



European Federation of Pharmaceutical  
Industries and Associations

# Industry Perspective on Formulation and Packaging Considerations

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**February 2012**

- Provide an overview of formulation / packaging elements of survey of member companies conducted by EFPIA
- Topics to Cover
  - The role of dedicated formulations
  - To what extent paediatric formulations might be useful in geriatric patients
  - Potential role of packaging in improving compliance in geriatric patients

- There is no ‘standard’ geriatric patient
- Age and frailty are not absolutely linked
  - Patients can be ‘physically well’ or ‘frail’ in a variety of ways
    - Physically, sensory deficits, cognitive impairment
- Patients can be suffering from a condition that affects predominantly the aged population OR can be suffering from a condition that is common in the wider population
  - e.g. Alzheimer’s disease vs. hypertension
- Treatments can be ‘short duration’ or ‘chronic’
- All these factors may impact on the appropriate product provided for the patient

- Parallels are often looked for between geriatric patients and paediatric patients
- There are some parallels
  - Both groups may benefit from product availability not ‘required’ by the general population – strengths, dosage forms etc.
    - Dose flexibility can be important
  - Both groups can have difficulty swallowing certain dosage forms
    - paedes favour liquids but geriatrics may not
    - sprinkles, small tablets / crushed tablets

- But there are significant differences
  - Paediatric products may be administered by a healthy care-giver (parent / guardian) whereas a geriatric patient may be independent or be supported by a care-giver who may themselves be aged or infirm.
  - Geriatric patients may be treated for multiple diseases, with multiple products (both prescription and dietary supplements)
- These factors can mean that the demands on compliance for a geriatric patient are considerable compared to the compliance challenge faced in paediatric medicine
- Dosage form selection is only one aspect of addressing the compliance challenge for geriatric medicine and a holistic approach is needed (perhaps on a case-by-case basis).

- The product and its compliance needs to be seen in the widest terms –
  - Disease
  - Patient group specific abilities / requirements
  - Dosing duration – acute / chronic
  - Dosing requirements – dose flexibility
  - Dosing regimen – doses per day
  - Specific ‘geriatric’ limitations
    - difficulty in swallowing certain dosage forms
    - manual dexterity (small products; packaging)
    - decreased visual acuity
  - Care situation – hospitalised / home – self medicating / care-giver
  - Polypharmacy potential challenges

- A fundamental tenet of pharmaceutical development is **design of a product that can be used by the patient group in a safe and efficacious manner**
  - Product development establishes fit for purpose '**design criteria**' for development
- Paediatric products design criteria : dosage form selection; dose flexibility; avoidance of particular excipients; provision of palatable product; assurance of dose accuracy etc.
- For geriatric products, design criteria may also be developed but may be more complex (given the population diversity and compliance challenges in this population)
  - Might involve elements of both dosage form selection; physical characteristics of product (size > taste); dosing flexibility; packaging utility; particular labelling needs
- NOT SIMPLE and further complicated as disease may also be prevalent in wider population and hence have an 'adult' product available
  - Which **may** not be optimal in all these dimensions but **may** be fully appropriate
  - **NOTE - if a new geriatric product / dosage form is required then this might also be useable in wider population and then would need to be BIOEQUIVALENT (a technical challenge) or of KNOWN RELATIVE BIOAVAILABILITY**
  - PK / PD in geriatric patients...

- No single answer to this question...
  - In some cases the adult product might be appropriate for use in a geriatric patient
    - Consider strengths, dosage form, dosing circumstances
    - Orally-dispersing tablets, patches, topical, suitably-sized tablets (and e.g. if crushed)
    - This may well be the cost-effective way to proceed
  - In other cases it may be that a formulation developed for paediatric use (e.g. an oral liquid, a sprinkle, a topical product) may be appropriate
    - Flavour and dosing volumes may be sub-optimal (ideality v. fitness for purpose)
  - In some cases it may be that a dedicated dosage form (or dedicated strengths, or dedicated packaging) might be warranted
    - e.g. for a disease where high % patients are geriatric / frail
- One cannot assume that a customised formulation is necessary, nor assume that a dedicated formulation ALONE will solve all potential usage and compliance challenges
  - Suitable holistic 'basis of care' can be as important



- Products for geriatrics may suffer different compliance challenges
  - There may be instances where prescribing an ‘adult’ product (or a paediatric product) might suffer from low compliance
    - Could be due to either the product or the patient / care circumstance
    - One might have compliance concerns, in some cases, with dosage forms that are difficult to swallow, or cannot easily be accessed (packaging) and taken (size / manipulation) by the patient or that have a complex dosing regimen
- No one solution may address every potential patient compliance issue
  - Potential approaches to addressing compliance concerns may need to be selected, considering holistic care, from
    - Devices such as posology reminders / pill dispensers
    - Geriatric friendly packaging
    - Geriatric friendly labelling
    - Simplified dosing regimens (may be product dependent)
    - Sometimes could be a fundamental product design solution (a specific product ... may add to overall costs)

- It would be very valuable if an existing paediatric product could have value in treatment of geriatric patients
  - This should always be considered
  - Sometimes an approved paediatric product may not be ideally suited for geriatric administration
    - Maybe strengths will not be optimal, maybe taste will not be optimal
    - Some learnings from paediatric development may be directly transferable (e.g. taste masking, solution stability, multi-particulate platform technology)
  - Overall holistic care has to consider patient needs
    - MUSTS and WANTS – fitness for purpose

- Not all adult or paediatric products will be in packaging that is geriatric-patient friendly
- In some cases, packaging requirements (e.g. for child-proofing) are in conflict with geriatric patient-friendliness
- Geriatric-friendly packaging may help (push-through blisters may be better than bottles; optimally-sized screw caps)
- Devices (like pill dispensers, dosing calendar cards) may help
- BUT no single approach should be seen as a panacea
  - A manufacturer may develop a ‘friendly pack’ for one product that the pharmacist opens to dispense to the patient in a poly-pharmacy pack as part of holistic care
    - In this case the pack from the manufacturer adds no value only potential cost

- Compliance is always important
- Avoiding medication error is always important
- This includes adequate labelling
  - Aspects of labelling legibility may be key for geriatric patients
  - Availability of large text label may be of importance
- And adequate counselling / advice to the patient (by the physician, pharmacist or at point of use)
- Maybe in future ‘smart’ packaging solutions / devices that indicate audio visual ‘alarm’ when a patient should take medicine may be favoured (will have associated cost in holistic care) – these may also have role in tracking adherence

- Geriatric patients may be taking multiple medicines / dietary supplements
  - These may involve complex dosing calendar
  - And provision of multiple individual doses
- Compliance and adherence when patient is poly-medicated is a complex problem
  - Combination products may be of some value
    - But make dose titration for patient more difficult
  - Holistically, it may be relevant for the pharmacist to provide a suitable tailored combined medicines 'pack' to support a patient
    - When this is the case the actual packaging provided by the manufacturer may be an unimportant factor

- Provision of medicines to geriatric patients in a way to optimise therapy and compliance is a complex area
- **A holistic approach is needed**
  - It's not as simple as saying (forgive me... 😊)  
‘a paediatric patient needs a paediatric product’
- The needs of a geriatric patient may be met, in part, by aspects of product selection, or packaging, or labelling
  - BUT conversely NONE of these may be necessary
  - OR NONE may meet the full need (polypharmacy etc)

- Medical devices (and integrated products – e.g. inhaled products etc.) are designed to be suitable for the user
- This includes risk-based design validation and ‘human factor’ testing (useability engineering)
  - EN 62366 – Medical device useability engineering
  - ISO 14371 – Risk management of medical devices
- Includes consideration of all potential users
- If a geriatric use was perceived this potential use would be designed in or tested for with representative group of users

THANK YOU