REGULATORY AFFAIRS

Europe needs change to drive added value

Adjustments to European health technology assessment (HTA) frameworks and "robust research support" are needed to "ensure that European patients can benefit from value-added medicines", according to the Value Added Medicines Group within European off-patent industry association Medicines for Europe.

Launching a study on value added medicines – existing molecules that are reformulated, repositioned or combined in a way that adds value – titled 'Time to adjust the HTA decision frameworks', the Value Added Medicines Group's interim chair, Umberto Comberiati, insisted that research on known molecules was "a valuable untapped opportunity for European patients and healthcare professionals alike".

"There is an urge to support research and adjust the HTA policy frameworks to encourage industry to invest in medicines with high potential value to patients and society," Comberiati said.

According to the study – conducted by Mondher Toumi, professor of public health at Aix-Marseille University, France, based on feedback from "key HTA experts across Europe" – value added medicines make a "major contribution to patients' quality of life, health outcomes or adherence". They also "address a number of medicine-related healthcare inefficiencies, improving healthcare provision and organisation while contributing to the sustainability of healthcare systems".

Emphasising the importance of "the eligibility of value added medicines for HTAs, whenever requested, in order to demonstrate these relevant improvements", the study insists there is a need to adjust HTA decision frameworks "to ensure that all benefits of value added medicines are appropriately captured and to ensure a patient-centric assessment". "The current European HTA decision frameworks represent various challenges for the full value recognition of these products, which need to be addressed," Toumi commented.

Setting out 10 "key recommendations", the study urges promoting complementary HTA methods by supporting "the development of a robust and reliable methodology to implement multiple criteria decision analysis (MCDA) techniques" as well as research on 'constraint optimisation' modelling. The remaining eight recommendations comprise "aspects of HTA decision frameworks that should be adjusted".

These eight aspects include making all medicines eligible for HTA "whenever requested", as well as eligible for early HTA dialogue "at national or European level". HTA decision frameworks should also encompass "all attributes recommended by the EUnetHTA core model", and should be "patient-centric and consider the patient perspective".

HTAs should also "when more appropriate" consider alternative study designs beyond randomised clinical trials, the study suggests. And HTA organisations should "encourage the use of coverage with evidence development, to allow some benefits that may be complex to demonstrate during development to be captured post-launch".

The final two recommendations are that HTA decision frameworks should "adopt a broader perspective in order to better reflect patients' and society's views of healthcare" and that a broad range of stakeholders – including patients, healthcare professionals, citizens and hospital administrators – should be voting members of HTA committees.

Furthermore, the study advocates, "the manufacturers of value added medicines should also have the opportunity to get early HTA advice in order to better shape their clinical development plan". Toumi believes that "taking into consideration the specific benefits of value added medicines will need efforts both on the research and policy fronts, but also the involvement of a broad range of stakeholders".

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REGULATORY AFFAIRS

WHO eyes October to prequalify biosimilars

A pilot project for prequalifying biosimilars will be launched by the World Health Organization (WHO) in October, with the body inviting manufacturers to submit prequalification applications for biosimilar rituximab and trastuzumab. Launching the project, the WHO stated, was "a step towards making some of the most expensive treatments for cancer more widely available in low- and middle-income countries".

The WHO first announced the decision to start prequalifying the two oncology treatments in May (**Generics *bulletin***, 12 May 2017, page 13). This followed a stakeholder consultation in Geneva, Switzerland, where the WHO, national regulators, pharmaceutical industry groups, patient and civil society groups, payers and policy makers discussed ways to increase access to biotherapeutic medicines (**Generics *bulletin***, 7 April 2017, page 8).

For manufacturers wishing to apply for the pilot project, the WHO will be using two assessment pathways, for applicants with products approved by a 'stringent regulatory authority' and for applicants with products approved by other national regulatory authorities (NRAs).

Furthermore, the WHO said it was "currently finalising three documents that will be used for the assessment of biosimilar products", including a pilot procedure for prequalification of similar biotherapeutic products. The other two documents would be guidelines, one on the submission of applications of similar biotherapeutic products – with dossiers prepared in common technical document format – and the other for applications for products approved by stringent authorities.

Separately, the WHO has added Cipla's generic sofosbuvir 400mg tablets to its prequalified medicines list, as well as Macleods' praziquantel 600mg tablets and rifampicin/isoniazid 75mg/50mg fixed-dose combination paediatric medicine to treat tuberculosis. The body has also added Amsal Chem's isoniazid to the list, under the WHO's active pharmaceutical ingredient (API) prequalification procedure.

Meanwhile, a public inspection report initiated by the WHO at Shijiazhuang Lonzeal Pharmaceuticals in China has found the manufacturing of the firm's emtricitabine, lamivudine and tenofovir to be compliant with WHO good manufacturing practice for APIs. The report will remain valid for three years.

MARKET RESEARCH

New Zealand sees patient bias

Low patient expectations about generics are "largely explained by perception and unconscious brand bias", according to Keith Petrie from the University of Auckland, New Zealand. Pointing out that feedback from fellow patients and availability of choice could also influence patients' assessment of a medication's effectiveness, he urged healthcare professionals to help "positively reframe their expectations".

Earlier this year, Petrie received a grant worth more than NZ$210,000 (US$153,000) from New Zealand's Pharmaceutical Management Agency, Pharmac, and the Health Research Council (HRC) of New Zealand (**Generics *bulletin***, 10 March 2017, page 12) to conduct research on "improving the acceptability of and response to generics" in the country. The study aimed to "look at how people's views on generic medicines can affect their acceptance of these medicines".

Medical professionals in New Zealand were "well-positioned to inject a dose of reality into those who doubt the efficacy of generic drugs", Petrie stated.