Terms and Conditions regarding re-packaging and over-branding activities with not-for-profit finished pharmaceutical products

Social Marketing Organizations ("SMOs" or "SMO") are permitted to conduct re-packaging and over-branding activities strictly subject to the terms and conditions set forth below (the "Terms and Conditions").

- The SMOs concerned must be duly licensed and authorized by local authorities for their re-packaging and over-branding activities and the activities they are proposing to undertake must be permitted under the applicable laws and regulations in the countries in which they intend to re-package/over-brand or distribute the not-for-profit finished pharmaceutical product (the "Product").
- Any proposed re-packaging/over-branding of the Product requires the prior written consent of Bayer, a commitment by the SMO to follow these Terms and Conditions, and must be conducted in accordance with the applicable good manufacturing practice ("GMP") standards, e.g. local GMP standards, WHO Guidelines, EU Guide on Good Manufacturing Practices for Pharmaceutical Products, and the packaging facilities concerned must hold the requisite licenses from the applicable Health Authorities to conduct these re-packaging/over-branding activities.
- The Product must be stored and distributed in accordance with applicable good distribution practice ("GDP") standards, e.g. local GDP standards, WHO-Guideline on Good Manufacturing Practices, WHO Guidelines on Good Distribution Practices for Pharmaceutical Products, and EU Guide on Good Distribution Practice of Medicinal Products for Human Use.
- All re-packaging/over-branding of the Product must meet applicable regulatory requirements.
- The SMOs agree that UNFPA will disclose its names and contact information to Bayer.
- Bayer requires a written agreement with the SMOs for re-packaging/over-branding.
- The appropriate regulatory approvals permitting re-packaging/over-branding of the Product must be obtained prior to the re-packaging/over-branding and/or distribution by any SMO. Bayer shall be provided with copies of such approvals.

Re-packaging and Over-branding

- Nothing in these Terms and Conditions shall be construed as a trademark license provided by the trademark owner. Use of any Bayer brand names or trademarks, including, but not limited to Bayer mark and logo, on the secondary packaging (i.e. beyond the foil or pouch) is prohibited unless otherwise agreed by Bayer. Use of Bayer brand names or trademarks other than as they already appear on the blister/pouch, is subject to the implementing SMO entering into a trademark license agreement with Bayer that will govern the terms of use of such brand names or trademarks.
- The SMO shall provide the artwork for re-packaging/over-branding to Bayer for prior approval and may not use any artwork without such approval by Bayer.
- No alterations or modifications of any kind to the primary packaging (blister/pouch) are permitted. For sterile Products this also applies to the secondary packaging. As such, the original brand name and Bayer and all other pre-existing labeling must remain clearly visible on the primary packaging of the Product and for sterile Products also on the secondary packaging of the Product. For sterile Products the primary and secondary package must remain sealed and intact when placed in any tertiary packaging.
    - The SMO shall provide Bayer with the artwork for the packaging material and patient inserts information for the over-branding packaging. The SMO shall not use any artwork without the prior written approval of Bayer.
    - Such approval shall be conveyed by Bayer in writing within 15 business days following the receipt of the complete artwork and a sample of the secondary/tertiary packaging.
    - Bayer will notify UNFPA and the SMO in case the above mentioned requirements are fulfilled.
    - The following information shall appear on the final packaging:
        1. Local brand name of the drug
        2. Bayer brand name of the drug
        3. Active pharmaceutical Ingredients of the drug
        4. Lot number and expiry date
        5. Name of Bayer/marketing authorization holder (MAH) andcountry
        6. Contact information of local distributors
        7. Number of unit(s)
        8. Color of tablets (if any) and the amount of active ingredient contained
        9. Indication

10. Mode of administration
11. Registration number if applicable (if required by the Health Authorities in the country where the Product is distributed)
12. Storage conditions
13. Cautionary statement

- In case all requirements are fulfilled Bayer shall provide its approval for the re-packing/over-branding of Product in the form of a Letter of Authorization.
- After the Health Authorities has given approval, the SMO has to ensure that one copy of the approved package insert (leaflet, part of secondary or tertiary packaging) is part of the re-packaged/over-branded Product.
- The SMO shall provide Bayer with a sample of the re-packaged/over-branded Product.
- The SMO is liable to maintain the quality and integrity of the Product and to follow Bayer's recommended storage conditions also during any re-packaging/over-branding operations.
- The SMOs are responsible for quality and regulatory conformance of the repackaged presentation following applicable laws and regulations as well as the contract with Bayer.
- It is the SMOs responsibility vis-à-vis Bayer to comply with these Terms and Conditions. UNFPA publishes this document on its website for the information and ease of reference of the SMOs.