Health Technology Assessment International
An International Society for the Promotion of Health Technology Assessment

HTAi RICC Interest Group:

Regulatory Interactions & Conditional Coverage

a new Interest Group formed from the merger of the HTA-Regulatory Interactions IG and the Coverage with Evidence Development IG

May 2016

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1 New Interest Group: the RICC

Following the unanimous support for the proposal to merge the HTA-Regulatory Interactions Interest Group with the Coverage with Evidence Development Interest Group, we are now pleased to announce the creation of the Regulatory Interactions and Conditional Coverage (RICC) Interest Group. This merger has been approved by the HTAi Board.

The new IG will focus on the changing dynamics around evidence development that are leading to greater interaction with regulatory stakeholders (i.e. in terms of scientific advice and convergence of evidentiary requirements, databases or activities) as well as the increasing interest in mechanisms that involve conditionality of access relating specifically to evidentiary development (i.e. managed entry mechanisms, adaptive pathways, performance-linked

reimbursement).

The scope of this Interest Group includes:

- Adaptive pathways
- Managed entry agreements (focussing on the outcomes-based ones)
    - Performance-linked Risk Sharing Agreements (PBRSAs)
    - Coverage with evidence development (CED)
    - Conditional treatment continuation (CTC)
- Post-marketing additional data collection
- HTA-Regulatory Interactions relating to evidence development
- Early dialogue / scientific advice (relating to the above)

The issues out of scope:

- Financial based Managed Entry Agreements
- HTA-Regulatory Interactions outside the context of evidence development

Next steps

Following the agreement of the Interest Group membership to merge to create the RICC IG we have some additional work to do.

1. **Transitional governance**

In the interim, the transitional IG be chaired by the current chair of the HTA-Regulatory IG, Franz Pichler (Eli Lilly) and co-chaired by the current co-chair of the CED IG, Urs Brügger (Winterthur Institute of Health Economics, Zurich University of Applied Sciences).

As of last week, HTAi have finalised the new IG mailing list and have transitioned existing members of the two IGs to the RICC membership. You can also contact the HTAi secretariat and opt out if this IG no longer meets your needs. New members are of course most welcome.

2. **Formal launch of the RICC IG**

The RICC will be formally launched at the 2016 HTAi Annual Conference in Tokyo during the Annual Business Meeting (ABM). The ABM will be held on Friday 13 May over the lunch session from 12:45 – 14:15 in the Keyaki meeting room.

During the ABM we will allow plenty of time for discussion about this new IG and everything will be open for discussion (even, or especially, the name). We will be holding elections for a chair and co-chair for the RICC and discuss how to transition the existing work streams as well as discuss potential new projects that could be conducted by the IG.

In preparation for this launch we have developed a new website which we hope to launch during the ABM. We will discuss the new RICC repository including the literature search methodology.

Finally, we will be updating our Terms of Reference following a review by the IG Steering Committee on Wednesday 11 May. We would be happy for your feedback as well as your inputs on how best to work with non-HTAi members (e.g. regulatory agency representatives).

2 RICC Panel at Tokyo HTAi Meeting

We are pleased to announce that the IG will be presenting a panel at the 2016 HTAi

conference. The panel follows on from an emerging issue uncovered during the Adaptive Pathways Workshop at the 2015 Oslo HTAi conference which was the first collaborative project between the two outgoing Interest Groups.

How can HTA's in the Asia-Pacific respond to increased clinical uncertainty as a consequence of expedited US and EU regulatory processes? Is risk-sharing the answer?
Thursday 09:30-11:00 in the Starlight Room

We have an excellent calibre of panellists:

- **Dr. Arnold Chan,** Director, Health Data Research Center, National Taiwan University, Taiwan
- **Dr. Simona Montilla,** HTA and Pharmaceutical Policy Expert, Agenzia Italiana del Farmaco (AIFA), Italy
- **Dr. Michelle Mujoomdar,** Director, Scientific Affairs, Canadian Agency for Drugs and Technologies in Health (CADTH), Canada
- **Dr. Soo-Mi, So:** General Manager, Pharmaceutical Listing Division, Health Insurance Review & Assessment Service (HIRA), South Korea
- **Professor Adrian Towse,** Director, Office of Health Economics (OHE), UK

Panel background

HTA depends upon clinical evidence that is largely developed to meet the requirements of two regulatory authorities, the FDA and the EMA. With the increasing use of the FDA Breakthrough Designation and European efforts to reform Conditional Marketing Authorisation and develop Adaptive Pathways, it can be anticipated that there will be an increasing number of approvals under expedited pathways in both jurisdictions. Products authorised under these expedited pathways will be those for the highest unmet need and therefore of greatest interest in other jurisdictions such as the Asia-Pacific. However, are HTA and payer systems equipped to review and manage products that have been approved based on positive Phase II data, or with limited Phase III trial data?

The panel will focus on the HTA implications of clinical uncertainty resulting from expedited reviews and will discuss options including a case study of an agency in the region that is proactively working to address this issue. One promising approach may be outcomes-based risk sharing which will be examined by looking at international best practice and comparatively. Following will be discussion of whether this is a suitable approach for the region and if not, then what are suitable alternatives.

3 Changes to the Regulatory Interactions Repository: introducing the RICC repository

Following the merger we will be expanding the content of the HTA-Regulatory Interactions Repository to include topics relating to Coverage with Evidence Development. We will also consider how to engage with the Information IG in order to import the publications into the HTAi Vortel, however it is important that we maintain the repository in the short term as reference for stakeholders outside of HTAi (such as the regulatory community).

In a further significant change, we are very pleased to announce that Dr Michelle Mujoomdar from CADTH has kindly agreed to take on the responsibility as the repository manager. She will oversee the development of a comprehensive search strategy for publications with quarterly updates and we will outline this process and seek your feedback, for example on search terms, during the Annual Business Meeting. The first update to the repository is

already available on the HTAi website with **over 50 new publications** (although please note some links on the website still call this the Regulatory-Interactions Repository).

4 Update on Coverage with Evidence Development

The NICE Decision Support Unit published a new report in January 2016: "Framework for analysing risk in Health Technology Assessments and its application to Managed Entry Agreements".

The DSU writes: *"Recent changes to the regulatory landscape of pharmaceuticals may require reimbursement authorities to issue guidance on technologies with an evidence base that is less mature than has previously been the case, resulting in greater uncertainty at the point of decision making in a Health Technology Assessment (HTA) that translates into a larger risk to the health-care payer. This risk can be mitigated using Managed Entry Agreements (MEAs) but it has been unclear how the need for and the value of such MEAs can be systematically assessed.*

In this report we propose the MEA risk analysis framework to address this. The framework includes the Payer Uncertainty Burden and the Payer Strategy Burden, both measures of payer risk, and offers methods of assessing reductions in these measures that are precipitated by different types of MEAs. Application of the MEA risk analysis framework to eight past NICE technology appraisals confirmed its feasibility within standard HTA timelines. We conclude that the MEA risk analysis framework is a feasible, consistent and transparent method of assessing the need for and the value of MEA schemes."

link to report on DSU website

5 New Green Park Collaborative project relating to use of RWE in decision-making

The original 2013 Green Park Collaborative (GPC) pilot project was an international dialogue developed in partnership between HTAi and the non-profit Center for Medical Technology Policy (CMTP) with the objective of developing guidance relating to how to design clinical studies to better meet the needs of HTA and coverage bodies in the area of Alzheimer's disease. Since that time, CMTP have continued this collaborative approach to develop a variety of US-focussed guidance documents relating to evidence development. The GPC has recently initiated a new project entitled "Promoting Better Decisions Using Real World Evidence" and which involves FDA, CMS, Private Payers, Academic and Industry partners.

link to site

6 FDA inviting private coverage bodies to participate in pre-submission meetings for devices

On 24 February 2016, the FDA issued a notice of request for expressions of interest from US private coverage organisations to be available to participate in FDA (CDRH) pre-submission meetings with device companies that would like to have payer input in regards to clinical trial design and other evidence gathering. For those organisations that do express interest, the FDA intends to list them on the CDRH website so that device sponsors can identify which organisations are interested and then have the option to invite them to participate in an FDA pre-submission meeting. The FDA views this initiative as a way to '*help avoid delays to patient*

access that may result if clinical trials are conducted, or data are collected, sequentially when it could have been done concurrently'.

In 2011, the FDA and CMS initiated a parallel review pilot programme for new devices. One output of this pilot was that the FDA '*found that early input from payers regarding their evidentiary needs can streamline the process from FDA approval or clearance to payer coverage'*. The FDA-CMS pilot programme was limited to Medicare national coverage policy while this new initiative represents an effort to help reduce the gap between FDA authorisation and securing reimbursement outside of the Medicare process.

link to FDA notice

6 Thank you all for your interest in this HTAi subgroup.

As always, we are very eager to hear your feedback as that is the best way we can ensure that this Interest Group remains….interesting. We want to meet your needs and so do let us know how we can improve our work.

Over the previous couple of years we have had some excellent suggestions as to potential new work streams and now that the merger is complete we want to return to those suggestions at the coming ABM. Therefore, if you have project ideas, especially if you would be interesting in contributing a little bit of your time, then do let us know – preferably in advance of the ABM so we can ensure we allocate sufficient time to discuss such projects.

Dr Franz Pichler, Eli Lilly, (fpichler@lilly.com), ISG Chair

Prof Urs Brügger, Zurich University of Applied Science (brgu@zhaw.ch), ISG vice-Chair
February 2016