and patient empowerment

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EESC

Background

- People searching for information, patients and healthcare professionals (HCP) have repeatedly highlighted the need for comprehensive, accurate and up-to-date information on medicinal products.
- "Digital applications and digital solutions are part of our daily lives - including in the area of healthcare" Commissioner Vytenis Povilas Andriukaitis in Riga, 12 May 2015

Readability?!

Das ist unser Senioren-Service: Beipackzettel in lesbarer Schrift

This is our service for elderly: Package leaflets in readable font size

PZ 23/2009 German Pharmaceutical Journal

Current situation

How do people search very often:

1. Disease (Erkrankung)
2. Medicines name via search engine

Existing electronic information

Various concepts:

- Authority websites with information from Medicines Regulatory Agencies
- Authority websites with information from pharmaceutical companies
- Independent website (industry association sponsored) with information from Medicines Regulatory Agencies
- Independent website (industry association sponsored) with information from pharmaceutical companies

Background and objectives of the own-initiative opinion

- The own-initiative opinion will present the EESC's views on the current shortcomings of information on medicinal products, package leaflets and information for healthcare professionals.
- It will indicate ways and means to overcome current problems by pursuing agreed objectives of the EU and by fully using the applicable legal provisions of the Union and proposing changes of the legislation, as appropriate.
- Experience from all stakeholders over the last decade have shown that minor changes of the paper leaflets will not solve the general concerns such as readability, usability and cannot appropriately address health and digital literacy.
- A digital solution was identified as best way to address these issues.

Collaboration of stakeholders

- The EESC holds the **pharmaceutical industry** responsible for accurate and up-to-date information on its products.
- How **officially approved information** is presented and can be accessed must be agreed with the relevant stakeholders (**authorities, patient associations, health professionals**).
- A consortium responsible for coordinating development of the database/portal could be established and financed under the **IMI initiative**.
- A technical solution that is freely available should be developed that makes the most effective use of existing sources and ensure **supervision by drug licensing authorities**.
- The designs of national databases are available. An additional prototype has also been developed to demonstrate a user-friendly and widely accessible database that also includes options for audio and video data.

Therapeutic Indications And Benefits

What [redacted] is and what is it used for

[redacted]nasal spray is used to treat symptoms of allergic rhinitis including stuffy, runny or itchy nose, sneezing and watery, itchy or red eyes, in adults and children aged 6 years and over.

Allergy symptoms can occur at specific times of the year and be caused by allergy to pollen from grass or trees (hayfever), or they can occur all year round and be caused by allergy to animals, house-dust mites or moulds.

[redacted]belongs to a group of medicines called glucocorticoids. works to decrease inflammation caused by allergy (rhinitis).

Outlook

- Art. 58 of Dir. 2001/83/EC requires: "*The inclusion in the packaging of all medicinal products of a package leaflet shall be obligatory unless all the information required by Articles 59 and 62 is directly conveyed on the outer packaging or on the immediate packaging*."
- Medicines licensing authorities accept links to dedicated websites with product information.
- Art. 58 should be rephrased and allow electronic product information
- Medicines Licensing Authorities should support the provision of electronic information in addition to package leaflets.