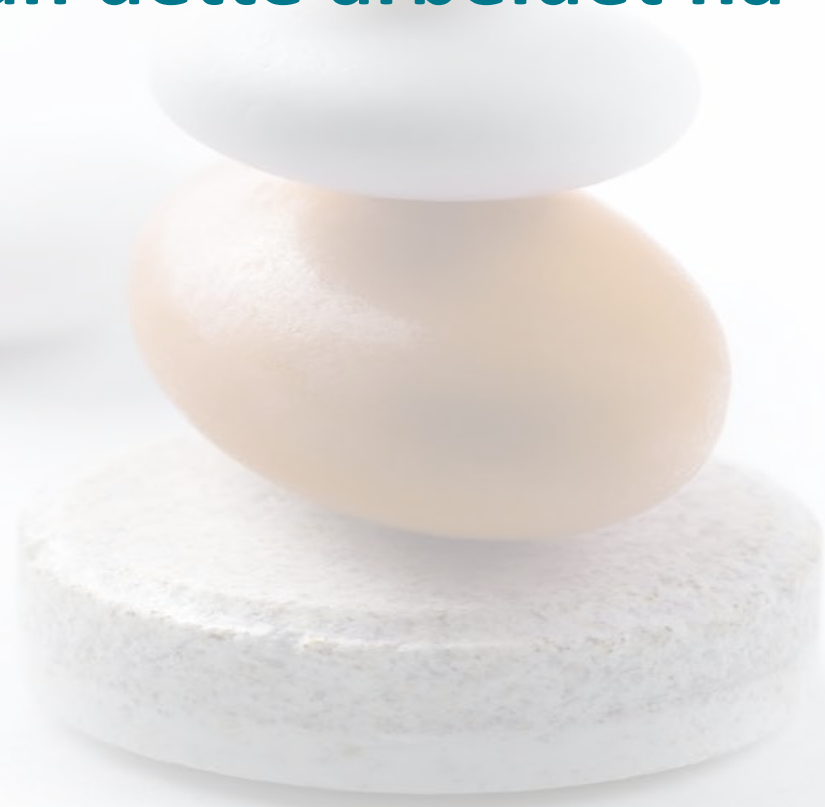
Pharmacutical strategy; review of pharmaceutical legislation - hvilken betydning kan dette arbeidet ha for produktinformasjonen?

Industrimøtet, 11. jan 2022

Nina Malvik, seniorrådgiver



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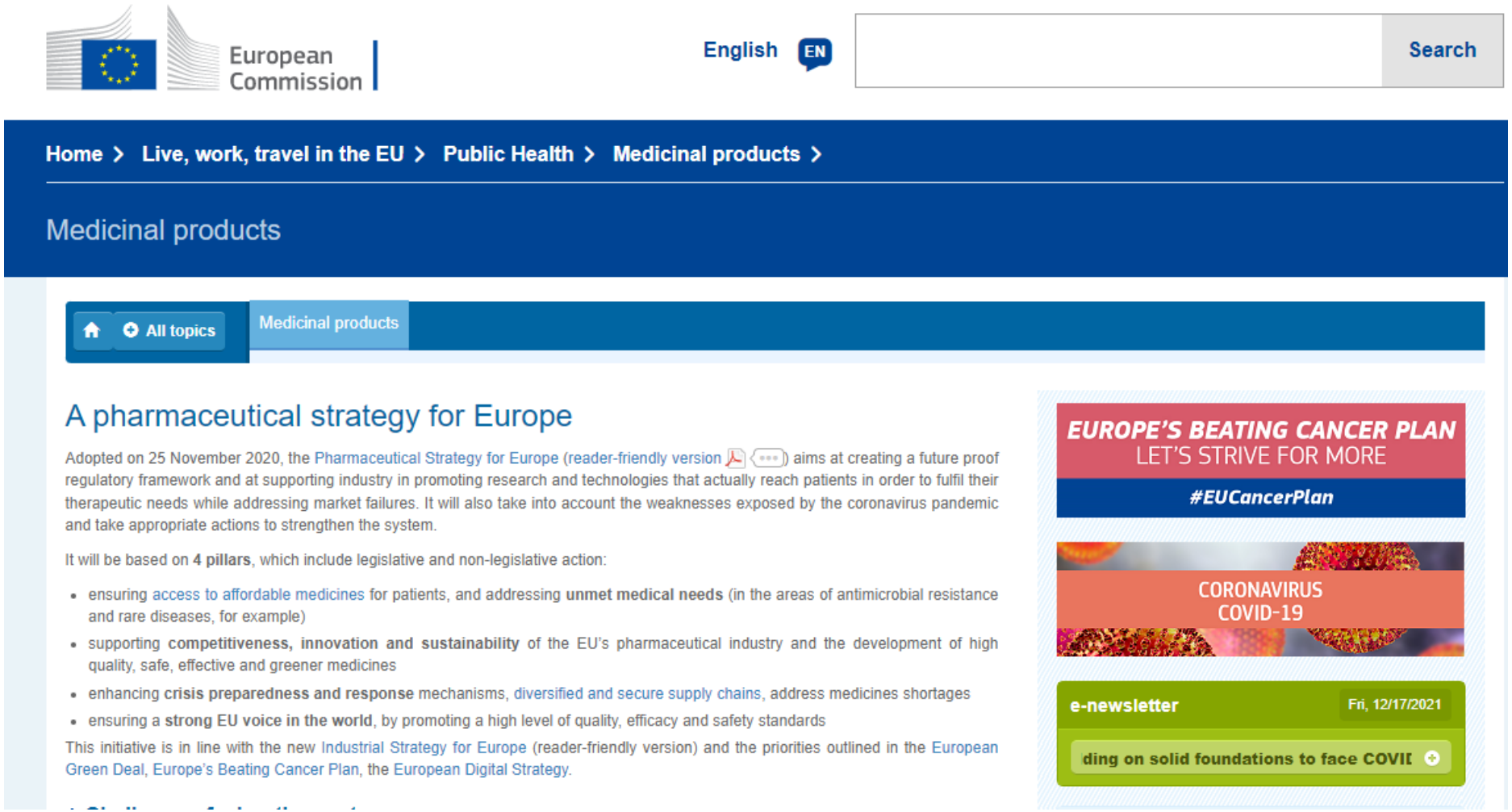

https://ec.europa.eu/health/human-use/strategy_en

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Consultation activities

Since the publication of the strategy roadmap in June 2020, the Commission has conducted a series of consultations and meetings to inform the designing of the strategy.

The Commission has taken account of the positions and priorities raised by interested parties and the public and has been working closely with Member State authorities in the context of its consultative committees.

Additional consultation activities are planned in the implementation phase.

Consultation activities related to the revision of the general pharmaceuticals legislation:

- Consultation strategy
- Online public consultation - The OPC will be open for replies from 28 September until 21 December 2021.
- Thematic Workshops 2021

Consultation activities related to the Communication on a Pharmaceutical Strategy for Europe:

- Online public consultation
- Stakeholders workshop of 14/15 July 2020
- Have your say web page
- Factual summary of the feedback to the roadmap
- Report of the analysis of the Online Public Consultation
- Synopis report of all consultation activities annexed to the Communication

In preparation

Roadmap

Feedback period

30 March 2021 - 27 April 2021

FEEDBACK: CLOSED

Public consultation

Consultation period

28 September 2021 - 21 December 2021

FEEDBACK: CLOSED

UPCOMING

Commission adoption

Planned for

Fourth quarter 2022

FEEDBACK: UPCOMING

About this initiative

Summary

As part of the EU pharmaceuticals strategy, and drawing lessons from the COVID-19 pandemic, the Commission plans to evaluate and revise the EU's general legislation on medicines for human use to ensure a future-proof and crisis-resistant medicines regulatory system.

The revision will aim to:

- ensure access to affordable medicines
- foster innovation, including in areas of unmet medical need
- improve security of supply
- adapt to new scientific and technological developments
- reduce red tape.

Topic Public health

Type of act Proposal for a regulation

Roadmap

FEEDBACK: CLOSED

Feedback period

30 March 2021 - 27 April 2021 (midnight Brussels time)

Flagship initiatives on regulatory efficiency

- Propose to revise the pharmaceutical **legislation** to provide for simplification, the streamlining of approval procedures and **flexibility** for the timely adaptation of technical requirements to scientific and technological developments, in order to address the challenges relating to the interplay of medicines and devices, and to strengthen pro-competitive elements – 2022.
- Propose to revise the variation framework for medicines, through changes in legislation and guidelines, to make the lifecycle management of medicines more efficient and adapted to **digitalisation** – 2021-2023.

Other actions

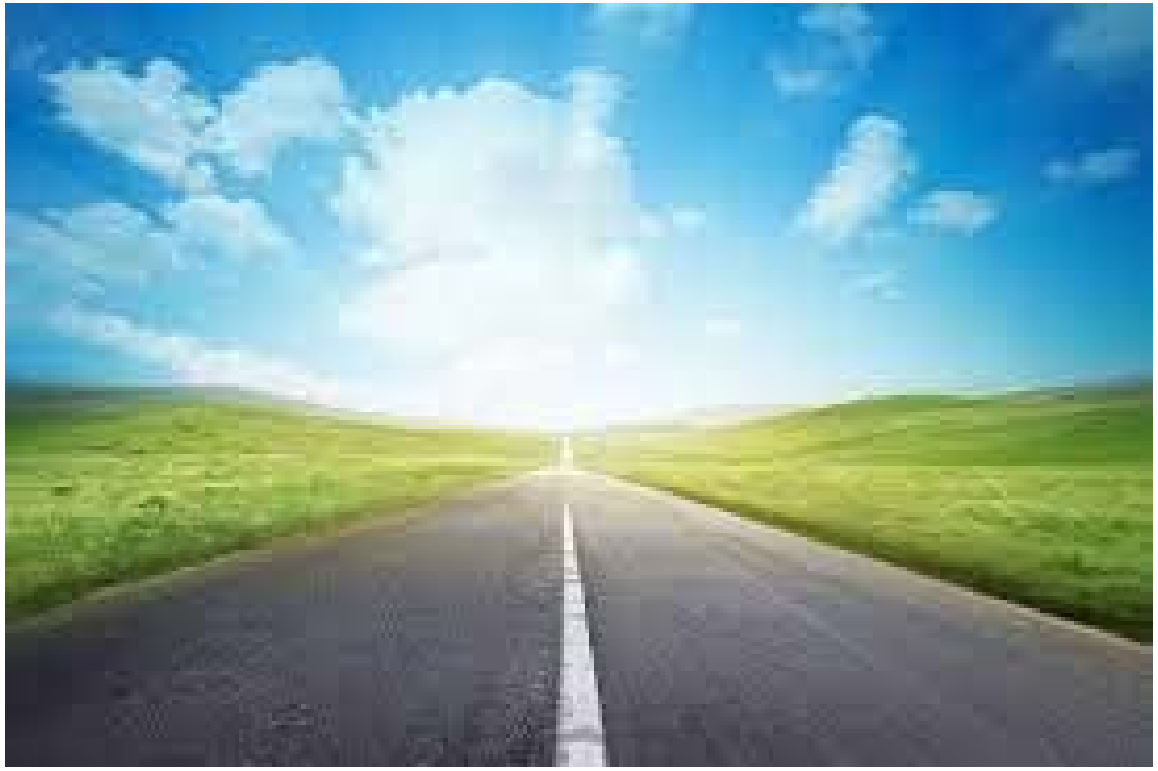
- Proposal for revised EMA fee legislation – 2021.
- Provide for a single assessment process across Member States for active substances used for different generic medicines (active substance master files) to facilitate their authorisation and life-cycle management – 2022.
- Consider adapting regulatory requirements in the pharmaceutical legislation, applicable to medicines for human use that contain or consist of genetically modified organisms (GMOs) – 2022.
- Upgrade the Commission's Union Register of centrally authorised products to include a statistical dashboard and make data fully available for secondary use as part of the EU open data initiative – 2021.
- Develop and implement electronic product information (ePI) for all EU medicines with involvement of Member States and industry, evaluate and revise relevant provisions in the legislation – 2022.
- Propose to revise legislation to give regulatory authorities more power to adapt on their own initiative the terms of marketing authorisations on the basis of scientific evidence – 2022.
- Simplify and streamline the system of penalties to address non-compliance in a proportionate and efficient way – 2024.

https://ec.europa.eu/health/sites/default/files/human-use/docs/pharma-strategy_report_en.pdf

Concept papers

- Kommisjonen har bedt om innspill til flere punkter, både hos legemiddelmyndigheten, industrien, akademia og allmenheten.
- Produktinformasjonen er ett av disse temaene (SmPC, labelling og PL)
- Blant annet har det vært nevnt ePI, flerspråklige pakninger, nasjonalt språk på fysisk pakning, elektronisk PL vs. trykt PL.

Mange har gitt innspill, veien videre er opp til kommisjonen



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