EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Indication and Labelling

2nd EMA - Payer Community meeting – 18 June 2019

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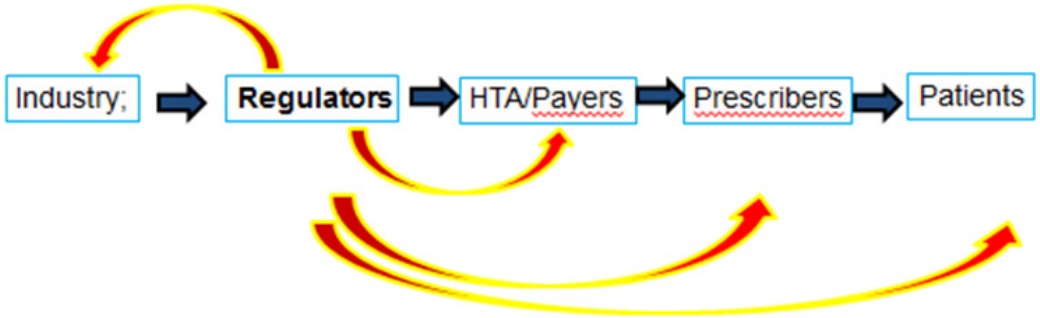
Outlines

- Progress status
- Looking forward



Ongoing collaboration

- CHMP reflection paper on wording of indication
  - A guide to assessors – finalisation
- EMA/EUnetHTA experience sharing on therapeutic indication definition and the impact of wordings in HTAs' definition of the medicine eligible population.
- Payer comments on recommendations on EPAR and SmPC – Letter August 2018
- May 2019 CHMP Presidency meeting: session with HTAs & Payers

Some outcomes

- CHMP reflection paper on the therapeutic indication welcomed – useful to better understand wording and process of indication definition – publication highly valued
- Strengthen (robustness) rationale in EPAR, e.g. regarding subgroups
- Section 5.1: use ad misuse; need for guidance - reflection paper?
- Investigate channels of continuous communication

Section 5.1- Pharmacodynamic properties; SmPC guideline:

- Mechanism of action (if known)
- Pharmacodynamic effects.
- Clinical efficacy and safety

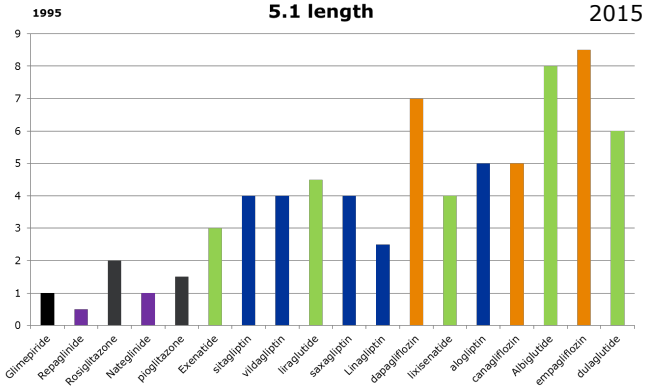
It may be appropriate to provide limited information, relevant to the prescriber, such as the main results (statistically compelling and clinically relevant) regarding pre-specified end points or clinical outcomes in the major trials, and giving the main characteristics of the patient population. Such information on clinical trials should be concise, clear, relevant and balanced, and should summarise evidence from relevant studies supporting the indication. The magnitude of effects should be described using absolute figures. (Relative risks or odd ratio should not be presented without absolute figures).

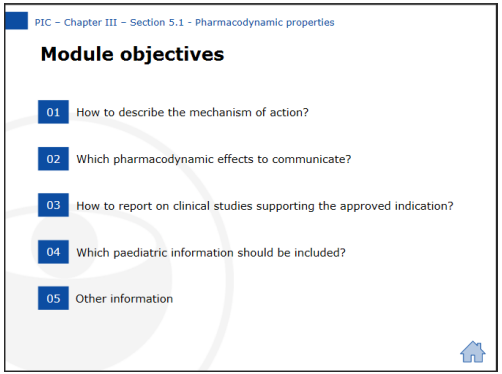
In the exceptional cases when clinically relevant information from subgroup or post-hoc analyses is presented, it should be identified as such in a balanced manner reflecting the limited robustness of both positive and negative secondary observations.

Any relevant pharmacogenetic information from clinical studies may be mentioned here. This should include any data showing a difference in benefit or risk depending on a particular genotype or phenotype.

Paediatric population

The results of all pharmacodynamic (clinically relevant) or efficacy studies conducted in children should be presented under this sub-heading.





A reflection paper on 5.1; points for consideration?

- To clarify audience and purpose? Place vs EPAR?
- Differences between old and new medicines?
- Difference between therapeutic classes?
- HTAs and Payers' expectations and concerns?
- How far can it support personalised therapy?
- Opportunity offered with eProduct Information?

➢ Strengthen, clarify or revise guidance on 5.1?

Any questions?

Further information

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First EMA – Payer Community meeting (September 2017)

- SmPC: basis of information for healthcare professionals on how to use the medicine safely and effectively. It is not a treatment guideline.
  - Therapeutic indication: disease and population in which benefit risk balance positive
  - Other sections of the SmPC provide additional information but aim neither at extending nor at restricting the indication(s).
- Payers observed a trend towards less specified populations covered by the approved labelling, which leads to problems for reimbursement decisions
  - Regulators to be explicit about their reasoning; e.g. EPAR to provide a judgement which sub-group is expected to be performing well and where there are more uncertainties.
  - Payers to consolidate comments and suggestions for improvement on EPAR and SmPC.

European Commission

PERSONALISED MEDICINE
FOCUSING ON CITIZENS' HEALTH

PERSONALISED MEDICINE
tailor-made prevention, diagnosis and treatment for individuals or groups of individuals

Enabling
HEALTHIER, MORE PRODUCTIVE LIVES

Significant EU investments in research on personalised medicine to

TREAT PATIENTS WITH THE THERAPIES THAT WORK BEST FOR THEM
many common medicines are not effective for many patients

CUT HEALTHCARE COSTS
as Europe's population ages and chronic diseases become more prevalent

DRIVE HEALTHCARE INNOVATION
Establish Europe as a global leader in healthcare industry and innovation, and create jobs and economic growth

AVOID ADVERSE REACTIONS TO MEDICINES
6% of acute hospital admissions are due to serious adverse reactions to medicines

Research and innovation investment in better health

Digital Health and Care

TRANSFORMATION OF HEALTH AND CARE IN THE DIGITAL SINGLE MARKET - Harnessing the potential of data to empower citizens and build a healthier society

European health challenges

- Ageing population and chronic diseases putting pressure on health budgets
- Unequal quality and access to healthcare services
- Shortage of health professionals

Potential of digital applications and data to improve health

- Efficient and integrated healthcare systems
- Personalised health research, diagnosis and treatment
- Prevention and citizen-centred health services

What EU citizens expect...

90% agree — To access their own health data (requiring interoperable and quality health data)

80% agree — To share their health data (if privacy and security are ensured)

80% agree — To provide feedback on quality of treatments

Support European Commission:

1 Secure access and exchange of health data

Ambition:
Citizens securely access their health data and health providers (doctors, pharmacies...) can exchange them across the EU.

Actions:
- eHealth Digital Service Infrastructure will deliver initial cross-border services (patient summaries and ePrescriptions) and cooperation between participating countries will be strengthened.
- Proposals to extend scope of eHealth cross-border services to additional cases, e.g. full electronic health records.
- Recommended exchange format for interoperability of existing electronic health records in Europe.

2 Health data pooled for research and personalised medicine

Ambition:
Shared health resources (data, infrastructure, expertise...) allowing targeted and faster research, diagnosis and treatment.

Actions:
- Voluntary collaboration mechanisms for health research and clinical practice (starting with "one million genomes by 2022" target).
- Specifications for secure access and exchange of health data.
- Pilot actions on rare diseases, infectious diseases and impact data.

3 Digital tools and data for citizen empowerment and person-centred healthcare

Ambition:
Citizens can monitor their health, adapt their lifestyle and interact with their doctors and carers (receiving and providing feedback).

Actions:
- Facilitate supply of innovative digital-based solutions for health, also by SMEs, with common principles and certification.
- Support demand uptake of innovative digital-based solutions for health, notably by healthcare authorities and providers, with exchange of practices and technical assistance.
- Mobilise more efficiently public funding for innovative digital-based solutions for health, including EU funding.

#DigitalSingleMarket #DigitalHealth @eHealth_EU @EU_Health