Emergency Use Authorizations of medical products for COVID-19: a cross-sectional study

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Background: Emergency Use Authorizations (EUAs) enable the US Food and Drug Administration (FDA) to facilitate the availability of medical countermeasures when public health emergencies are declared. EUA authority was used extensively for rapid authorizations of medical products during the COVID-19 crisis. Herein we describe COVID-19-related products authorized by the FDA and report on the quality of supporting evidence.

Methods: COVID-19-related EUA information up to January 22, 2021 was collected from the FDA EUA webpage. Evidence was categorized according to supporting trial design. Data were descriptively reported for the entire cohort and according to medical countermeasure type.

Results: Of 393 products granted EUA for COVID-19, most were diagnostics (n=329, 83%), followed by medical devices (n=54, 14%) and drugs or vaccines (n=10, 3%) (Table 1). EUAs of diagnostics were mostly supported by comparisons with various previously authorized assays (n=254, 77%), followed by analytical in-vitro studies (n=47, 14%). No supporting evidence was specified for most medical devices (n=32, 59%), and when evidence was cited it was mostly lab data (n=20, 37%). EUAs of drugs and vaccines were mostly supported by randomized controlled trials (RCTs) (n=7, 70%) (Table 2). Most drugs and vaccines (n=8, 80%) were not previously FDA approved for other indications. Seventeen (4%) products (2 drugs, 7 medical devices, 8 diagnostics) were revoked by the FDA, mostly for ineffectiveness or safety issues (n=10, 59%) following a median of 230 days (IQR 107-429). One drug and one vaccine were granted FDA approval.

Table 1. Medical Products Granted Emergency Use Authorization for COVID-19 and Supporting Evidence

	No. (%)			
Supporting evidence	All products (n = 393)	Drugs and vaccines (n = 10)	Medical devices (n = 54)	Diagnostics (n = 329)
Comparison with a previously authorized assay	254 (64)	0	0	254 (77)
Analytical in vitro study	47 (12)	0	0	47 (14)
Not specified	36 (9)	1 (10)	32 (59)	3 (1)
Laboratory data	27 (7)	0	20 (37)	7 (2)
Single-group prospective study	16 (4)	1 (10)	2 (4)	13 (4)
Retrospective data	6 (2)	1 (10)	0	5 (2)
RCT	7 (2)	7 (70)	0	0

Table 2. Drugs Authorized for COVID-19

Drug	Authorization date	Supporting evidence	Previous FDA approval for other indications	EUA status[a]	Time to status change, d
Chloroquine/hydroxychloroquine	March 28, 2020	Retrospective	Yes	Revoked	79
Remdesivir					
For adults	May 1, 2020	RCT	No	FDA approved	174
For children	May 1, 2020	RCT	No	Active	NA
Fresenius Kabi Propoven 2%	August 5, 2020	Unspecified	No	Active	NA
COVID-19 convalescent plasma	August 23, 2020	Prospective, single group	No	Active	NA
Bamlanivimab	November 9, 2020	RCT	No	Revoked	159
Baricitinib	November 19, 2020	RCT	Yes	Active	NA
Casirivimab and imdevimab	November 21, 2020	RCT	No	Active	NA
COVID-19 vaccine					
Pfizer-BioNTech	December 11, 2020	RCT	No	FDA approved	401
Moderna	December 18, 2020	RCT	No	Active	NA

Conclusions: most EUAs are not supported by high-quality evidence. These data might inform regulators regarding the current status of EUAs and assist in guiding future improvement efforts.

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