Horizon Scanning for pharmaceuticals

EMA – Payer Community meeting, 19 September 2017

Presented by Michael Berntgen
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The foundation: what do we mean?

Elements that drive the approach to horizon scanning:

- Objectives / desired impact
- Scope of technologies / interventions
- Observation period
- Data sources and detection methodology
- Triage
- Reporting mechanisms

“Horizon scanning” means different things to different people.
Understanding the payers’ needs

Using the KCE report* as (exemplifying) basis:

• Focus on pharmaceuticals (4 listings)
  – mostly in later development and during the regulatory approval process plus some specific early development (e.g. orphan designations)
  – considering the impact on health care system, i.e. financial, clinical or organisational impact

• Need for voluntary information from companies (e.g. face-to-face pipeline meetings)

* Horizon scanning for pharmaceuticals: proposal for the BeNeLuxA collaboration
Information that can be used as source data (1/2)

During the regulatory review of the marketing authorisation application:

- Monthly listings of “Medicines under evaluation”
- Progress updates through milestones in published CHMP agendas/minutes
Making it real: examples of available information

Case 1: accelerated assessment agreed

<table>
<thead>
<tr>
<th>Drug</th>
<th>Category</th>
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<tbody>
<tr>
<td>Brexpiprazole</td>
<td>Psycholeptics</td>
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<tr>
<td>Brigatinib</td>
<td>Antineoplastic medicines</td>
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<tr>
<td>Ciclosporin</td>
<td>Ophthalmologicals</td>
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<tr>
<td>D-biotin</td>
<td>Vitamins</td>
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<td>Dengue tetravalent vaccine (live, attenuated)</td>
<td>Vaccines</td>
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<tr>
<td>Dolutegravir (sodium)/raltegravir (hydrochloride)</td>
<td>Antiretrovirals for systemic use</td>
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<tr>
<td>Emicizumab</td>
<td>Haemostatics/antihemorrhagic</td>
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<tr>
<td>Enclomifene (citrate)</td>
<td>Sex hormones and modulation of the genital system</td>
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Emicizumab - Orphan - H0004406

Roche Registration Limited; indicated for routine prophylaxis to prevent bleeding or reduce the frequency of bleeding episodes in patients with haemophilia A (congenital factor VIII deficiency) with factor VIII inhibitors, can be used in all age groups.

Scope: Briefing note and Rapporteurs’ recommendation on the request for accelerated assessment

Action: For adoption

The CHMP agreed to the request for accelerated assessment and adopted the briefing note and Rapporteurs’ recommendation on the Request for Accelerated Assessment.

Minutes of the CHMP meeting in May 2017

--- brigatinib - EMEA/H/C/004248

treatment of anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC)

Scope: Day 120 list of questions

Action: For adoption

The Committee discussed the issues identified in this application.
The Committee adopted the CHMP recommendation and scientific discussion together with the list of questions.

Minutes of the CHMP meeting in June 2017
Information that can be used as source data (2/2)

During the development phase:

- Products that received an **orphan designation**, including details of the condition and high-level information about the development stage

- Products with confirmed eligibility for the PRIority MEdicines scheme (PRIME)
EMA experience with business pipeline meetings

Development of a framework in which companies voluntarily provide information on their pipeline

- Meeting frequency depending on needs
- Confidential provision of information (commercially sensitive)
- “e-updates” to provide additional data
- Instrumental in contributing to preparedness
EMA’s aims with business analysis and forecasting

To support for “the near future”
• operational workload
• expertise needed
based on type of applications, therapeutic areas, medicinal products, indications etc. (not: prices / medicines budget)

To facilitate development activities by identifying ‘road blocks’, signpost companies to interaction opportunities and support reviews of trends (environmental analysis)
Additional observations

- "Horizon scanning" has been identified as an area for collaboration between regulators and HTAs
  - The EMA/EUnetHTA work plan has a dedicated item
  - The Synergy group from the HTA Network is formulating an action plan
- Opportunity to link up activities on European level, capitalising from synergies in data needs whilst recognising differences in objectives (due to different mandates)
To start the debate: where to go from here?

• Part of the data needs identified by payers can be addressed already:
  – Jointly explore how to optimise the reporting of available data
  – Payers to perform product selection based on their needs
• Benefit from experience with setting up a business pipeline monitoring:
  – Exchange on learnings from development and conduct of company meetings
  – Possibility to reach out to industry to see readiness to engage
• Opportunity to see how data held by different actors can be mutually beneficial
• Importance to avoid duplication of efforts hence proposal to link up with other activities from payers and from HTAs on European level