MINISTERIO DE SANIDAD, SERVICIOS SOCIALES E IGUALDAD

agencia española de medicamentos y productos sanitarios

HMA
Heads of Medicines Agencies

Heads of Medicines Agencies Subgroup on Timely Access

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ABOUT HMA

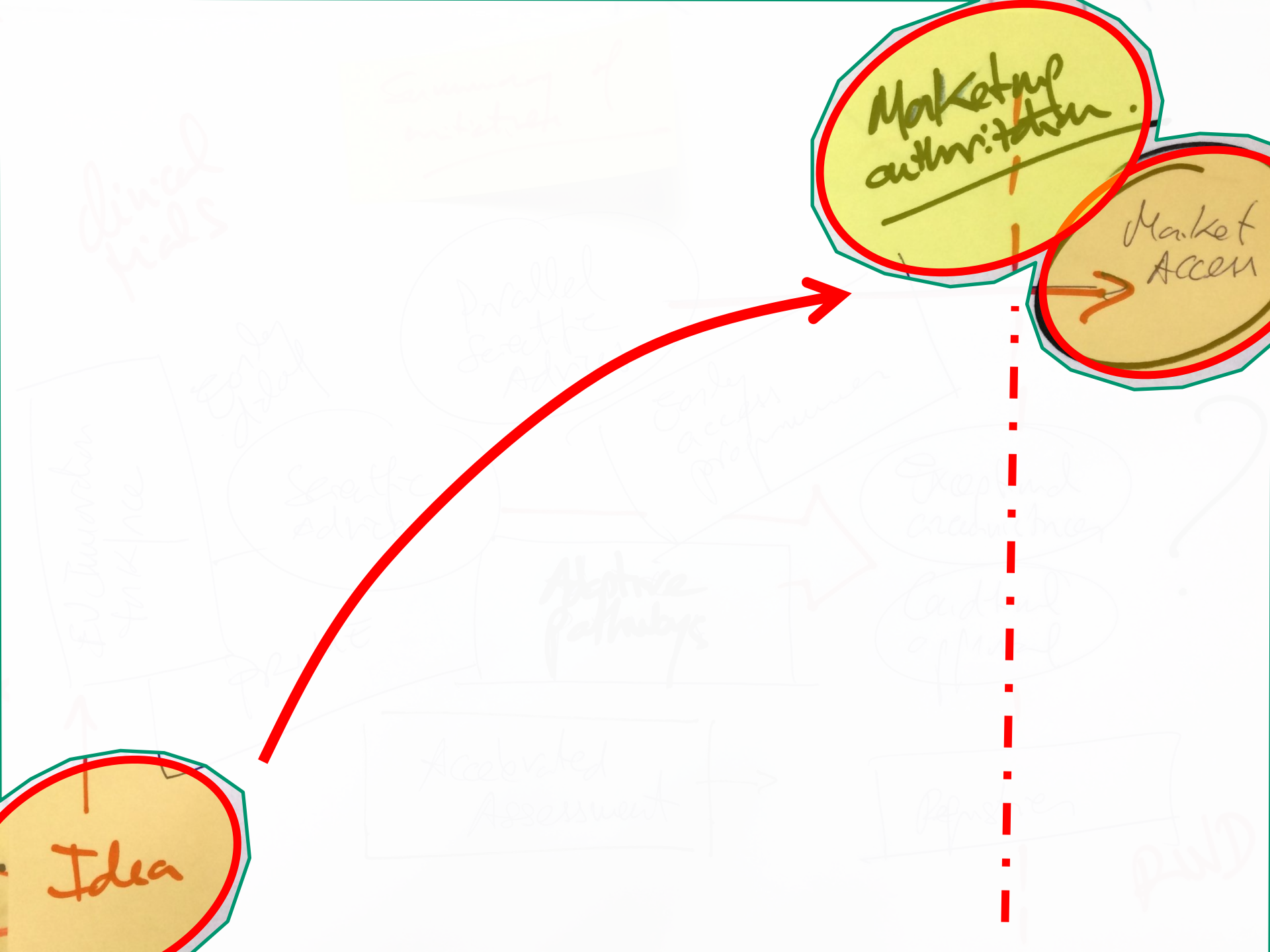
The Heads of Medicines Agencies (HMA) is a network of the heads of the National Competent Authorities (NCA) whose organisations are responsible for the regulation of medicinal products for human and veterinary use in the European Economic Area.

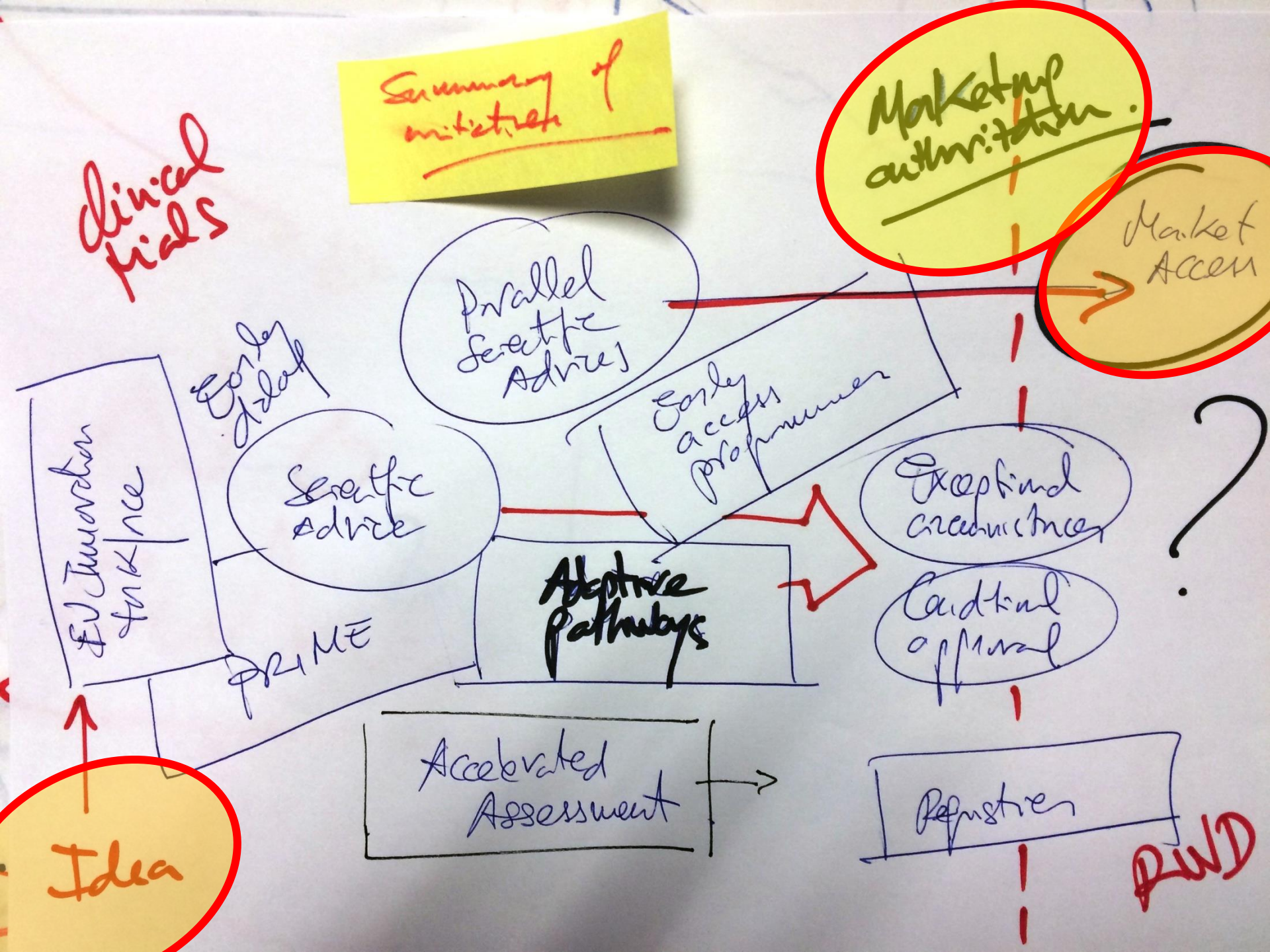
The HMA co-operates with the European Medicines Agency (EMA) and the European Commission in the operation of the European medicines regulatory network and it is a unique model for cooperation and worksharing on statutory as well as voluntary regulatory activities.

The HMA is coordinated and supervised by a Management Group and it is supported by several Working Groups, covering specific areas of responsibility, and by a Permanent Secretariat.

timely access

- Increasing demand for access to new and innovative medicines at earlier stages for patients with unmet medical needs
- Need to balance in a proportionate risk-based approach a positive R/B against the need for early access
- Need to explore different tools to support timely access to all medicines while not lowering bars for authorisation


Idea
Market
Market Access


Summary of evidence
Marketing authorisation
Clinical trials
Market Access
Parallel Scientific Advice
Early access programmes
Early dialogue
Scientific advice
EU Innovation Network
PRIME
Adaptive pathways
Conditional approval
Accelerated Assessment
Registries
Idea
RWD

timely access

- Increasing demand for access to new and innovative medicines at earlier stages for patients with unmet medical needs
- Need to balance in a proportionate risk-based approach a positive R/B against the need for early access
- Need to explore different tools to support timely access to all medicines while not lowering bars for authorisation
- Some of this tools are under the governance of the EMA but others under the competence of NCA
- Timely access will also benefit of the consensus amongst regulators, HTA bodies and P&R authorities

Timely Access involves

- early detection of promising products and guiding an appropriate clinical development
- tailored access adjusted to knowledge during pre-authorization phases through CT and/or early access programs,
- efficient and fair regulatory processes, and
- integration of all these activities with subsequent, HTA and P&R decisions and the pharmacovigilance activities for the entire life cycle of medicines

multiple initiatives

EU Council Conclusions
Innovation for the benefit of patients (2014), Personalised medicines (2015), Strengthening the balance in the pharmaceutical systems in the EU and its MS (2016)

EU Medicines Agencies Network Strategy to 2020 (HMA and EMA MAWP): EU Innovation network, HMA's Timely Access Subgroup, HMA/EMA Joint TF Big Data, PRIME, Adaptive pathways, RWE

Timely Access to new beneficial and safe medicines for patients

European Commission
3rd programme of the Union´s action in the field of health (2014-2020), Work programme 2015, 2016, and 2017, Horizon 2020-IMI, **STAMP**, EUnetHTA, Synergy Group

Other initiatives:
Voluntary cooperation among member states (i.e, BENELUXA, The Valletta Declaration) or ICMRA (Strategic priority on innovation Horizon Scanning)

Timely Access Subgroup (i)

- Innovation and access to new medicines is one of the eleven key business priorities of the HMA-MAWP
- Timely access Subgroup of HMA since late 2016
- Links with other HMA groups and task forces like EU Innovation Network, Big Data TF, CTFG…
- Close cooperation with STAMP and Synergy Group
- Meetings by teleconference, chaired by ES and attended by BE, DE (Bfarm), HU, NL, NO, RO, UK, and the Commission (invited)

Actions of MAWP

HMA
Heads of Medicines Agencies

Timely Access

Action 6
HMA should further explore the flexibilities that the EU regulatory framework offers for the early access of innovative products at national level…

Action 8
(…) to improve the involvement of patients/users, HCPs and academia (…) the collaboration with other key bodies (such as HTAs, pricing and reimbursement authorities and payers)

Action 7
In conjunction with EMA explore ways to harmonize the regulatory requirements of registries and defining circumstances for use of real world data (RWD) …

Action 14
to consider the necessity, feasibility and capability to generate independent data or reanalyze raw data …

Timely Access Activities (i)

1. **Discuss and generate a common framework of activities related with Timely access at HMA level**

- To discuss and adopt a position (or reflection) paper of HMA depicting all activities related to timely access in which the HMA and the NCAs may be involved either at global or national level.
- Expected outcome: Paper published at the HMA website and discussed with stakeholders
- Status: Ongoing

Timely Access Activities (ii)

2. Explore the flexibilities that the EU regulatory framework offers for the early access of innovative products at national level

- Either participation in CT (phase II, phase III or expanded access clinical trials under CTFG) or early access programs (either named-patient basis or cohort approaches)
- Expected outcome: a position (or reflection) paper of HMA about CUPs and HMA website updated
- Status: Ongoing

Timely Access Activities (ii)

3. Explore the possibility of increasing the cooperation in off-label use between MS and sharing of good practices

- Advice the EC, from the perspective of the NCAs, in the development of possible actions that may arise as a result of the analysis on the off label use performed in early 2016. Specifically, provide the MS view on how to include the knowledge generated with off-label use within the regulatory framework (what, when and how).

- Status: Ongoing

Timely Access Activities (iv)

4. Collaborate with the EMA to optimize the timely access regulatory tools and integrate them into national circumstances

- To contribute to a greater optimization of conditional approval, exceptional circumstances approval or accelerated assessment/PRIME scheme, specifically on how to avoid national barriers or how to adapt them to the national realities.
- Status: awaiting

Timely Access Activities (v)

5. Strengthen collaboration with the different partners: HTAs bodies, P&R, HCPs and patients

- Increase collaboration with HTA and P&R to ensure programs designed to meet the needs of all parties.
- Potential involvement of patients and HCP to be explored.
- Annual meetings in the margins of the HMA with patients, HCPs, HTA bodies and/or P&R authorities, to engage them in the timely access subgroup discussions
- Status: planning

Timely Access Activities (vi)

6. Assessment of emerging trends: RWE & registries

- Explore alternatives to obtain clinical evidence for the benefit of patients. Explore emerging trends such as the use of real world evidence or registries data has to be considered by the subgroup.
- Status: awaiting big data TF

Conclusion, next steps and future challenges

- Most work ahead
- Important to keep working together and collaborate to prevent duplication of efforts
- To engage HMAs in discussions around timely access and increase their awareness of different initiatives
- Continuing an open and constructive multi-stakeholder dialogue