6 January 2021

WHO Solidarity Secretariat

Subject: *Destruction of the Solidarity unused study drugs (hydroxychloroquine, lopinavir/ritonavir, sc interferon beta 1a, and iv interferon beta 1a)*

Dear Solidarity Trial Principal Investigator,

As you are fully aware, study drugs should not be destroyed without prior written authorisation by the Sponsor and destruction should be conducted in compliance with international good clinical practices (GCPs) and local regulatory and waste management requirements. Study drugs should also not be used outside clinical trials, unless a specific donation has been duly approved by the sponsor who will indicate the conditions.

After liaising with manufacturers of hydroxychloroquine, lopinavir/ritonavir, sc interferon beta 1a, and iv interferon beta 1a, it has been decided that any unused study drugs that you have received as a donation for the Solidarity trial should be destroyed.

Please ensure that you have full documentation for product(s) accountability from receipt through to destruction. International GCP guidance requires that the investigator or the pharmacist designated by the institution should maintain records of the product(s)'s delivery to the trial site, the inventory at the site, the use by each subject, and the return to the sponsor or destruction of unused product(s).

The delivered, used and recovered/unused quantities of product(s) should be recorded, reconciled and verified before destruction.

The attached forms could be used to document:

i. drug inventory at the site (Investigational Product Accountability Log: **Stock Record**);
ii. drug accountability subject record (Investigational Product Accountability Log: **Subject Record**);
iii. drug destruction (Investigational medicinal product **destruction log**).

It is recommended to liaise with your central national coordinating trial pharmacy to appropriately perform and document the destruction of unused study drugs. The study drugs to be destroyed include ALL the remaining stocks of hydroxychloroquine; lopinavir/ritonavir; sc interferon beta 1a; and iv interferon beta 1a delivered to the site for the purpose of the Solidarity trial.

Remdesivir stocks MUST NOT be destroyed as Remdesivir has not been discontinued in the trial.

The **Procedure for Destruction of study drugs** is as follows:

a. Contact the local Safety and Regulatory Compliance Administrator (or equivalent) to arrange for pickup of unused study drugs for destruction as biomedical waste.
b. Prepare accounted study drugs and place them in a biohazard bag. Secure and tape the bag closed.
c. Keep the bag with the study drugs locked at the site until they may be released to biomedical waste management personnel.
d. Document that the study drugs were destroyed according to policy. Documentation shall be maintained concerning the destruction of the study drug(s), which shall contain:
    - The quantity of the study drugs destroyed;
    - The date and method of destruction;
    - The staff member who conducted the destruction.

Documentation

International GCPs require that the investigator and the sponsor maintain records that document shipment, receipt, disposition, return, and destruction of study drugs. Documentation of destruction shall be therefore kept at the Investigator site/pharmacy with the research records and a copy shared with the National Sponsor.

We remain available for any clarification you may need on the above. Please do not hesitate to contact Dr Kolawole Salami (salamik@who.int) for any issue you may encounter in implementing this.

Yours Sincerely,

Dr Soumya Swaminathan
Chief Scientist