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Information to patients

Commission amended proposals on Information to Patients (COM (2011) 632, 633)

- Art 88a requires COM to report on current practice with regard to information provision and make proposals
- Initial proposals on information to patients-10 December 2008
- European Parliament adopted legislative resolutions on the proposals-24 November 2010
- Commission adopted revised proposals (COM (2011) 632, 633)-11 October 2011

The proposals consist of:

Amending directive to Directive 2001/83/EC

Amending regulation to Regulation (EC) No 726/2004

The issue

- Gap in current pharmaceutical legislation
  - Fully harmonised rules on advertising
  - Harmonised rules on the product information with the MA
  - Limited rules on other information
- MS have adopted divergent national practices / interpretations regarding the provision of information
- Unequal patient access to information on medicinal products

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General aim and scope

- Harmonised framework for the provision by MAH of non-promotional information to the general public on prescription-only medicinal products for human use

- Maintain prohibition of advertising by MAH to the general public on prescription-only medicines

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Key elements proposed relate to

- Types of information to be disseminated
- Channels for the dissemination of information
- Quality criteria and conditions to be fulfilled
- Specific rules on Internet websites
- Monitoring mechanism
- Sanctioning in case of non-compliance

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Main changes in the amended proposals-1

- **SCOPE**: Industry will have the **obligation, and no longer just the right**, to make available certain information

- **CONTENT:**Distinction between **obligatory** information and **other well defined information** which MAH **may** make available subject to strict quality criteria

- **CHANNELS:** Limited channels of communication, excluding general printed media. "pull" approach (rather than "push")

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Main changes in the amended proposals-2

- **CONTROL** :Pre-control of information by national authorities as a matter of principle, but exceptions provided for existing control systems or in case of constitutional problems.

- **PHARMACOVIGILANCE**: Strengthening of the new pharmacovigilance rules on three points on basis of the Mediator "stress test"

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Amended proposal for a Directive amending Directive 2001/83/EC (COM 633 final)

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Scope of Title VIII advertising (Art. 86(2))

- Article 86(2) currently in force identifies information not covered by "advertising" (Title VIII). New elements:
- not to be covered by "advertising" factual, informative **announcements for investors and employees** on significant business developments provided they are not used to promote the product to the general public.
- however, for information on **individual medicinal products**, the conditions relating to information to the general public on prescription medicines apply (new Title VIIIa)
- Marketing authorization holders and any third part acting on their behalf

Exception to advertising (Article 88(4)

- Further requirements on vaccine exemption from advertising ban:

  Such vaccination campaigns shall be approved by the competent authorities of the Member States **only if it is ensured that objective, non-biased information is provided** by the industry in the framework of the campaign regarding **the efficacy, the adverse reactions and contra-indications** of the vaccine

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Scope of new Title VIIIa-information to general public on prescription medicines (Art. 100a)

- **Covered:** information made available to general public by **MAH(also 3rd parties acting on their behalf)**.
- **Not covered:**

a) **public announcements on PhV concerns, which are subject to Article 106a;**

(b) information on human health or diseases, provided there is no reference, even indirect, to **individual** medicinal products;

(c) material provided to healthcare professionals for **their own use**;.

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Scope of new Title VIIIa-information to general public on prescription medicines (Art. 100a)

(d) information to investors and employees on business developments, provided it does not concern individual medicines and is not promotional

- **When information is made available to the public by 3rd persons, any financial or other benefits from MHAs shall be declared by the person making the information available.**

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Information which shall be made available (Article 100b)

- Summary of product characteristics
- Labelling and package leaflet
- Most recent publicly available assessment report

Types of information which may be made available (Art. 100b)

Information on

- the environmental impact
- prices
- pack changes
- instructions for use; possibility for still or moving images demonstrating the proper way of using the product
- pharmaceutical and pre-clinical tests and the clinical trials
- a summary of frequently submitted requests for information and the answers
- Other information approved by competent authorities to support the proper use of the medicine.

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Channels for making available the information (Art. 100c)

- **printed materials about a medicinal product prepared by the marketing authorisation holder made available to the general public or member thereof on request or through healthcare professionals**
- Internet websites on medicinal products, to the exclusion of unsolicited material actively distributed
- Written answers to **specific** requests for information of a member of the general public

Television and radio are excluded

« Pull » not « push »

Chart 1 scope

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Legal basis

Out of legal basis

INFORMATION

On medicinal products under prescription

By marketing authorisation holder

On website/leaflet/direct answer to the public

Obligation:
Labelling,
Package information,
Summary of product Characteristics,
Assessment report.

Possible:
Environment impact,
Price,
Pack changes,
Instructions for use,
Pharmaceutical and pre-clinical tests and clinical trials
Summary frequent questions
Other types

~~TV/radio~~

By press/Third parties

Statement: if received financial or other benefits from MAH or third party acting on behalf of MAH

By competent authorities

National medicines web-portal:
Already in Directive
Public assessment reports, with summary
Summaries of product characteristics and package leaflets

On prevention and disease

By press

By third parties

By competent authorities

Quality criteria (Article 100d) – 1

- Objective, unbiased; benefits and risks to be stated alike
- **patient-oriented** to adequately meet the needs and expectations of the patient
- Evidence-based, verifiable, including a statement on the level of evidence
- Up-to-date, including the date of publication or last revision
- Reliable, factually correct and not misleading

Quality criteria (Article 100d) – 2

- Understandable and **legible**
- Stating the source of the information (author, reference to a documentation)
- Not contradicting the approved SmPC, labelling and package leaflet

➡ Quality criteria agreed in the Pharmaceutical Forum (09/2008)

Control of information (Art. 100g) – 1

General principle:

- *MS to ensure that information is approved by the competent authorities before it is made available to the public*

Derogation, ex-post control if:

- *content of the information already approved by MS' competent authorities*
- *pre-existing systems (before 31.12.2008) or constitutional issues*
  - *equivalent level of adequate and effective monitoring is ensured through a different mechanism*

- Guidelines on allowed information to be drawn up by the Commission

Monitoring (Article 100g) -2

- **Printed media:**
  - *MS of publication responsible for monitoring*
- **Internet:**
  - *MS of registration of Internet website responsible for monitoring*
  - *Recognition of registered Internet website by other MS*
  - *Possible arbitration by the Pharmaceutical Committee*

Internet websites (Art.100h)–1

- Registration of an Internet website prior to making it available. Website must include:
  - *registration statement identifying the CA monitoring the website;*
  - *Link to the European medicines web portal*
- Information contained may then be provided by MAH on other websites if content is identical
- If MS of registration applies ex-post control, another MS may require approval before reproduction in that MS
- Links to other websites prohibited unless these websites are also registered

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Specific rules on Internet websites (Article 100h) – 2

- Identification of persons having access to websites shall not be possible
- Monitoring of an Internet website by MS where it has been registered
- Internet websites shall conform to W3C Web Content Accessibility Guidelines Version **2.0**, Level A (Article 100f(2))

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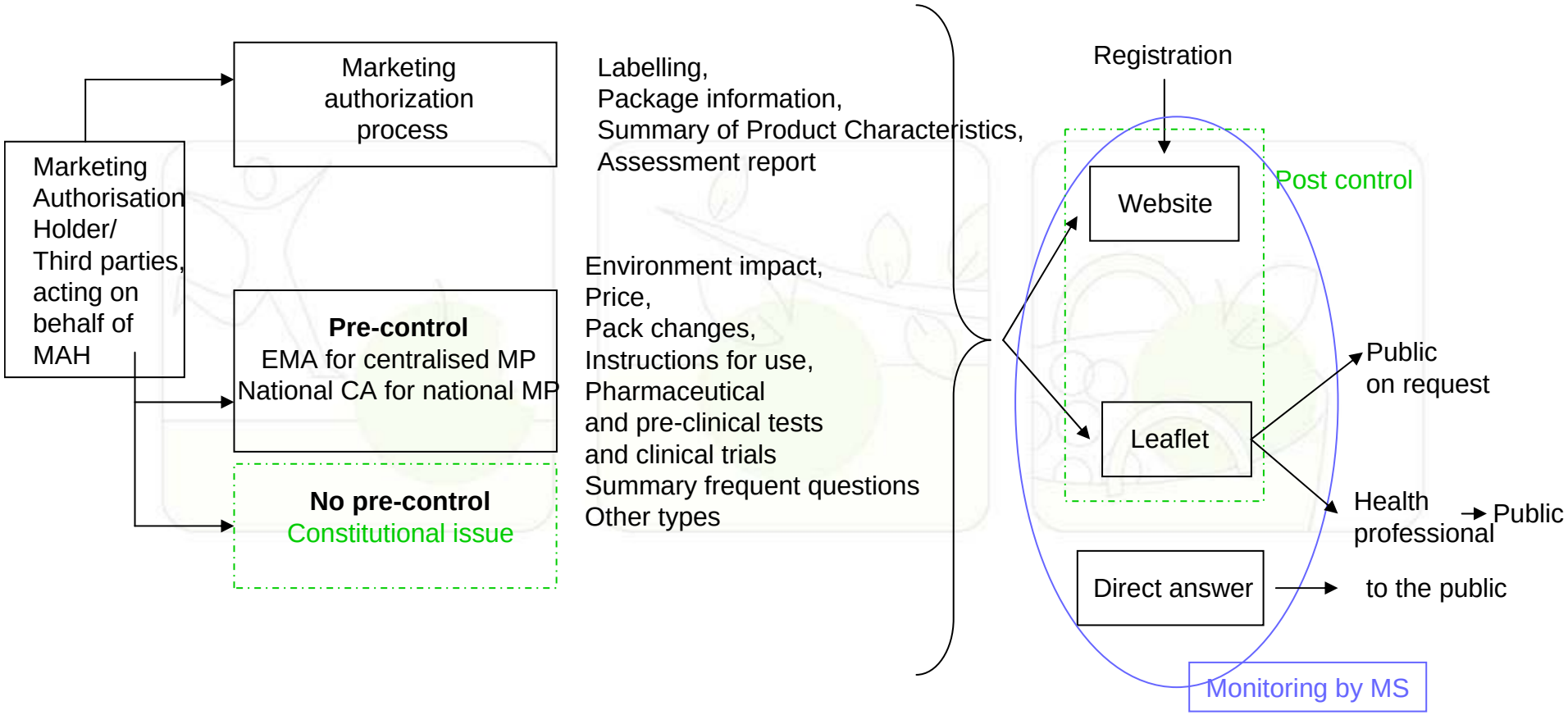
Chart 2 on control mechanisms



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Sanctioning in case of non-compliance (Art 100i)

- MS shall ensure that effective measures are adopted to ensure sanctioning of non-compliance
- Measures shall include:
  - *Determination of the penalties to be imposed*
  - *Obligation to sanction cases of non-compliance*
  - *Conferment of powers to courts or administrative authorities – cessation of dissemination or prohibition of dissemination of non-compliant information*
  - *Possibility to publish name of MHA responsible for non-compliant information*
- Right of MAH to be represented and heard and to appeal

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Amended proposal for a Regulation amending Regulation (EC) No 726/2004(COM 632 final)

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Art 20b

- **General rule:** Rules laid down in the directive shall also apply to centrally authorised prescription-only medicinal products for human use
- **Derogation:** prior control of medicinal product-related information by EMA
  - *MAH to submit mock-ups of information to EMA*
  - *EMA may object to submitted information within 60 days; information is deemed accepted if EMA does not object*
  - *If MHA resubmits mock-up, EMA may object in 30 days*
  - *EMA evaluation fee funded*
- Subsequent monitoring by MS competent authorities

Art 20c

- For centrally authorised products, EMA responsible for pre-control of information made available through internet websites registered in the Member States

- If a MS has doubts as to whether the approved information is in accordance with the requirements of the Directive, it shall inform EMA. If fail to reach agreement within two months, the case referred to the Pharmaceutical Committee.

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Art 26

- European medicines web portal should be the single point of reference for access to information on medicinal products:
  - Orphanet
  - Eudrapharm
  - Eudravigilance
  - Eudra GMP
- Registered Internet websites of MAH shall include link to European medicines web portal (Article 100h(5) of the proposed Directive)
- MS (through national web portals) to ensure objective, unbiased information is made available on medicinal on their markets (Art. 100j (11) of the proposed Directive)

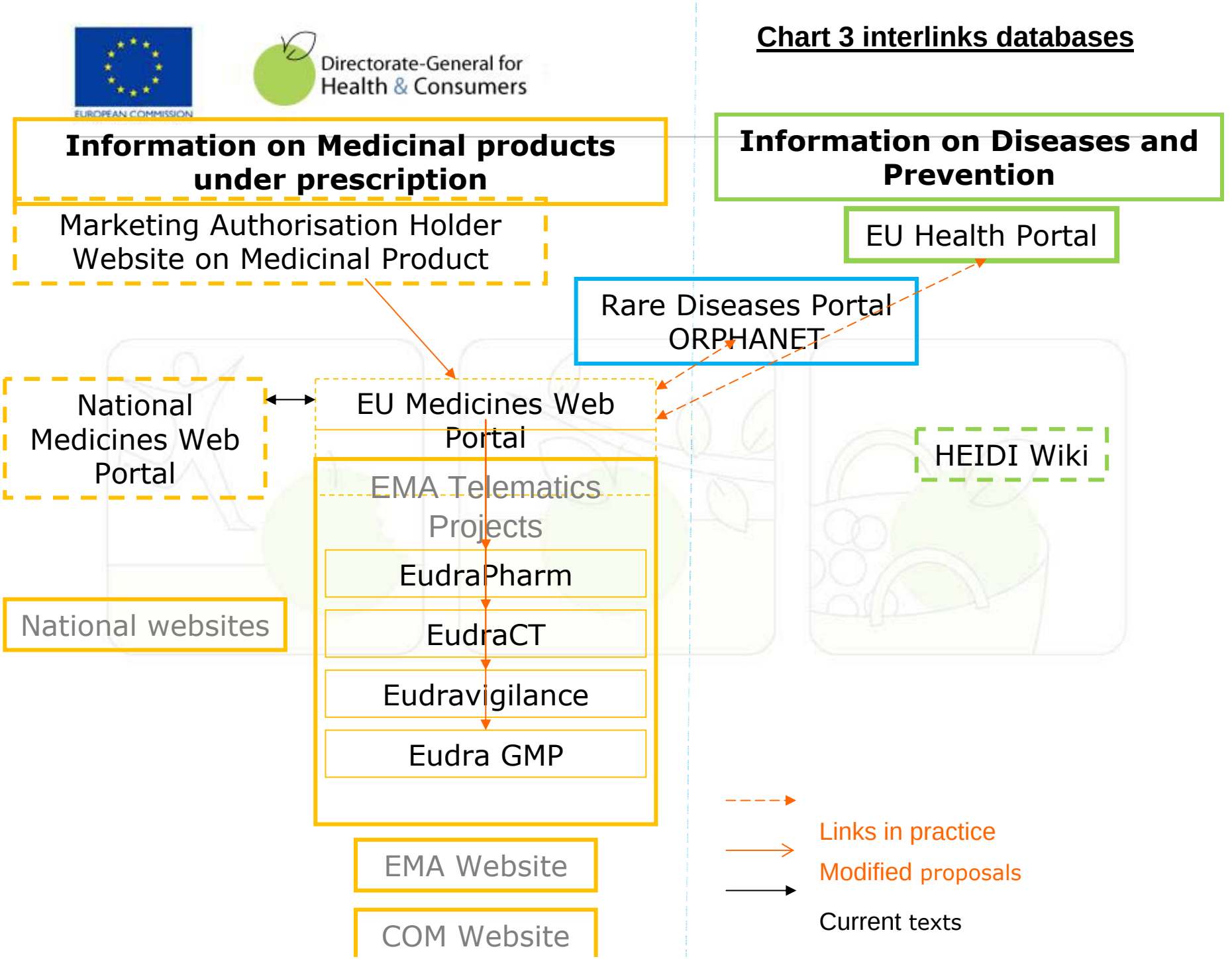
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Chart 3 interlinks databases
Information on Medicinal products under prescription
Information on Diseases and Prevention
Marketing Authorisation Holder Website on Medicinal Product
EU Health Portal
Rare Diseases Portal ORPHANET
National Medicines Web Portal
EU Medicines Web Portal
HEIDI Wiki
EMA Telematics Projects
EudraPharm
EudraCT
Eudravigilance
Eudra GMP
National websites
EMA Website
COM Website
Links in practice
Modified proposals
Current texts

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Pharmacovigilance points

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Pharmacovigilance points: automatic examination at EU level

- whenever a Member State takes action on a medicine due to serious safety concerns, this will automatically trigger an examination at EU-level in order to ensure equal safety for patients throughout the European Union

Proposed Directive: Articles 31, 34(3), 107i(1)

Proposed Rgulation: Article 20(8)

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Pharmacovigilance point: reasons for withdrawal, revoke or non-renewal of MA

- Companies who voluntarily withdraw a medicine from the market will be obliged to explain the reasons. Withdrawal for safety concerns must not be disguised as commercial activity, in order to ensure appropriate follow-up

Proposed Directive: Articles 23a, Art. 100i (13) amending Article 123(2) of 2001/83

Regulation: Articles 13 and new 14b

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Pharmacovigilance point:

- All authorised medicines that require special surveillance by national authorities will be included in a publicly-available list of medicines

Proposed Regulation: Article 23