MEDICINAL PRODUCTS UNDER ADDITIONAL MONITORING

Additional monitoring aims to enhance reporting of suspected adverse drug reactions for medicines for which the clinical evidence base is less well developed. The main goals are to collect information as early as possible to further inform the safe and effective use of these medicines and their benefit-risk profile when used in everyday medical practice.

A medicine can be included on the list for additional monitoring when it is approved for the first time or at any time during its life cycle. A medicine remains under additional monitoring for five years or until a decision to remove it from the list is made based on available data or change in market authorization status.

Additional monitoring status is always applied to a medicine in the following cases:

1. Medicinal product contains a new active substance.

2. Biological medicine, such as a vaccine or a medicine derived from plasma (blood).

3. Medicinal product is given a conditional approval (where the company that markets the medicine must provide more data about it) or approved under exceptional circumstances (where there are specific reasons why the company cannot provide a comprehensive set of data).

4. The company that markets, the medicine is required to carry out additional studies, for instance, to provide more data on long-term use of the medicine or on a rare side effect seen during clinical trials.

5. Medicinal product has an additional Risk Minimization Measure (aRMM) in place.

List of medicines under additional monitoring are shown in Table 1. Initiated in 2019.

Note: All products removed from the list are shown with a strikethrough for the period of one month after which they are excluded.

Table 1: List of medicines under additional monitoring.

Product Name	Reason(s) on the list	Marketing Authorization Holder	Date of Inclusion
~~RTS,S Malaria Vaccine~~	~~Conditional approval for pilot implementation~~	~~GSK~~	~~2019~~
~~Hydroxychloroquine Tablet~~	~~Repurposed for COIVD-19 management~~	~~Multiple~~	~~2020~~
~~Sputnik V (Gam-COVID-Vac)~~	~~New active substance/Emergency Use Authorization~~	~~Gamaleya Research Institute of Epidemiology and Microbiology.~~	~~2021~~
~~Covishield (ChAdOX1Ncov-19 Corona Virus Vaccine (Recombinant)~~	~~New active substance/Emergency Use Authorization~~	~~AstraZeneca~~	~~2021~~
~~COVID-19 Vaccine Janssen Suspension for Injection (Ad26.COV2-S [recombinant])~~	~~New active substance/Emergency Use Authorization~~	~~Janssen~~	~~2021~~
~~Moderna's Dispersion for Injection [COVID-19 mRNA Vaccine (nucleoside modified)]~~	~~New active substance/Emergency Use Authorization~~	~~Moderna Biotech~~	~~2021~~
~~Comirnaty Concentrate for Dispersion for Injection [COVID-19 mRNA Vaccine (nucleoside modified)]~~	~~New active substance/Emergency Use Authorization~~	~~Pfizer~~	~~2021~~

Product Name	Reason(s) on the list	Marketing Authorization Holder	Date of Inclusion
~~COVID-19 Vaccine AstraZeneca Suspension for Injection (ChAdOx1 S [recombinant])~~	~~New active substance/Emergency Use Authorization~~	~~Astrazeneca~~	~~2021~~
Enbrel (Etanercept)	Medicine with aRMM	Pfizer	2021
MabThera(Rituximab)	Medicine with aRMM	Roche	2021
Xarelto (Rivarobaxan)	Medicine with aRMM	Bayer	2021
nOPV2	New active substance	BioPharma	2022
Axaban Denk (Apixaban)	Medicine with aRMM	Denk	2023
Paracetamol Sandoz (Paracetamol)	Medicine with aRMM	Sandoz	2023
Paraconica (Paracetamol)	Medicine with aRMM	Acino	2023
Movfor (Molnupiravir)	Medicine with aRMM	Hetero Labs	2023
Hucog-HP (Chorionic Gonadotrophin Injection)	Medicine with aRMM	Bharat Serums and Vaccines Limited	2023
Vabysmo (Faricimab)	Medicine with aRMM	Roche	2023
Oleptiss (Deferasirox)	Medicine with aRMM	Norvatis	2023
Pulmofirst (Bosentan)	Medicine with aRMM	MSN	2023