

2 Page Leaflet Assurances

1. How do you ensure both (all) pages are included?

Our Packaging Batch Record (PBR) draws data from an excel Print Master sheet – which contains data to show how many of each component type are required for each pack.

During the repacking process, there are many checks carried out by the labellers, the Quality operatives and the Production supervisor. At the end of each labelling job a reconciliation process is conducted to ensure the correct number of components have been used, and that none have not been used.

2. For products with a healthcare professionals' leaflet/instruction for use leaflet; how do you ensure both leaflets are put into packs, i.e., one of each. How do you manage version control of both leaflets?

Please refer to my answer to question 1.

Additionally, we operate an in-line labelling process; which in practice, means one operative will pick up one PIL and pass it to the next operative. The second operative will pick up one Instruction Manual, and both will be inserted into the pack. This ensures one of each document is packed into each pack, and not two of one and none of the other.

Version control is controlled by our Regulatory department. The PIL will have a different component code to the Instruction Manual. And both of them will incorporate a date within their respective component codes. These are changed each time the documents are revised through granted variations. The component codes are documented within our Master Reference Files (MRF), which link the granted licence documents to the PBR – showing which components are required, how many of each, and their placement. If the PIL and Instruction Manual are printed in-house, we only print to order. If the documents are printed by an external supplier, we manage the use of such printed components by use of a Master Form which is issued by the Regulatory department to the Production department – and requires their signature to confirm that any obsolete printed components have been removed for destruction – before the new revision is issued.

3. Which order are the pages/leaflets placed into the packs? How do you ensure the same orientation of leaflets? Are they attached to each other?

The PIL and Instruction Manual are not attached to each other. The Instruction Manual is placed underneath the PIL, and both the same way up. Before the labellers start each job, they are provided with a fully labelled sample by our Quality department, which shows exactly how each pack must be labelled and packaged.

4. An assurance that the appearance of the re-packaged product will be of professional quality and not bulky.

I provide our assurance that the appearance of the repackaged product will be of professional quality and not bulky. If, during the licence application process, we felt that the over labelled option would be too bulky, we would ensure we proceeded with only the recarton option. We would design our carton to ensure the medicine and PIL/Instruction Manual fit properly without being bulky.

5. An assurance that production staff know to follow these instructions when packaging this product. How will you ensure this?

I provide our assurance that the production staff do know to follow the instructions when packaging this product, and indeed, any products we repackage. The labellers are provided with a fully labelled sample by our Quality department, and this is produced in accordance with our granted licence documents, via our MRF and PBR. Many checks are carried out during the repackaging process for every batch, to ensure Quality Control is maintained.