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## Medical supply donations for Ukraine

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Guidance Note for the acceptance of donations of medical supplies in support of the Ukraine emergency response WHO appreciates offers of contributions of supply support in solidarity with the affected population of the current conflict in Ukraine.

Please note that supply into and within Ukraine is seriously constrained by continuously shifting conflict zones, damage to infrastructure and potential shortages of power and fuel. The WHO priority is to supply critically needed items in a manner that is safe, secure, and responsive to the environment in which we are operating in. Access constraints require that logistics planning and capacity are paramount if supplies are to move smoothly to destinations where they are needed.

The guidance below outlines the process for contributing donated supplies specifically in support of the WHO response inside Ukraine.

- 1. Based on communication with the Ukrainian Ministry of Health WHO will continuously revise and publish a list of critical needs against which we are requesting support. The current list can be found <u>here</u>.
- 2. Offers outside of the published list cannot be considered. Donors are advised to check when lists are updated
- 3. Offers that comply to the request list to be sent to WHO HQ hqoslquality@who.int
- 4. Offer should include specific details about product(s) being offered namely:

General information:

- a. Estimated total value of donation, and value per item in USD.
- b. Type of packing unit, specification of packing material and quantity of product
- c. Location of product
- d. Confirmation that donor will cover transport costs to named destination
- e. Name of product (manufacturer/brand/model)

For medicines

- a. Generic description or INN
- b. Presentation
- c. Manufacturer name and country, site, of manufacture
- d. Manufacture, batch number and expiry date of product
- e. Certificates of conformity and lab analysis
- f. Regulatory approval from one Stringent Regulatory Authorities (SRAs) (<u>https://www.who.int</u>/initiatives/who-listed-authority-reg-authorities/SRAs).

For medical devices

- a. Technical Specifications in the form of technical data sheets, with declaration of conformity (performance and quality standards) for medical devices
- b. Regulatory approval in country of manufacture, WHO PQ or 3<sup>rd</sup> party country regulatory approvation (e.g., EU EC certificate or US FDA approval, 510(k) pre-market notification clearance letter).
- c. Certificate of Free Sale (CFS), Free Sales Certificate (FSC), Certificate to Foreign Government (CFG), or Export/Import Certificate for the medical device provided by the regulatory authority

the manufacturer's country of origin for medical devices

- d. Quality Management System certificate, ISO 13485
- e. Power supply input 220 V, 50 Hz, C/F plugs, for medical devices, unless battery operated
- f. Battery operated devices must be offered with extra batteries, preferably rechargeable and swappable unless designed with internal, rechargeable batteries
- g. For medical devices susceptible to brown outs or black outs, additional uninterruptible power supply unit is preferable
- h. Medical devices are new and unused, not prototypes, and are not refurbished devices
- i. For large donations of a given medical device, maintenance kits including typical spare parts and bundles including accessories and consumables, for a range of patient ages, and necessary for the instantaneous use of the device must be included
- 5. After QA screening, contribution agreement will be provided for signature. This will include delivery point and terms
- 6. Upon signature WHO will communicate consignee, destination, shipping instructions and documentation requirements to a named logistics focal point provided by the donor.
- 7. Shipping instructions to be adhered to. ETA to be confirmed by WHO <u>prior</u> to booking being made
- 8. Donor logistics agent to provide all pre-alerts to named WHO logistics focal point
- 9. Ship and receipt by WHO in 3<sup>rd</sup> country, currently Poland
- 10. Onward transport by WHO to Ukraine