## Clean Care is Safer Care

# Alcohol-based Handrub Formulation & Production

### Q: How and why is the proposed WHO formula different from those currently in use?

A: The “recipe” for two different formulations is available and undergoing testing (an iso-propyl based handrub and an ethanol based handrub). The recipe contains emollients to protect hands, as well as a specific ingredient that eliminates spores from components or reused bottles. Recommended WHO formulations meet both ATSM (US) and EN (European) norms. The recipe is being made available for those facilities which at present do not have access to commercially available alcohol-based handrub due to logistical or cost issues, or would prefer to undertake local production instead of procurement from the market. The WHO is in no way suggesting that health-care facilities with access to efficacious, well-tolerated products should switch to the WHO formulation.

### Q: Who will make it?

A: The intention is that the formula can be manufactured within an individual health-care facility, with a pharmacy laboratory on-site. However, in some instances, local companies with the correct facilities are manufacturing the WHO formula on behalf of the health-care facility.

### Q: Will current manufacturers lose business?

A: Offering a validated procedure for local production of alcohol-based handrubs to those settings that do not currently have the finances or infrastructure to purchase commercial products, will not have an impact on current global business of alcohol-based handrub manufacturers.

### Q: What incentives will there be to use the WHO formulation?

A: The incentive for a health-care facility that is committed to improve hand hygiene to use the WHO formulation is that it is a quality product, which can become affordable. The WHO formulation makes available a product that is fast-acting, effective and well tolerated by health-care workers, usually in a context where no alternative commercial product is available, or not available at an affordable price. In randomized, cross-over trials, WHO formulations were as efficacious, and as well or even better tolerated on skin, as other market products tested.

### Q: Can a health-care facility produce alcohol based handrub and then distribute to nearby hospitals?

A: This should be decided locally and under the scrutiny of governing bodies in the region. If this offers a reliable way of ensuring widespread availability of the product, then WHO would welcome such an approach.

### Q: It is suggested that the WHO-recommended alcohol-based handrub should be produced in quantities not exceeding 50 L.

**Is it possible to exceed this volume?**

A: If the alcohol-based handrub is being produced in a small hospital facility, it must not be produced in quantities exceeding 50 L. However, if the formulation is being produced on behalf of a health-care facility, by a commercial company with good laboratory and safety facilities, then it can be produced in larger quantities exceeding 50 L. The reason for limiting production to no more than 50 L at a time is to minimize fire hazards.

**Q: Can deionized water be used instead of distilled water, and is this an issue when it comes to quality of the final product?**

A: Deionized sterile water is acceptable. However, if the deionized water is not sterilized, the microbiological quality should be regularly monitored.

**Q: How long does the alcohol-based handrub remain active?**

A: The 'shelf life' of the WHO-recommended formulations, produced according to the Guide to Local Production, is at least 2 years after production. There may be some variability depending on local storage temperatures. The key to producing a high-quality product is adherence to general rules of good manufacturing practices. Longevity is also dependent upon the alcohol being stored as recommended in the Guide to Local Production document.

**Q: If a facility locally produces the WHO formulation containing 75% w/w isopropyl alcohol, is it necessary to test the formulation to meet the requirements of CEN and ASTM?**

A: The WHO formulation based on isopropanol should be produced in a pharmacy or a laboratory following instructions included in the document 'Guide to Local Production'. If the instructions are carefully followed, including the quality control test on the final production, it is not necessary to test according to CEN and ASTM norms. If Isopropanol is bought from a reputable company, the concentration stated should be exact and it should be achievable to make up 75% isopropanol correctly.

If instead ethanol is produced *locally*, then checks should be undertaken to determine its exact concentration before producing the alcohol-based handrub.