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MSSG Toolkit and Solidarity Mechanism for Medicines Shortages

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BY IRENE KYRIAKIDES, VICTORIA MERTIKOPOULOU, AITHRA-VALENTINA ANTONIADOU

In light of the European Commission's mission to combat medicines shortages in the future, the Regulation (EU) 2022/123 provided for the establishment of the European Medicines Agency ("EMA") Medicine Shortages Steering Group ("MSSG") for crisis preparedness and management for medicines and medical devices within the EU. The MSSG published on October 24th, 2023, the MSSG Toolkit with recommendations on tackling shortages of medicinal products as well as details of the newly created Solidarity Mechanism complementing the actions presented in the MSSG Toolkit.

The MSSG Toolkit provides for the following recommendations that should be assessed each time on a case-by-case basis:

- ❖ Monitoring the available stocks, supply and demand of products;
- ❖ European and international cooperation for combating shortages;
- ❖ Increasing the manufacturing capacity, the supply and the fair distribution of medicinal products;
- ❖ Implementation of regulatory flexibilities;
- ❖ Communication and engagement between different stakeholders, the authorities and the public.

From the aforementioned recommendation, this Newsletter highlights the importance of the following recommendations that concern monitoring the available stocks, supply and demand of products:

- ❖ Interacting between authorities and marketing authorization holders and manufacturers to agree on mitigating measures such as:
 - Increasing the manufacturing capacity (increase of manufacturing shifts);
 - Reorganizing the manufacturing capacity;
 - Establishing minimum safety stocks;
 - Redistributing the available stock between Member States to cover urgent needs.
- ❖ Identifying alternative treatments.
- ❖ Gap analysis – Assessing the possibility of individual national decisions on importation of unauthorized products.
- ❖ EU purchases to facilitate central negotiation and central or joint purchase of medicines for EU/EEA Member States.
- ❖ Using of pharmaceutical preparations (e.g. magistral or officinal) where appropriate.
- ❖ Lifting of export restrictions at national level and other recommendations to ensure fair distribution of medicines.

Moreover, the EU Solidarity Mechanism is a voluntary mechanism for Member States facing critical shortages of medicinal products in case all other available options and possibilities have been exhausted. This mechanism should be used only when the following conditions are fulfilled:

- ❖ Such critical shortage has been notified to the European Medicines Agency, the Medicine

Shortages SPOC WP and the MSSG for further actions.

- ❖ The Member State does not have other sufficient therapeutic alternative options to cover patients' needs.
- ❖ There are insufficient quantities to treat critical indications.
- ❖ Importation of medicinal products from other countries or other temporary measures do not provide a solution in a timely manner or in sufficient quantities.
- ❖ It is an urgent request (such in case there is only 1 month or less stock of such product).

In further details, the Solidarity Mechanism works as follows:

- ❖ Member States have to send relevant requests to the MSSG Secretariat.
- ❖ EMA has to validate those requests by assessing whether the aforementioned conditions are met.
- ❖ EMA has to launch the Solidarity Mechanism in case the aforementioned conditions are met and information provided is complete, start the procedure and notify accordingly the members of the MSSG and the European Commission.
- ❖ EMA will review the compiled information and confirm whether any other Member State can support the shortage crisis.
- ❖ EMA will organize meetings between the Member States and any other relevant concerned parties (e.g., MAHs, wholesaler, Ministry of Health) to discuss operational requirements.
- ❖ Information on the Solidarity Mechanism and specifically on the active substance and the outcome of the Solidarity Mechanism will be published as part of the minutes of the MSSG meetings.

In light of the above, we are expecting to see how the aforementioned recommendations and the Solidarity Mechanism will be implemented and how stakeholders will respond.

Contact Us



Irene Kyriakides
PARTNER

i.kyriakides@kglawfirm.gr



Victoria Mertikopoulou
PARTNER

v.mertikopoulou@kglawfirm.gr



Follow Us

ATHENS OFFICE

28, Dimitriou Soutsou Str.,
115 21 Athens

T +30 210 817 1500
F +30 210 685 6657-8
E kg.law@kglawfirm.gr

THESSALONIKI OFFICE

31, Politechniou Str.,
551 34 Thessaloniki

T +30 2310 441 552
E kg.law@kglawfirm.gr

www.kglawfirm.gr

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