KEY green = no/little interruption | yellow = running with modifications | red = temporarily suspended

PROGRAM	DESCRIPTION	STATUS
Europe		
EMA standard scientific advice	Voluntary, non-binding, and confidential regulatory advice on clinical development	Running with modifications • Meetings held virtually[1]
Parallel consultation with EMA and EUnetHTA	Provision of advice from EMA alongside multiple HTA bodies from European countries (coordinated by EUnetHTA) to enhance clinical development and plans for economic assessment Two pathways are available:[¥] • Consolidated Parallel Consultation • Individual Parallel Consultation	Temporarily suspended/reduced input from EUnetHTA into parallel consultation (affecting procedures beginning March 2020) • No information available on timeline for resuming (however, the next available slots for LOI are anticipated for June 2020, leading to meetings between 28 September and 1 October 2020)[2,3]
Europe and United States		
Parallel scientific advice with EMA and FDA	Voluntary, non-binding, and confidential advice from two regulatory agencies on clinical development Each agency retains its independent authority for approvals of these products	No explicit statement/information relative to the impact of the COVID-19 pandemic on parallel advice activities is available from either agency in the public domain. Implicitly, however, the timelines for parallel advice requests for non-COVID-19 programs will depend on the volume of requests for COVID-19 programs and the workload prioritization under the various new initiatives to expedite the development of these programs in both agencies.[4]
United States		
FDA-Sponsor Meetings	Meetings with IND sponsors at Pre-IND, EOP1, EOP2, and Pre-NDA/BLA stages to obtain FDA input on clinical development	There is sporadic, anecdotal information that such meetings for non-COVID-19 programs are facing some delays, given the significant volume of COVID-19 requests coming into the FDA and the directed focus to expedite those programs. FDA has not issued any formal notification relative to altered or delayed timelines for such meetings.[4]
Canada		
Standard scientific advice with CADTH	Clinical and economic HTA advice in a voluntary, non-binding, and confidential process	Temporarily suspended • No information available on timelines for resuming[2,5]
Parallel scientific advice with CADTH and Health Canada	Combined regulatory and HTA advice including one meeting and separate advice reports from each organization	
Canada/United Kingdom		
Parallel scientific advice with CADTH and NICE	Advice from two HTA bodies including one meeting, separate advice reports from each organization, plus a summary of alignment	Temporarily suspended • No information available on timelines for resuming[2,5,6]
United Kingdom		
Standard scientific advice with NICE	Clinical and economic HTA advice in a voluntary, non-binding, and confidential process	
Express scientific advice with NICE	Accelerated version of standard scientific advice to suit a more immediate need in a shorter timeframe	Running with modifications • Meetings held virtually (via Zoom) • Next meeting availability is September 2020, however, discussions can take place to identify if there are any cancellations which would allow for earlier meetings*[2,6] • COVID-19 product requests are being prioritized
Joint NICE-MHRA scientific advice	Combined regulatory and HTA advice including one meeting and a single advice report	
European HTA and regulatory concurrent advice with NICE	Provision of advice from NICE within similar timelines to the EMA standard advice process, using the same briefing book with the addition of NICE advice to that from the EMA	
Free scientific advice from NICE on COVID-19 products	Free fast track advice for researchers developing novel diagnostics or therapeutics for COVID-19	
France		
Standard procedure for early dialogue with HAS	Clinical and economic advice in a voluntary, non-binding, and confidential process, including a face-to-face meeting	HAS procedure was updated in April 2020 to include standard and accelerated options; these are running with modifications • Advice provided in writing or via teleconference • Potential prioritization of medicinal products for COVID-19, oncology, paediatrics, or targeting an unmet need[7]
Accelerated procedure for early dialogue with HAS	Clinical and economic advice in a voluntary, non-binding, and confidential process, without a face-to-face meeting	
Germany		
Scientific advice on benefit assessment with the G-BA, with or without input from BfArM or PEI	Clinical advice on the dossier and included studies for the benefit assessment, including appropriate comparators, with or without input from regulatory authorities	Running with modifications • Meetings being held virtually • No availability until 2021[2,8]
Italy		
Standard scientific advice with AIFA	Quality and clinical development advice or HTA scientific advice in a voluntary, non-binding, and confidential process	Temporarily suspended^ • No information available on timelines for resuming[2]
Spain		
Standard scientific advice with AEMPS	HTA advice on quality, pre-clinical, and clinical development (in various combinations) in a voluntary, non-binding, and confidential process Three types of engagements are available including initial advice, follow-up advice, and pre-submission meetings	Running with modifications • Advice provided in written format or via teleconference instead of face-to-face meetings • Minimal impact on process by pandemic with delays of only ≤2 weeks expected[9]

¥ The process for parallel scientific advice/early dialogues with the EMA and EUnetHTA will be updated under the recently published EMA-EUnetHTA three-year work plan (29 April 2020) which will aim to design and implement a single, common, European procedure for Parallel Consultation (https://eunethta.eu/wp-content/uploads/2020/05/EMA-EUnetHTA-work-plan-2017-2021-for-publication_en-.pdf).

* While NICE advice programs are at full capacity until September 2020, anyone considering seeking advice is encouraged to contact NICE who will try to accommodate the request and, at the very least, add them to a waiting list in case other commitments fall through.

^AIFA announced that all national scientific consultancy activities are temporarily suspended, with the exception of the pilot project National Simultaneous Scientific Consultancy (SNSA) and limited to the topics covered by the EU Innovation Network.

AEMPS = Spanish Agency of Medicines and Healthcare Products; AIFA = Italian Medicines Agency; BfArM = Federal Institute for Drugs and Medical Devices; BLA = biologics license application; CADTH = Canadian Agency for Drugs and Technologies in Health; CEBR = Center for Biologics Review; EMA = European Medicines Agency; EOP = end-of-phase; FDA = Food and Drug Administration; G-BA = Federal Joint Committee; HAS = la Haute Autorité de santé; HTA = health technology assessment; IND = investigational new drug; LOI = letter of intent; MHRA = Medicines and Healthcare products Regulatory Agency; NDA = new drug application; NICE = National Institute for Health and Care Excellence; PEI = Paul Ehrlich Institute.