Special populations addressed in vaccines approved via the European Medicines Agency

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Objectives: To investigate which populations are addressed in vaccines approved via the European Medicines Agency (EMA), to describe pivotal trials' settings and eligibility criteria, and explore what questions remain unanswered after vaccine MA.

Methods: We identified all vaccines centrally approved between 2012-2022 and collected the following data: populations indicated in summary of product characteristics (SmPCs); pivotal studies supporting vaccine approvals; and risk management plans (RMPs) information. We compared SmPCs and RMPs data available at initial MA and at the end of study follow-up (03/2023).

Results: 31 vaccines approved between 2012-2022 were included. Initially, only 3 were indicated for immunocompromised individuals, 1 vaccine was indicated for pregnant individuals and 2 for breastfeeding. Although most vaccines had RMPs acknowledging missing information about pregnancy/breastfeeding (24 vaccines) and immunocompromised populations (25), there was little change in indications in more current SmPCs: 7 vaccines for immunocompromised patients, 3 for pregnant and 4 for breastfeeding. We identified 90 pivotal trials supporting vaccine initial MA and 46 trials supporting later variations. About 12% of trials enrolled special populations and only 15% (encompassing 37% of vaccines) were conducted in at least one lower middle-income or low-income country. The country that hosted the highest number of trials was the United States (59 studies). Most trials excluded populations with underlying diseases, pregnant/breastfeeding, and with immunocompromising conditions/treatments.

Conclusions: Vaccine studies rarely include special populations and seem to present the same stringent eligibility criteria as trials investigating therapeutic drugs. Several questions remain unanswered after vaccine MA regarding different populations and settings.