

Providing information to the older population

An industry perspective

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Introduction

- Current Product Information (SmPC and Package Leaflet) does not meet the need of stakeholders
- Applies in general, not specific for older patients
- Specific characteristics older adults to be addressed

Introduction

Characteristics to be addressed:

- Format
 - Readability – font size, colour, contrast
- Content
 - Age-related changes in Pharmacokinetics and/or Pharmacodynamics
 - Concomitant illness/concomitant medication: not unique for but more frequent in older adults
 - Gradual scale: older population is not a homogeneous group
 - Risks well-known and avoidable to large extent

EFPIA survey

- Part of the bigger survey on Geriatric Medicines Strategy
- Five questions on Product labelling and Information
- Responses from 15 member companies

Do you consider current guidance and practice fully adequate?

- In depth review may be needed but this is not only determined by age, any patient need to be taken into account
- Flexibility needed, current guidance allows this
- Labeling can only reflect available data, guidance cannot compensate missing info
- More focus on Package Leaflet than on SmPC
- Specific needs older adults would be captured during readability testing
- Few companies appreciate more guidance/standard text

Consolidate all relevant aspects in comprehensive section?

- Advantages and disadvantages - involve stakeholders (physicians/patients)
- Not only for SmPC but more importantly for Package Leaflet;
- Information should be succinct, repetition/redundancy to be avoided
- Specific information not always related to only age (e.g. concomitant disease)
- Alternative delivery methods may facilitate targeted/personalised information

Summary of other suggestions

- Product information to reflect all relevant data (efficacy and safety) to allow appropriate Benefit/Risk presentation
- Increase prescriber knowledge on drug-specific effects of medication
- Increase patient understanding on appropriate use of medicines
- Long-term strategy to aim for customised/personalised prescriber information

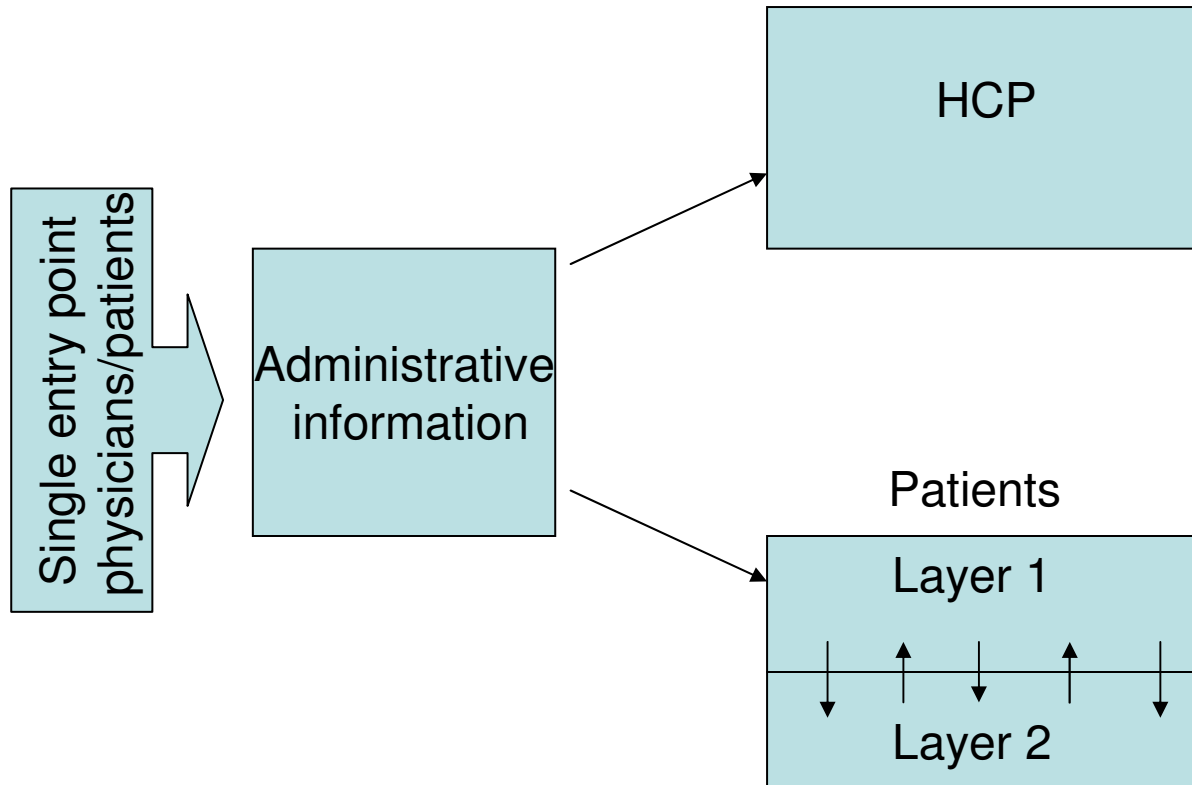
EFPIA Temporary WG Product Information - Objectives

- ✓ Identify shortcomings with the SmPC and PL
- Make proposals how these shortcomings can be overcome by amending readability, layout and content
- Explore alternative methods of dissemination

General principles for Product Information

- All Product Information to support adherence to treatment and focuss on improving health outcome
 - Single, trustful source (physician, all patients)
 - Adress physician and all patients through one entry point
 - Fair balance of benefits and risks
 - Easy access to preferred information level (tailored to needs of physicians or various types of patients)
 - Up-to-date information
- } Electronic tools?

Proposals to amend layout and content



Same sub-headings

Logical location of info (may differ HCP and patients)

Brief and concise information

Easy to navigate

Hyperlinks with more details for those who need it

Concrete instructions for use

Proposed sub-headings

- Product details
- Therapeutic indications and benefits
 - Therapeutic indications
 - Benefits
- Correct use of the medicinal product (e.g. dosage)
- Risks
- General information (storage, ..)*
- Special populations (paediatric, geriatric, patients with impaired liver function...)*

* Headings deviate from current QRD template

Attention points for older adults

- Age*-related changes PK
 - Distribution volume changes
 - Changes in renal function
 - Age*-related changes PD
 - Receptor density/sensitivity
 - Antagonistic balance mechanisms work less well
 - Concomitant disease/medication
 - Interactions
 - Specific adverse reactions related to polypharmacy
 - Multiple leaflets per patient?
 - Not homogeneous group
- } Dosing recommendations ?
- } Dosing recommendations ?
- } Dosing recommendations/ warnings ?

Electronic dissemination

- Facilitates tailor-made presentation with language reflecting different literacy levels
- Easy to make alternative formats available (audio, different font size, illustrative videos, charts etc.)
- Information available anywhere at all times
- Ensures rapid updates
- Not yet accessible to everyone, printed leaflet to be available (likely to change in future)

Look to the Future

- Industry/regulators/patient groups are working to improve Product Information in general
- User-driven: input patients and HCP essential
- Revision to take into account specific needs of older adults
- EFPIA proposal outlines vision for structure that is easily accessible and aims to maximise safe and effective use:
 - Ideas to be translated into pilot SmPC/Package Leaflet
 - Web-based information system (in addition to printed version)
- Long-term aim more personalised approach
- **Industry/ Regulator + patients/HCP discussion needed**



THANK YOU