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ANALYSIS OF APPROVAL TIMING FOR 89 NEW DRUGS IN ITALY FROM JANUARY 2015 TO MAY 2018

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Objective

Analyse trends in drug reimbursement time through tracking the Italian Medicines Agency (AIFA) P&R approval process from submission to publication.

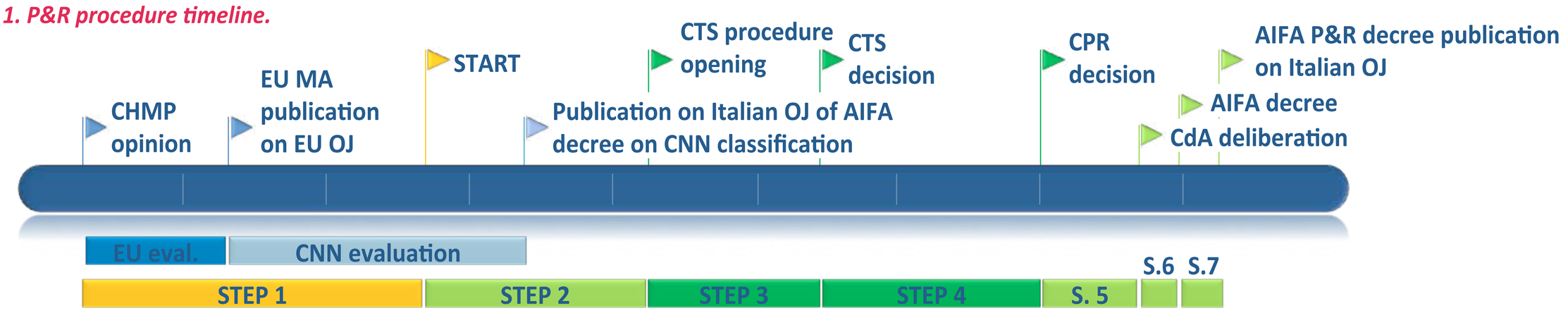
Methods

This analysis covered evaluation of new active principles approved by EMA and then tracked by AIFA. Analyzed data were taken from official documents published on EMA and AIFA websites [1-4]: EMA approval dates and each single step/checkpoint of the Italian P&R process (dossier submission, scientific assessment by CTS, price negotiation with CPR, publication on Official Journal [OJ] [5]) at AIFA level were tracked monthly from January 2015 to May 2018 through updates of an internal database. The database currently houses 190 drugs. Drugs were categorized into pre-defined categories and analysis was performed by year, by therapeutic area and by approval step.

Results

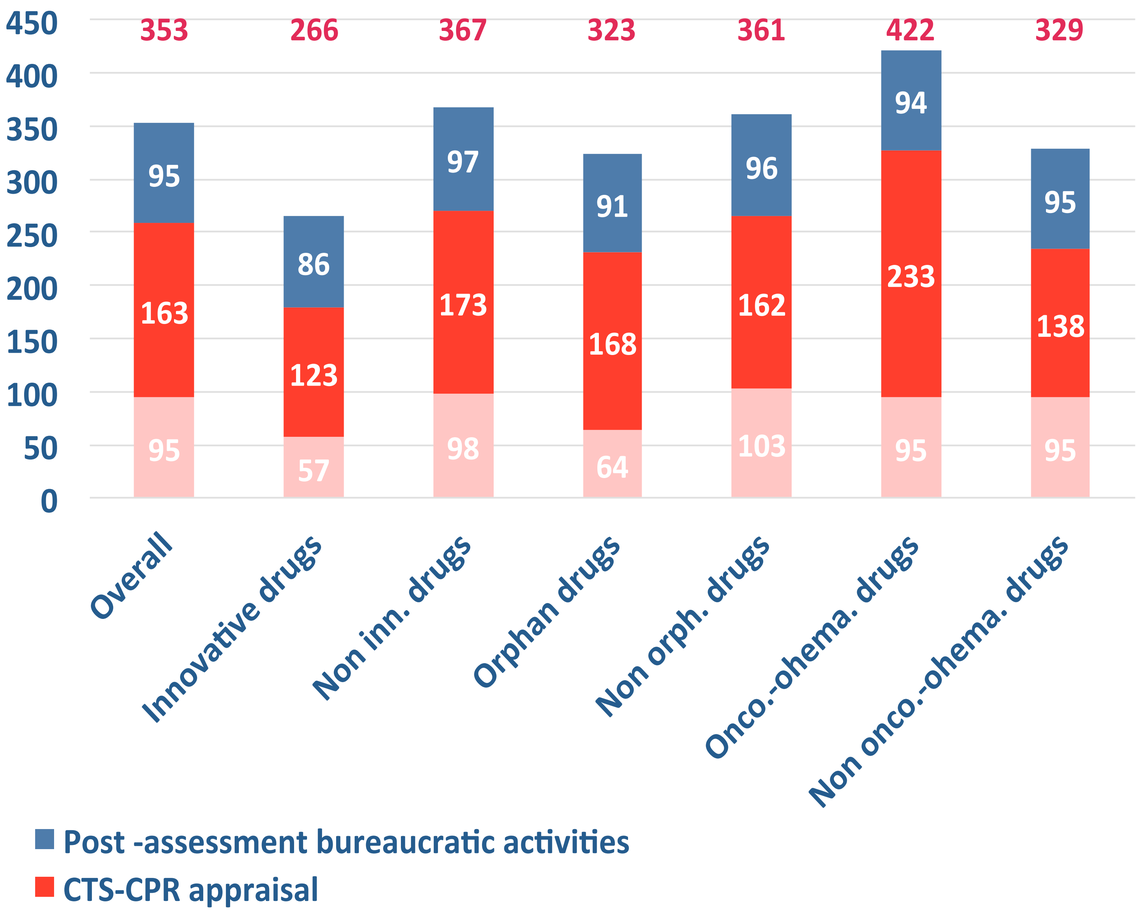
Up to May 2018, 89 new drugs were reimbursed and categorized in: innovative (17), orphan (23), innovative and orphan (5), oncological (23) and other approved drugs. The analysis showed an average time between Start and OJ publication (step2 → step7) of 353 days, of which 163 due to CTS-CPR active assessment. The average total administrative delay, considering also the pre-assessment phase from Start to CTS opening, is therefore 190 days (54% of total time). Timing (step3 → step7) was consistently reduced in all steps for innovative drugs (196 days), while resulted longer for oncological drugs (327 days), particularly the CTS assessment (233 days), which appears slightly shorter compared to previous publications (247,5 days in 2013-2015) [5]. Orphan drugs had shorter pre-assessment procedures, but longer committees assessments. Other drugs have longer openings and faster CTS assessments.

Figure 1. P&R procedure timeline.



CHMP: Committee for Medicinal Products for Human Use; EU: European Union; MA: Marketing Authorization; OJ: Official Journal; CTS: Technical Scientific Committee; CPR: Price and Reimbursement Committee; CdA: Board of Directors; START: P&R dossier submission date.

Figure 2. Italian P&R procedure timing (average days for each category).



HTA office assessment: STEP2; CTS-CPR appraisal: STEP3 – STEP4; post assessment bureaucratic activities: STEP5 – STEP 7

Table 1. Timing details (days) for each step analysed.

	Overall		Innov		Non innov		Orph.		Non orph.		Onco-ohema.		Non onco-ohema.	
	MN	n	MN	n	MN	n	MN	n	MN	n	MN	n	MN	n
EU eval.	63	89	63	17	63	72	65	22	62	67	61	23	63	66
Cnn eval.	124	66	97	7	127	59	176	12	112	54	164	15	112	51
STEP 1	86	53	-14	4	94	49	57	11	94	42	69	14	92	39
STEP 2	95	53	57	4	98	49	64	11	103	42	95	14	95	39
STEP 3	68	87	47	16	72	71	101	22	56	65	124	23	47	64
STEP 4	96	87	75	16	100	71	67	22	105	65	109	23	91	64
STEP 5	45	87	41	16	46	71	37	22	47	65	35	23	49	64
STEP 6	33	88	33	17	33	71	37	22	32	66	43	23	30	65
STEP 7	17	89	12	17	18	72	17	22	17	67	16	23	17	66
STEP 3-7	253	87	196	16	265	71	259	22	250	65	327	23	226	64
*STEP 2-7**	353	-	266	-	367	-	323	-	361	-	422	-	329	-

*MN: mean; n: number sample; Innov: innovative drugs; Orph: orphan drugs; onco-ohema: oncological – oncohematological drugs; eval: evaluation. *sum.*

Conclusions

Despite a speed up in the approval process over the last 3 years compared to previous publications, the subanalysis by category reveals a variety of pathways linked to the different categories, impacting on approval timings. The analysis also reveals that most of the overall timing is not linked to active committees assessment, but to HTA office assessment and post-assessment bureaucratic procedures.

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