Industry Perspective on Formulation and Packaging Considerations

Ron Ogilvie (Pfizer)
EFPIA
February 2012
Industry Perspective on Formulation and Packaging Considerations

• 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
    – paeds favour liquids but geriatrics may not
    – sprinkles, small tablets / crushed tablets
Pharmaceutical Products for Geriatric Patients

- 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…
Value of Dedicated Geriatric Formulations?

• 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)
To what extent can paediatric formulations be useful in geriatric patients?

• 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
The role of packaging in geriatric compliance?

- 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