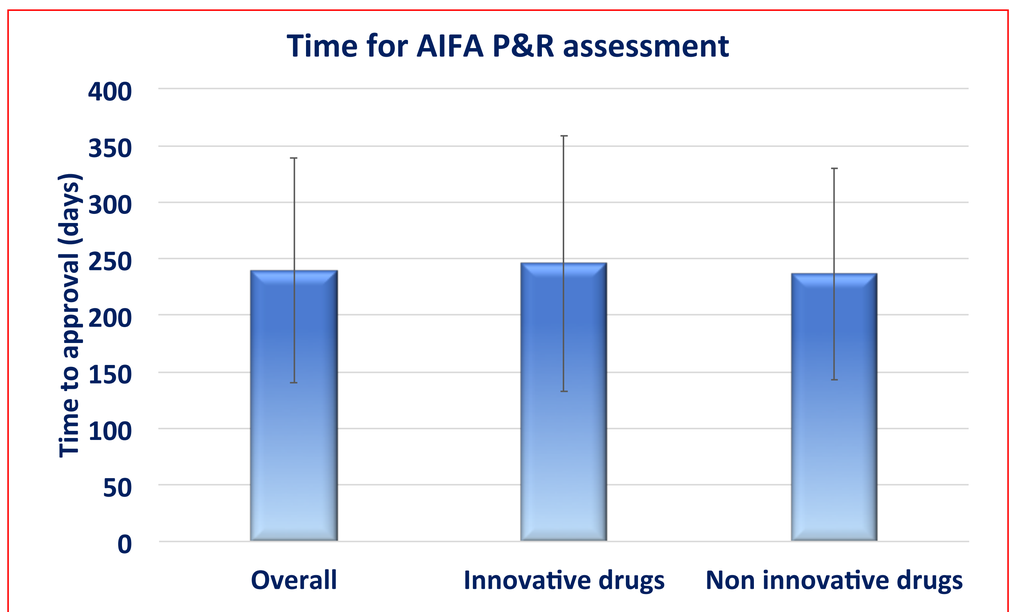


Figure 1. Graphical representation of analyzed drugs.



Time for AIFA P&R assessment

	AVERAGE (days)	MAX (days)	MIN (days)	ST.DEV
Overall	239,44	480	78	99,64
Innovative drugs	245,71	480	124	113,04
Non innovative drugs	235,92	435	78	93,61

Figure 2. Time for AIFA P&R assessment. The graph represents the average time in AIFA assessment, from procedure opening to the publication of the assessment on GU. Error bars are standard deviation. Value are reported in the table.

Results: The dataset collected up to September 2016 consisted of 123 drugs mentioned in AIFA report. Drugs which were not analyzed by AIFA for P&R were excluded (47). 36 out of the 123 drugs reported in the database are currently under AIFA evaluation, while 40 have been approved and published on the Italian Official Gazette (GU). Focusing on the 40 approved drugs, we analyzed innovative vs non innovative drugs time of approval. Overall, the time of approval, from procedure opening to the publication on GU is 239,44 days, with a minimum of 78 days and a maximum of 480 days. Surprisingly, a great difference in time of approval was not observed in innovative drug (N=14) evaluation compared to non innovative ones (N=26), where the average of time for AIFA evaluation is 245,71 days (minimum: 124; maximum: 480) vs 235,92 (minimum: 78; maximum: 435).

DRUG	ACTIVE SUBSTANCE	THERAPEUTIC AREA	CTS PROCEDURE OPENING	GU		TIME TO APPROVAL (days)
				Date	N°	
SOVALDI	sofosbuvir	HCV	10-Mar-14	05-Dec-14	283	270
ABRAXANE	nab paclitaxel	ONC	10-Mar-14	06-Feb-15	30	333
XALKORI	crizotinib	ONC	02-Dec-13	27-Mar-15	72	480
OLYSIO	simeprevir	HCV	15-Sept-14	24-Feb-15	44	162
DAKLINZA	daclatasvir	HCV	10-Dec-14	04-May-15	101	145
KALYDECO	ivacaftor	PNE	15-Sept-14	04-May-15	101	231
XOFIGO	Ra 223 dichloride	ONC.	07-Apr-14	27-May-15	121	415
IMNOVID	pomalidomide	HONC	19-Jan-15	05-Aug-15	180	198
ZYDELIG	idelalisib	HONC	19-Jan-15	27-Aug-15	198	220
IMBRUVICA	ibrutinib	HONC	10-Dec-14	21-Dec-15	296	376
HARVONI	ledipasvir/sofosbuvir	HCV	10-Dec-14	13-May-15	109	154
EXVIERA	dasabuvir	HCV	01-Jan-15	23-May-15	118	142
VIEKIRAX	ombitasvir/ paritaprevir/ritonavir	HCV	19-Jan-15	23-May-15	118	124
OPDIVO	nivolumab	ONC	16-set-15	24-May-16	70	190

Figure 3. Single time to approval for innovative drugs. Time to approval is consider from CTS opening procedure to assessment publication on GU.
ONC.: oncology; HONC: onco-hematology; PNE: pneumology

Conclusions: Even if Italian regulatory framework has been indicated as one of the most up-to-date, Italy has always been pointed at as a slow country in terms of approval timings of new drugs. Furthermore, innovativeness attribution does not mean an advantage in terms of time in AIFA assessment. The analysis reveals a possible improving trend.