

The Benefits of Labelling Harmonisation

Gina Partridge

SAAPI President 2021 - 2022



Product Labelling

- Product labelling = the Product Information (PI) and Patient Information Leaflet (PIL)
- Product labelling is designed to serve multiple functions:
 - Communicates information on the benefits and risks of the product
 - Offers advice on the effective and safe use of the product



Benefits of Labelling Harmonisation

- Will provide HCP's and patients across the continent with the same information irrespective of the country in which they reside
- Reduce the complexity of the labelling variation process and provide updated information in a timely and consistent manner
- Has the potential to increase access to effective high-quality medicines across the continent
- Has the potential to reduce the cost of medicines through economies of scale
- Could reduce administrative and cost burdens faced by resource-limited NRA's and pharmaceutical manufacturers alike
- Allows for more flexibility in the supply chain
- Less wastage

Is aligning the PI and PIL requirements for an INN across the continent a pipe dream?

