Brussels, 14 July 2014

Joint response to EMA's public consultation on its "Best practice guidance for Pilot EMA HTA parallel scientific advice procedures"

Parallel scientific advice: the first step towards undermining independent Health Technology Assessment (HTA)?

In this joint consultation response, the *ISDB*, *MiEF*, HAI Europe and *AIM* caution that early, opaque trialogues between the European Medicine Agency, Health Technology Assessment (HTA) bodies and pharmaceutical companies will lead to increased regulatory capture and could threaten the independence of pricing and reimbursement decisions.

Contents:

In May 2014, the European Medicines Agency (EMA) released for public consultation a draft guidance that seeks to boost the use of parallel scientific advice procedures that the EMA and national Health Technology Assessment (HTA) bodies propose to pharmaceutical companies (1). This guidance sets out the different phases of the process for EMA-HTA parallel scientific advice (1).

Respondents to the consultation are requested to answer an online questionnaire (**a**) (2). We have responded to the questionnaire and further developed our position in this joint response, by examining the current context, and highlighting important principles to be taken into account in order to protect public health.

EMA's consultation on parallel scientific advice: a part of a broader picture

The EMA consultation takes place in a specific context: Health Technology Assessment is an increasing strategic target for pharmaceutical and medical devices companies wishing to influence the market; the EMA is weakening the pharmaceutical regulatory framework through its "adaptive licensing" project; and pricing and reimbursement policies are currently being discussed in the context of the EU/US Transatlantic Trade and Investment Partnership (TTIP).

HTA bodies are a priority target for pharmaceutical companies (annex 1). One of the main mandates of

a- The questions are for example:
- "*The applicant is responsible for contacting and engaging with HTA bodies (HTABs); do you agree that HTABs contact details and HTABs' prerequisites for parallel scientific advice should be made public at a central location?*";
- "*Should all the Applicant's questions be discussed during the Face to face meeting?*";
- "*Should the EMA send the EMA list of issues routinely to participating HTABs?" The 3 possible answers are: "Always", "Never", "Only after seeking the Applicant's permission*" (ref. 2).

Health Technology Assessment bodies is to advise those responsible for paying for medicines (e.g. States or national social insurance bodies) on:

- whether or not a new medicine brings about a tangible therapeutic advance to patients ('therapeutic added value') compared to established therapies;
- whether or not a new product should be reimbursed (and if so, at what price point and for whom).

HTA is widely used in the European Union (**b**), and engagement in the process has become a strategic target for the pharmaceutical industry that wants to ensure their products are reimbursed at the highest possible price (see annex 1 on page 6). HTA bodies' recommendations are increasingly challenged by companies arguing that HTA bodies should be bound by EMA's decisions (**c**).

EMA's increased control over HTA bodies is part of its "adaptive licensing" (AL) project. The EMA recently launched an "adaptive licensing" pilot project, which "*builds on existing regulatory processes and intends to extend the use of elements that are already in place, including scientific advice*" (3).

However, adaptive licensing can be interpreted as a deregulation process under the guise of a "*prospectively planned, flexible approach to regulation of drug and biologics*" (4). Adaptive licensing seeks in fact "*more timely and potentially more cost-effective, market entry*" for all new medicines, not only in order to treat unmet medical needs as already allowed by the EU conditional marketing authorisation or compassionate uses (**d**,**e**) (4).

According EMA's chief medical officer, "*to be successful, AL would require (…) to reduce the development misalignment between marketing and reimbursement decisions*" (**f**) (4). In order to do so, the proposal is to conduct parallel scientific advice: *"the current prelicensing interaction between regulators and sponsors may need to include payers in order to enable an early development program (…)*" (4).

Towards greater intervention by companies in pricing and reimbursement decisions. According to the developers of "adaptive licensing'', "*"coverage with evidence development" is the payers' analogue to the regulators concept of AL*" (**g**) (4).

In addition, the Pharmaceutical Research and Manufacturers of America (PhRMA) is attempting to limit the influence of European HTA bodies in the transatlantic trade agreements currently being negotiated. For example, PhRMA is advocating to "*add language clarifying that in the framework of pricing and*

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b- HTA bodies exist in a majority of Member States (for example: the NICE in the UK, the IQWIG in Germany, the HAS in France, etc.). Contrary to the European Medicines Agency (EMA) and to many national drug regulatory agencies, HTA bodies are generally not financed by fees paid by pharmaceutical companies but from public funds.

c- For example, Servier challenged the National Institute for Clinical Excellence (NICE) on its recommendations on Protelos® (*strontium*) as they differed from the EMA's conclusions. The appeal court agreed that NICE was not bound to EMA's decisions, but stated NICE should provide clear explanations to appellants when its recommendations ran "*contrary to the reasoned decision of an equivalently eminent body*" (ref. 17).

d- The developers of "adaptive licensing" explain: "*potential benefits for companies would be an earlier revenue stream than under a conventional licensing pathway and less expensive and shorter clinical trials*" (ref. 4). However, the move to extend a conditional marketing authorisation to all new medicines was rejected by the European Parliament and the Council in 2010. The new pharmacovigilance legislation further underscores that: "*It is essential that a strengthened system of pharmacovigilance not lead to the premature granting of marketing authorisations*" (ref. 18, recital 10).

e- Other particularly worrying proposals to put adaptive licensing into place include: "*a prohibition on product liability lawsuits*" by injured patients or payers (notably achieved by "*communicating the higher than usual level of uncertainty to patients and providers*"); and the "*"delinking" of the populations in which the fundamental efficacy hypothesis and the overall safety hypothesis are tested*" (ref. 4).

f- The "new paradigm" of adaptive licensing (AL) was developed in partnership between the EMA's chief medical officer and the Massachusetts Institute of Technology (MIT) Center for Biomedical Innovation (CBI) whose mission is "*to improve global health by overcoming obstacles to the development and implementation of biomedical innovation*". The CBI merged with the Program on the Pharmaceutical Industry (POPI) in 2008 (ref. 19). According to the CBI, "*the close partnership between the two Centers [CBI and the MIT Center for International Studies] are mirrored in his [Dr Eichler's] work, which will be cutting across national boundaries and biomedical industry stakeholders*" (ref. 5).

g- Also called "adaptive pricing", the *"coverage with evidence development"* could seem attractive to payers. But there is a risk that the pharmaceutical industry will argue that the agreed post-marketing studies cannot be completed due to a failure to recruit participants. In fact, if the medicine is already on the market, why would patients be willing to take part in a trial with its attendant constraints (visits at the hospital, etc.)? (ref. 4) Evidence from conditional marketing authorisations has shown that once a medicine is on the market, pharmaceutical companies often fail to meet their commitments. If health authorities decide to withdraw the medicine from the market due to a lack of promised data on its efficacy or on its safety, they are placed in a delicate position vis-à-vis patients who are already being treated with the medicine (ref. 14).

reimbursement decisions, countries shall not duplicate the assessment conducted by regulatory agencies for market approval purposes" (6). An identical provision was foreseen in the European Commission's proposal for a Directive on transparency measures regulating the prices of medicinal products and their inclusion in the scope of public health insurance systems (**h**) (7).

However, marketing authorisation and HTA have different objectives. Marketing authorisations guarantee a standard of consumer protection, i.e. that a new drug has shown some efficacy and that its adverse drug reactions profile is acceptable. In contrast, HTA is about the comparative assessment of the new drug versus the best existing proven intervention. Contrary to marketing authorisation which can currently be granted based on intermediate results (efficacy demonstrated only on surrogate endpoints), HTA has to rely on clinically relevant endpoints, namely endpoints which mean a real difference to patients (i.e. overall survival). HTA in fact aims to determine whether the new drug is worth the expense for the national social protection system.

Scientific advice procedures enable institutional capture by pharmaceutical companies

The EMA has since 2005 made efforts to develop its scientific advice as a service that pharmaceutical companies have to pay for (8,9). In contrast, in the US, the Food and Drug Administration (FDA) makes systematic and mandatory requirements as part of its expedited programs (10,11).

According to the EMA guidance proposal, parallel EMA HTA scientific advice are presented as a means to enable pharmaceutical companies ("applicants") to "*receive simultaneous feedback from both regulators and national HTA bodies on their development plans for new medicines*" (1). However, based on the experience of Independent Drug Bulletins (ISDB) in drug reviews, dialogues between the regulators and pharmaceutical companies are not necessary when the data is sufficiently robust and when clinical trials are designed to address important health needs (**i**). Moreover, a serious risk of institutional capture exists, especially in institutions such as the EMA, where there is no strong policy in place aiming at avoiding conflict of interest (product team leaders directly in contact with companies without any interface, many oral explanations behind closed doors).

Early opaque interactions with pharmaceutical companies implies regulatory authorities are becoming co-developers of medicines. The objective of the EMA's scientific advice process is: "*to facilitate access of medicinal products (…) by optimising Research and Development, reducing uncertainties in regulatory outcomes, and accelerating time to approval of a marketing authorisation application*", even though several accelerated procedures already exist to facilitate faster market entry where there is an unmet medical need (conditional approval, approval under exceptional circumstances) (12). In exchange for this advice, pharmaceutical companies are requested to pay fees (**j**) (9). Clearly speaking, in Europe, pharmaceutical companies are given the opportunity to pay the EMA in exchange for advice on the minimal level of clinical evaluation acceptable by the EMA in order to grant a marketing authorisation.

If the EMA is responsible for both providing advice on drug development to the pharmaceutical industry and at the same time marketing authorisation approvals of those same drugs, this can be interpreted as regulatory capture whereby the regulator becomes the partner of the regulated (13,14). Regulatory capture can for example be witnessed by the fact that the scientific advice is formally adopted by the Committee responsible for granting marketing authorisation (Committee for Medicinal Products on Human Use, CHMP) on the basis of "detailed minutes" prepared by the applicants (**k**) (see Annex 2 on page 6).

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h- The directive proposal on the "transparency of prices and reimbursement measures" is currently showing little progress due to many Member States' opposition to measures interfering with the organisation of their national health systems (e.g. the proposal that the manufacturer can impose its price and price increase when timelines are not met or use judiciary remedies; the intervention of the European Commission in Member States' cost containment policies) (ref. 7).

i- For example, randomised comparative trials which compare a new drug to the best proven available intervention ('gold standard') on clinical endpoints that are relevant to patients (i.e. mortality rate in case of myocardial infarction or the prevention of complication such as strokes in hypertensive patients).

j- For example, a "basic fee" for an initial request for scientific advice on safety and clinical development is 83 600 euros in 2014 (ref. 9).
k- According to EMA's draft guidance, "*the scientific advice provided by the EMA is adopted by Committee for Medicinal Products for Human Use (CHMP) having been elaborated through the Scientific Advice Working Party (SAWP)*", and "*SAWP members may be CHMP members*" (ref. 1).

If the pharmaceutical company follows the EMA's advice, the Agency can in practice be considered "co-developer" of the medicine, which constitutes a major conflict of interest: it would then be increasingly difficult to deny a marketing authorisation, even if trial results are disappointing. Moreover, the EMA guidance proposal on parallel scientific advice states that "*the process is confidential*" (1), thus ignoring the fact that the EMA is a public institution and, as such, it has to function according to high standards of transparency and accountability (**l**). As a consequence, public scrutiny about what happened during the discussions (i.e. what were the advice of the EMA and of the HTA bodies, and whether or not the company followed them) will not be possible even afterwards, when the marketing authorisation process will be completed.

The EMA wants to be recognised as the "leading authority" in the evaluation and supervision of medicines (12). By establishing joint parallel scientific advice with HTA bodies since 2008, the EMA potentially spreads its institutional capture to HTA bodies, particularly since "*some HTA agencies may charge fees*" to pharmaceutical companies (**m**) (1).

Cost-effectiveness assessment must remain independent from Drug Regulatory Agencies. According to EMA's draft guidance: "*a strong interaction between regulators and HTABs is critical to enable innovation to reach patients*" (1). By "innovation" one should however read "newly marketed medicines", the vast majority of which offer no therapeutic advance (**n**,**o**). Indeed, drug regulatory agencies too often approve insufficiently evaluated drugs which sometimes may even be considered as a backward step when safer treatments are available by unnecessarily exposing patients to adverse drug reactions (**p**) (15).

Since HTA bodies have expertise in benefit-risk assessment and in cost-effectiveness assessment, they are in a privileged position to act as the final gatekeepers. They can ensure that a new product that provides no therapeutic added-value compared to another safer or cheaper well-established treatment does not reach too many patients by recommending that this new medicine does not receive reimbursement (**q**).This is the HTA's key role that pharmaceutical companies want to undermine with EMA's adaptive licensing project and with parallel advice procedures.

Conclusion: Engaging in early opaque exchanges with pharmaceutical companies is a slippery slope

HTA bodies play an important role at national level in ensuring the sustainability of Member States' social insurance systems. They must remain independent from drug regulatory agencies, and from any influence of pharmaceutical companies.

Our advice to HTA bodies would be to refuse to engage in early trialogues with the EMA and pharmaceutical companies. HTA bodies should rather require drug regulatory agencies to provide them with

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l- This includes making available the names and declaration of interest of the experts who prepare each scientific advice.

m- Even if some HTA bodies do not charge fees, HTA bodies engaged in parallel scientific advice will be confronted with intellectual conflict of interest due to their position as co-developers of a new medicinal product.

n- In the last decade, the paucity of new products that offer even a modest therapeutic advantage stands in stark contrast to the large number of new products that expose patients to unjustified risks. Since 2005, an average of 20 products with little or no therapeutic advantage is approved on an annual basis (ref. 15).

o- An example highlights the perverse effect of a model favoring "innovation" over "therapeutic value" for patients: according to the European Federation of Pharmaceutical Industry and Associations (EFPIA)'s director, "*some governments in Europe pay too much for off-patent medicines*" (ref. 20). We, however, support sustainable prices for off-patent medicines which are essential medicines for patients, to prevent these medicines from being withdrawn from the market when they are no longer economically profitable to their manufacturer.

p- This was the case for *rofecoxib* (formerly marketed under the brand name Vioxx°), an anti-inflammatory agent that was marketed even though it was no more effective than *ibuprofen* and exposed patients to greater risks of harm. In 2004, having been marketed for several years, it was withdrawn when thousands of adverse cardiovascular reactions occurred, some of which were fatal (particularly myocardial infarction) (ref. 21). It was also the case for the anti-obesity drug *rimonabant* (Acomplia°), found to increase suicides by patients taking it and withdrawn from the market shortly after having been approved (ref. 20). It also applies to several classes of medicines still on the market: anti-diabetics drugs such as glitazones and gliptines, anti-Alzheimer drugs, etc. (ref. 23).

q- In Germany, the position taken by the Federal Joint Committee that a number of new drugs have no additional therapeutic benefit (and sometimes even cause more harm) has led to the withdrawal of some of the "new" drugs from the market – which in fact protects consumers. In France, the decision by the Haute Autorité de Santé (Transparency Commission) to stop reimbursing the anti-diabetes medicine *pioglitazone* has limited the market share for this drug in the country, thereby protecting the French patients from its reappearance on the French market after EMA's recommendation to keep it on the European market (ref. 24).

complete assessment reports, including comparative trials against the best proven available intervention, as well as any relevant data corroborating the Drug Regulatory Agency decisions. Were this information to be transferred, then HTA bodies would be able to engage early in their in-depth reviews and facilitate work-sharing schemes and exchanges among each other. HTA bodies should also bear in mind that the aim of early confidential dialogues with companies is likely less about sharing scientific analysis and potentially establishes a platform that leads to regulatory capture and enables companies to influence pricing and reimbursement decisions.

Instead of using time and resources in custom-made advice to pharmaceutical companies, the EMA should continue to develop guidelines to help manufacturers to make development choices addressing real health needs. In addition, rather than trying to support approaches that would lead to a "levelling down" of HTA methods and that will disregard the diverse context of different Members States, the EMA should **refocus on its role as a provider of reliable safety and efficacy information** (clinical data). Rather than backtracking its ambitious draft access to clinical data policy and succumbing to the pressures of the European Commission and of the pharmaceutical industry, the EMA should provide HTA bodies, the scientific community and the public with complete assessment reports (16).

International Society of Drug Bulletins (ISDB) ***Medicines in Europe Forum (MiEF)***

Health Action International (HAI) Europe ***Association Internationale de la Mutualité (AIM)***

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Annex 1: **Health technology assessment (HTA): a strategic target to be influenced by the pharmaceutical industry**

● Health technology assessment has clearly become a new strategic target for the pharmaceutical and medical devices industry. These quotes clearly illustrate how 'industry' is keen to use the HTA Network to increase their influence on HTA bodies.

"*The remit of healthcare payers is growing, then. They are not just negotiating prices, they are starting to stipulate best medical practice - and access to extensive amounts of outcomes data will give them much more ammunition.*
By 2020, ***Pharma (...) will have to build very much better relationships with the agencies that perform the health technology assessments*** *on which many healthcare payers will rely, since* ***it currently has very little input into such evaluations****.*
(…) the decision making authority is gradually moving from doctors to healthcare policymakers and payers. (...)" (1).

"*Pharma companies must (…) adapt their strategies (…). The speed with which such guidelines [guideline produced by HTA bodies] influence prescribers highlights the* ***need for the pharmaceutical companies to change their perception of HTAs and communicate more closely with them****, through changing their traditional sales models and setting up communication units."* (2)

"*In light of the use of HTA and economic assessment to help reimbursement authorities determine which medical treatments to include in their formularies,* ***drug manufacturers must seek to make the most of their limited influence over the HTA process.*** *What strategies can manufacturers pursue to ensure they maintain a role in the reimbursement decision-making process?*" (3).

"[Payers] are passively sitting at the end of the whole development and arbitrarly decide." (4)

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Annex 2: **Summary of the proposed process for EMA-HTA parallel scientific advice: the applicant in the driving seat**

● The EMA guidance proposal for consultation sets out the different phases of the process for EMA-HTA parallel scientific advice and advises ideal timelines.

After choosing which HTAs will participate during a **"pre-notification phase"**, a **"pre-validation phase"** can include a teleconference with HTAs (pre-submission meeting), especially "*suitable for (…) very complex or controversial programs*". The applicant provides his development plans for his new medicine ("briefing document") (**a**). The EMA and HTA bodies have 40 days to comment on it. The applicant then furnishes a "final briefing document".

Then the **"meeting phase"** starts: two members of the EMA's Scientific Advice Working Party (SAWP) have 20 days to prepare their first reports, which are discussed by the SAWP in order to prepare a "list of issues" to be submitted to the applicant. The applicant has 15 days to answer EMA's "list of issues" and to send his answers to the EMA and the HTA bodies. In the meantime, HTA bodies internally discuss and assess the "final briefing document" submitted by the applicant.

A pre-face-to-face meeting teleconference can take place between the EMA and HTA bodies in order "*identify critical divergences between HTABs and the EMA on the proposed development plan*", with "*feedback on possible divergence communicated to the applicant*".

Around day 60, the face-to-face meeting between all stakeholders takes place: the applicant prepares the agenda, and "*is expected to circulates detailed minutes*" for individual HTA agreement. The SAWP prepares a final regulatory advice letter which is adopted by the CHMP, and the applicant can decide whether or not to share this letter with the participating HTA bodies.

a- The briefing document template contains similar sections to the regulatory agencies assessment reports produced as a basis to justify the granting or the refusal for a marketing authorisation.

Reference:

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About us

ISDB. The International Society of Drug Bulletins, founded in 1986, is a worldwide Network of bulletins and journals on drugs and therapeutics that are financially and intellectually independent of pharmaceutical industry. Currently ISDB has around 80 members in 41 countries around the world. More info: www.isdbweb.org. Contact: press@isdbweb.org.

MiEF. The Medicines in Europe Forum (MiEF) is an informal network. It was launched in March 2002 and reaches 12 European Member States, including more than 70 participating organisations representing the four key players on the health field, i.e. patient groups, family and consumer bodies, social security systems, and health professionals. It is a testament to the importance of European medicines policy. Medicines are not merely consumer goods, and the European Union represents an opportunity for European citizens to seek further guarantees of efficacy and safety. More info: http://english.prescrire.org. Contact: pierrechirac@aol.com

HAI Europe. Health Action International (HAI) Europe is a non-profit, European network of consumers, public interest NGOs, health care providers, academics, media and individuals working to increase access to essential medicines and improve their rational use through research excellence and evidence-based advocacy. More info: www.haieurope.org. Contact: ancel.la@haieurope.org

AIM. The Association Internationale de la Mutualité (AIM) is a grouping of autonomous, not-for-profit health insurance and social protection bodies that operate on the principle of solidarity. Currently, AIM's membership consists of 42 national federations representing 25 countries. In Europe, they provide social coverage against sickness and other risks to more than 160 million people. AIM strives via its network to make an active contribution to the preservation and improvement of access to health care for everyone. More info: www.aim-mutual.org. Contact: corinna.hartrampf@aim-mutual.org