LERU Office
Schapenstraat 34
3000 Leuven, Belgium

Open Letter from the League of European Research Universities (LERU) regarding the Innovative Medicines Initiative (IMI)

LERU updated recommendations for IMI2 strategic research agenda

June 2013

This letter[1] focuses on the Financial and Intellectual Property aspects of the current (2013) IMI rules, considering also a short list of other issues and recommending the harmonisation of the IMI financial and contractual rules with the expected regime of Horizon 2020.

Background

In September 2010, the League of European Research Universities (LERU) wrote an open letter ("September 2010 Letter"[2]), in response to the July 2010 Joint Statement on IMI issued by the European Universities Association (EUA), the European Association of Research and Technology Organisations (EARTO) and others.

LERU welcomes EFPIA's (the European Federation of Pharmaceutical Industries and Associations) consultation on "IMI2" and wishes to provide further and updated comments.

As we stated in our September 2010 Letter, the academic community welcomes opportunities to collaborate with colleagues in the pharmaceutical industry and endorses the stated goal of such collaboration: "to deliver effective and sustainable healthcare solutions for society".[3]

We do, however, re-affirm one of the messages of our September 2010 Letter: that any publicly funded research collaboration between the academic community and the pharmaceutical industry should reflect a true equal partnership between these communities. Our September 2010 Letter highlighted areas where the academic community considered there was a lack of parity between the academic and pharmaceutical research communities and our concern remains that not enough has been done by IMI in the intervening years to redress this perceived imbalance. We affirm our original concerns raised in the September 2010 Letter, that a real or perceived imbalance of interests discourages the academic community from entering into these collaborations. A lack of collaboration between these two communities risks undermining the ability of IMI to deliver its stated goals.

---

[1] This Letter was drafted by the steering group of the LERU Community of European Research Project Managers (ERP), consisting of Michael Browne (UCL), Stijn Delauré (KU Leuven), Anna Groeninx (Leiden), Carole Meads (Imperial College), Angela Noble (Edinburgh) and Pasi Sihvonen (Helsinki). Angela Noble is the main contact person for correspondence on IMI matters (Angela.Noble@ed.ac.uk).

[2] League of European Research Universities. (2010). *Letter on the Innovative Medicines Initiative*. Retrievable from http://www.leru.org/files/publications/LERU_Letter_on_IMI_2010_09_02.pdf

[3] European Federation of Pharmaceutical Industries and Associations. (2013).*The right prevention and treatment for the right patient at the right time.* Retrievable from http://www.efpia.eu/sites/www.efpia.eu/files/public_sra.pdf

Finance

We acknowledge the steps EFPIA has taken to eliminate differences between IMI-specific financial rules and procedures and the Framework Programme 7 (FP7) rules. For example, in December 2011 EFPIA introduced changes to the IMI financial rules[4] to allow "full-cost" participants to claim full indirect costs. The vast majority of universities, however, do not use a "full-cost" accounting method and the alternative 20% indirect cost flat rate remains unattractive and a significant deviation from FP7 rules (which allow 60% indirect cost rate to universities). Therefore, whilst EFPIA has introduced some welcome changes, the changes have had no real impact on the academic community and we have to conclude that the changes have been oriented towards EFPIA partners. The IMI financial rules remain a disincentive for the academic community to choose to participate in IMI as compared to the alternative funding available through FP7 and other funders.

LERU asks EFPIA to extend its programme of positive change further, with the goal of bringing IMI in line with FP7 and the proposed financial rules for Horizon 2020. The following examples are areas where we would welcome positive change by EFPIA to reflect the balance of the collaboration between the academic community and the pharmaceutical community:

- The majority of academic partners receive only 75% of direct costs for research and 20% of indirect costs, which means they are operating at a financial loss. This formula does not cover even the direct costs of research. Academic partners are thus making a substantial financial contribution towards each IMI project, a point which is rarely acknowledged (if even realised) by industry partners. **This is not sustainable;** funding rates should be the same as for Horizon 2020 projects, in order to ensure the feasibility of future university participation in IMI. The danger is that any failure to address these concerns now will result in a future reluctance to participate in any calls.
- There has been much uncertainty over how financial matters should be handled, with conflicting advice being given at second-stage proposal and during projects.
- The IMI financial rules lead to greater complexity, rather than to simplification. For example, section 4 of the current IMI Financial Guidelines[5] (page 51 and following) states the following:

  "EFPIA companies are allowed to make financial contributions to beneficiaries (academic partners, SMEs) in the same project to reimburse part of the beneficiaries' eligible costs. This financial contribution will be considered as part of EFPIA's in-kind contribution and be recorded as such. Most likely, this financial contribution will be subject to a bilateral agreement between EFPIA and the beneficiary."

However, from the perspective of an academic partner, this leads to **greater** complexity and workload, requiring the negotiation and execution of an **additional** agreement with the contributing EFPIA member, in addition to the IMI Grant Agreement and the Project Agreement. Rather than imposing this additional administrative burden on both the academic partner and the EFPIA company, which can lead to delay and the risk of inconsistent contractual terms, would a simplification not be for the relevant partner company to pay its cash contribution into the central consortium "pot" managed by the Managing Entity, for the academic partner to perform the work and report via its Form C and to then receive reimbursement of such work from the Managing Entity, following submission and acceptance of project reports?

Recommendation 1

LERU proposes that for Horizon 2020 all Private Public Partnerships[6] ('PPPs') have consistent rules, including the same reimbursement rates. Additionally, LERU requests that IMI financial

[4] http://www.imi.europa.eu/sites/default/files/uploads/documents/Press%20Releases/PressReleaseIMINewFundingRulesIMIfinal.pdf
[5] http://www.imi.europa.eu/sites/default/files/uploads/documents/Rev_Grant_Agreement_2011/IMI_Financial_Guidelines_rev2012.pdf

reimbursement rates be consistent with Horizon 2020 by covering 100% reimbursement and the same flat rate for indirect costs.

Intellectual Property

As we have stated above, LERU feels that the IP terms of the IMI Grant Agreement and its model Project Agreement favour the interests of the pharmaceutical community over and above those of the partner academic community.

Our primary concern is that the interests of the pharmaceutical companies in EFPIA seem to override all other considerations often with an EFPIA pre-agreed position on IP favouring the pharmaceutical companies, which puts universities in a difficult position. There also seems to be an assumption that the interests of all parties are aligned and what is good for EFPIA is good for Europe and also for HEIs. This is not necessarily the case. The IP terms seem to concentrate on the marketing of pharmaceutical and diagnostic developments by EFPIA partners, rather than giving equal weight to the interests of academic or SME partners, which might be to undertake further research or to put the results in the public domain.

The Commission funds universities in IMI to carry out research on priority areas identified by the pharmaceutical industry which in turn can take those results anywhere, including outside the EU – and all on IP terms which are extremely favourable to industry. That is not a reasonable 'balance'.

LERU would like to revisit some practical concerns as we look towards the future development of the Biomedical Research Public Private Partnership under Horizon 2020.

IMI's Intellectual Policy Guidance Note[7] (November 2011) provided some rationale for the IMI IP rule positioning, but did not address concerns which had been repeatedly raised by the academic community. The following examples are areas where we would welcome positive change by EFPIA to reflect the balance of the collaboration between the academic community and the pharmaceutical community.

- The definition of 'Research Use' is extremely broad and covers everything except Direct Exploitation; the IMI definition of 'Research Use' does not have the same meaning as when the term is used elsewhere (e.g., broader than for patents exemption).
- Access rights are granted to IMI project partners and automatically to any of their affiliates (which they might form at any time), who may not specifically have been involved in the project without the latter having to specifically request them from an IP owner. This is problematic for academic institutions, which in any such scenario lose the ability to control and track the whereabouts and potentially use of what might be extremely valuable IP. **This loss of control over own IP is of significant concern to LERU.**
- The IMI Grant Agreement does not allow for the restriction of access by Third Parties to Background or Foreground for Research Use – this loss of control over own IP causes concern. The effect is that the IMI Grant Agreement encroaches on a Party's ability to deal with its own Background, that is anything that was created before entering into a project, and this encroachment and encumbrance on pre-existing knowledge is significantly at odds with the FP7 rules and the rules of other public funding bodies.
- There is no time limit for requesting access rights to Background or Foreground. This is problematic because:
    - It creates administrative, practical and financial problems for universities (and SMEs) - staff and academic priorities change over time and it is impossible to maintain, for example, a

[6] It is understood that Joint Technology Initiatives will be known as PPPs in the future.

[7] http://www.imi.europa.eu/sites/default/files/uploads/documents/Intellectual%20Property/GuidanceNote_Draft3-1_10Nov2010.pdf

mouse strain, software or database in perpetuity. This needs to be recognised and the IMI IP rules changed, failing which academic partners will either have to withdraw from the scheme or sign all IMI Project Agreements knowing they potentially, (i.e. at some unanticipated future date), may be in breach of obligation on this point. **This is additional risk for universities to consider/manage when participating in IMI, and it is likely to cause reluctance to participate**.

- It makes it impossible to grant exclusive licences in relation to Background/Foreground which remains subject to such access rights, which (ironically) may be the most effective way of exploiting Foreground and achieving the aims of a project. In addition, such a restriction would appear to be imposed 'just in case' access rights may be requested. We suggest that a time limit be included, as in FP7.

- There still seems to be the presumption amongst EFPIA members that all access rights should be granted royalty-free rather than on fair and reasonable terms. Whilst academic institutions will normally be happy to disseminate results, this provision is not acceptable as a default, especially in light of the other IP terms listed above which go against standard practices.

Recommendation 2

LERU would like to see a shift in the Intellectual Property position so that IMI projects offer a better balance between industry interests and those of the academic community whose participation will necessarily underpin every project.

Other issues

EFPIA partners are now allowed to put in non-EU in-kind contributions (up to a 30% limit) and have them count as part of their in-kind contributions to an IMI project. Is it really in the interests of the EU to let pharmaceutical partners carry out work outside the EU on EU-funded projects? LERU would recommend this is clarified in the IMI guidelines.

The lack of flexibility by the IMI Joint Undertaking (JU) is another difficulty. A more pragmatic and flexible approach to individual projects would be beneficial for all parties. One LERU member has given an example where all project partners (i.e. EFPIA partners in the project too) signed the Project Agreement agreeing to limit access to software and any updates thereof for up to five years after the earlier of (i) termination of the Project or (ii) termination of the participation of the Software owner in the Project only for this clause to be thrown out by the IMI JU and an amendment with no time limit substituted. This is exactly the type of behaviour which causes concern within the academic community.

In summary

IMI should not put academic institutions in a position where their concerns about the risks will encourage non participation. The unfavourable reimbursement rates and IP provisions which do not properly reflect respective input of collaborating participants are detailed above.

LERU therefore requests that further consideration be given to these areas to provide a clear balance of rights and obligations amongst all collaborating participants and that IMI adopt financial and intellectual property rules which will be largely consistent with Horizon 2020.