# Workshop

# A practical approach: Compilation of the SmPC and PIL for Generics

**Please note : This course does not cover the compilation of the SmPC and PIL for New Chemical Entities, based on data obtained from Drug Discovery, Drug Development, and Clinical Trials**

**Presenter:**

Dr. Carine Page (PharmaIntelligence Consulting)

**Introduction:**

The Summary of Product Characteristics (SmPC) is a document that provides essential information about a medicine to the Healthcare Professional (HCP). It includes details about the active ingredients in the medicine, its dosage and administration instructions, any potential side effects or interactions with other medicines, and important safety information. It also provides information on the medicine's identification, presentation, storage requirements and its expiry date. The SmPC is a crucial resource for healthcare professionals, as it helps them understand the medicine and make informed decisions when prescribing or administering it to patients as a single medication or in combination with other treatments. It ensures that the medicine is used safely and effectively for the benefit of patients.

The patient information leaflet (PIL) on the other hand, is an essential component of any medicine packaging, providing valuable information to users. It is designed to ensure that patients have a clear understanding of how to use the medicine safely and effectively. The leaflet is written in laymen's terms and typically includes details on the medicine's indications, dosage instructions, and any specific precautions or warnings that need to be followed. It also outlines potential side effects that may occur, as well as what to do in case of an overdose or missed dose. The leaflet provides guidance on storage conditions and the medicine's expiry date. Additionally, it may include information on how to safely dispose of the medicine when no longer needed. The patient leaflet aims to empower individuals to take an active role in their own healthcare by providing them with the necessary knowledge to make informed decisions about their treatment.

The inclusion of the proposed SmPC and PIL in the registration dossier, and the format, content, and structure of the SmPC, and approval thereof as a condition for registration, is clearly stipulated in the relevant ICH, EMA and SAHPRA guidelines. Subsequent to product registration, Regulation 10, 11 and 12 of the Medicines Act (Act 101, 1965) is also clear on the requirements for the availability of such approved information on / in the primary and secondary packaging of the marketed product. The guidance is very clear with regards to the format, minimum required information and allowed deviations form this, should the container / pack not have enough space for all of the details as approved.

During a product's life cycle, the constant updating of the SmPC and PIL to include the most recent safety data and dossier specific information is a crucial activity of any Regulatory Affairs team, always working closely with the applicant's local qualified person for pharmacovigilance (QPPV) or pharmacovigilance officer (PVO), medical advisors where applicable, and the vigilance units of local and foreign competent authorities,

**Who should take this course?**

Regulatory Affairs pharmacists / scientists

Local qualified persons for pharmacovigilance (QPPV) or pharmacovigilance officer s (PVO) responsible for compilation of safety updates

**Course format:**

Online on Microsoft Teams (2 half-days)

**Course Content:**

**<u>Day 1 – 13 September 2023 (8:00 – 13:00)</u>**

**ICH, EMA and SAHPRA Guidelines**

1. Format, content, and structure of the SmPC
2. The annotated SmPC
3. The "clean copy"
4. References

**<u>Day 2 – 14 September 2023 (8:00 – 13:00)</u>**

**ICH, EMA and SAHPRA Guidelines**

1. Format, content, and structure of the PIL
2. The annotated PIL
3. The "clean copy"
4. References
5. How to approach a safety update of a SMPC and a PIL

**Course Outcomes:**

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At the end of this course the attendee will have a clear understanding of and a practical experience in:

1. the format, content, and structure of the SmPC and PIL for a generic medicine.
2. how to compile the SmPC and PIL for a generic medicine;
3. the references to use during the compilation process;
4. the approach to take when a safety update is due.