



Standardized patient information leaflets for oral anticancer drugs

ESOP Global Special Interest Group (SIG) *Oral Cancer Drugs*

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Introduction

The European Society of Oncology Pharmacy (ESOP Global) has multiple “special interest groups” (SIG). The SIG *Oral Cancer Drugs* has, among others, the objective to improve health literacy in oncology patients. Written patient information leaflets (PIL) about oral anticancer drugs (OAD) are important for patient education. Until now, there are no multi-national standards for PIL about OAD.

The template is a trifold brochure with three main sections:

- Left Panel:**
 - Side effects:** (These are the most common side effects that you can recognize yourself) - followed by a series of horizontal dashed lines for text.
 - Prevention of side effects and how to deal with them (incl. supportive medication)** - followed by a series of horizontal dashed lines for text.
 - Contact your doctor immediately if you notice:** - followed by a series of horizontal dashed lines for text.
- Middle Panel:**
 - Contact data:**
 - Local contact: [rubber stamp]
 - Emergency number: 112
 - Optional national additions: [dashed lines]
 - Disclaimer:** This leaflet does not contain all the available data for the medication, only the most important information.
- Right Panel (Yellow background):**
 - ESOP Global logo
 - PATIENT INFORMATION LEAFLET for:** [dashed line]
 - [picture of drug]
 - Date of giving the leaflet:** [dashed line]
 - [national logo] [pharmacy logo]

Figures 1, 2 (above, below): Preliminary version of the SIG's template for a patient information leaflet (trifold brochure style)

The detailed view shows the following content:

- Why are you taking this medication?** - followed by horizontal dashed lines.
- How should you take your medication?**
 - As the patient, you are an important part of the therapeutic team.
 - It is your responsibility that you take your drug regularly and exactly as instructed.
 - Swallow the medication with a big glass of water. Do not chew/suck it. Do not open/crush it.
 - Take _____ mg _____ time(s) per day:
- Medication Schedule:**
 - am: [6] [7] [8] [9] [10] [11] [12]
 - pm: [1] [2] [3] [4] [5] [6] [7] [8] [9] [10] [11] [12]
- Take with food** (☺) or **Take without food** (☹) *no food _____ h before/ _____ h after*
- Take your medication every day** or **Take your medication only on the following days:**
- Additional information:** - followed by horizontal dashed lines.

- What should you do when you forget to take the medication or when you vomit?** - followed by horizontal dashed lines.
- Information on safe handling and storage:**
- Do not crush tablets or open capsules.
- Discard damaged medication into trash.
- Keep out of reach for children.
- Must not be handled by pregnant or breastfeeding persons.
- How to deal with body fluids:
- Precautions:**
- This medication increases your sensitivity to sunlight. You will receive further information.
- This medication impacts your ability to drive/operate machines.
- Do not use this medication while pregnant or breastfeeding.
- You must use condoms as contraception when you or your partner take this medication.
- This medication can impact your fertility. You will receive further information.
- Interactions:**
- Other drugs/herbs/food supplements can influence your medication. Tell your doctor/pharmacist about everything that you are taking now and inform them **every time** you get a new drug prescription or buy a new drug/herb/food supplement yourself.
- Do not take drugs/supplements with St. John's wort. Do not eat/drink Grapefruit(juice).
- Do not take:
- Storage:**
- Room temperature (max. 25°C)
- Fridge (2-8°C)
- Additional information:** - followed by horizontal dashed lines.

Material and methods

After six online meetings over the course of one year, the SIG organized a live workshop in July 2023. The goal was to agree on a standardized template (ST) for PIL about OAD. The available national PIL were used as sources.

Results and discussion

Out of the 13 countries represented in the SIG, eleven members from eight countries participated in the workshop. The national PIL differ greatly from one another. For the ST, a brief format (max. two pages) and 12 categories in patient friendly language were agreed on (see figures 1, 2).

These categories are:

- International nonproprietary name (INN) of the OAD (optional: brand name)
- Photo of the OAD (optional)
- “Why are you taking this medication?”
- “How to take your medication”
- “What should you do if you forget your medication or if you vomit?”
- Handling and storage
- Specific precautions
- Interactions
- “The most common side effects that you can recognize yourself”
- “When should you contact a healthcare professional?”
- Local contact, emergency number
- Disclaimer

Creating a ST for PIL about OAD is a first step towards improving health literacy in oncology patients. Using the ST for selected OAD as an example, the SIG needs to reassess suitability and comprehensibility of the PIL, users' acceptance as well as organizational matters, e.g., translation and distribution via ESOP Global.

Conclusion

Pooling multi-national knowledge has led to a new and unique ST for PIL about OAD. The SIG's joint work will need to continue to pursue its goal of improving patient education. The aim is to make the ST broadly available to ensure easy and global access and usage.

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