

Letter from the League of European Research Universities (LERU) to the IMI board, the member states representatives (SRG), and the IMI IP working group

LERU Letter on the Innovative Medicines Initiative (IMI)

The League of European Research Universities (LERU) is very much in favour of the spirit and scientific merit of the Innovative Medicines Initiative (IMI) and considers it a valuable mechanism to overcome the research bottlenecks in the drug development process. LERU warmly welcomes the recent Joint Statement on IMI issued by the European Universities Association (EUA), EARTO et al. in July 2010, agrees with the principles expressed therein and wishes to add some further remarks with regard to financial and IP issues in IMI.

Academic scientists are keen to collaborate with their colleagues in pharmaceutical companies to find solutions to common problems and enhance the competitiveness of the European pharmaceutical sector. However, any such development can only be achieved by scientists working together as equal partners with clear benefits for both sides. In the absence of such mutual benefits, the first two calls for proposals have shown a marked disinterest on the academic side, leading to muted participation from universities and research institutions to the detriment of the scientific excellence achievable in those projects. The European Commission, EFPIA and the IMI Joint Undertaking have done little in those two years to address the concerns expressed by a multitude of academic institutions.

The first two years of IMI's existence have shown clearly that various issues exist to prevent such equal partnerships to form and for the IMI mechanism to become the leading programme to efficiently explore and establish new drug development processes. The deficiencies in the conceptualisation of this new programme can be seen predominantly in the financial and intellectual property rights arrangements. If the benefits and disadvantages to both sectors cannot be balanced out in the third call for proposals, the quality of the programme, and with it its international credibility, will further deteriorate.

The Financial Issue

IMI is funded jointly (50/50) by the European Commission and the EFPIA partners, i.e. the EC funds the participation of the academic institutions from its FP7 budget, and the EFPIA partners fund their own participation. Although academic institutions have their participation fully funded from FP7 and it therefore constitutes public funding for them, it remains a fact that currently the IMI-financial rules deviate from the usual FP7 mechanism as they only provide a capped 20% indirect cost rate. This, combined with the 75% reimbursement rate, results in loss-making projects as the funding for universities amounts only to an overall 90% of direct costs, giving even no margin for indirect costs. The standard FP7 funding base is the direct project cost plus a 60% indirect cost results, so that even with a funding rate of 75% at least part of the indirect costs are also covered. It is unclear why such a mechanism was introduced in economically difficult times when the sustainability of research funding is imperative and a full quarter less of costs covered is not affordable. It is not possible to contribute matching funding

from grants awarded by other sponsors as those sponsors would quite rightly not allow such a misappropriation of funds awarded for other projects.¹

The EC has pushed universities and research organisations for many years to professionalise their accounting systems by moving to full cost mechanisms. It makes no sense that now, when some of the leading universities and research centres have made this effort, that these organisations now are penalised by funding mechanisms that are further removed from full cost coverage and sustainability than FP6 or any of its predecessors have been.

RECOMMENDATION: The funding of universities and research organisations in IMI should be adjusted at the very least to be in line with FP7 rules. IMI cannot attract the most excellent scientists by underfunding their participation.

The Intellectual Property Rights Issue

Under the window-dressing of IMI as a 'private-public partnership' (PPP), a new IP policy was introduced without consultation of academic institutions that saw a clear push towards providing advantages to the EFPIA partners. This was followed by a Project Agreement template drafted by the EFPIA partners that followed the same IP principles to the extent that EFPIA lawyers and contracts specialists refused to even negotiate them. It is one thing for EFPIA lawyers to agree on such terms but it is another thing entirely to assume academic institutions - and SMEs - would simply accept such unfavourable terms without even the pretence of negotiation. The way most of these 'negotiations' were conducted showed without a doubt that IMI is not about equal partnerships, and this is in fact a deterrent to academic participation.

The intellectual property rights issues in particular are:

1. The definition of 'Research Use' is overly vague and includes indirect exploitation. Neither the IP policy nor the Project Agreement template foresee any monitoring process of what happens with Foreground or Background used for 'Research Use', so nobody would ever know when indirect exploitation would turn into direct exploitation, to which the royalty-free access would not apply.
2. The wording of the IP policy is very suggestive towards certain ways of handling IP issues that are not acceptable as a default position and should only be accepted on a case-by-case basis. For example, section III.2.1 on Foreground states "*Ownership of the Foreground belongs in the first instance to the Participant(s) who generated it. The Participants may agree on a different allocation of ownership in the Project Agreement.*" The wording clearly anticipates that academic partners would just assign ownership of such Foreground to the EFPIA partners. Another example is the 'choice' of Access Rights granted to Foreground and Background for Research Use either "*on fair and reasonable terms or royalty-free*" in the IP policy, which invariably in practice seems to

¹ There may be national variations as some national funders allow for top-up funding for IMI projects to be applied for. However, that does not apply to the majority of EU Member States and raises the question why top-up funding should be necessary.

turn into royalty-free conditions in the IMI Project Agreements as it is more favourable for the EFPIA partners.

3. Access Rights for affiliates and third parties beyond the duration of the project: EFPIA partners oppose to list their affiliates in an attachment, which means academic partners have to grant access to their Foreground and Background for an unlimited time or scope to unknown entities without any monitoring provisions in place. The result has been that most academic partners provide as little Background as possible to an IMI project for fear of a) losing control over it, and b) their inability to grant any exclusive licences to such Background to any third parties, should they wish to do so.
4. Access Rights to Background and Foreground have no time limitation: such rights may be requested by EFPIA partners in the project, or by affiliates or third parties, at any time. For comparison: the standard FP7 rule is that Access Rights may be requested up to one year after the end of the project. After that time, every project partner is free to commercialise his own Foreground, either exclusively or non-exclusively. An unlimited period of being able to request Access Rights leads to the ability of the owner to only grant non-exclusive licences, which is not conducive to commercialisation, and cannot be in the interest of any IMI participant. As above, this has led to academic institutions to not provide access to their Background.

RECOMMENDATION: The above issues are stumbling blocks in all IMI Project Agreements and need to be addressed urgently at policy level. The third call should not be published without these issues having been resolved.

Other Issues

The application process for IMI and subsequent evaluation deviates considerably from standard research projects, to the extent that any expertise of the EFPIA partners is largely unknown and not evaluated at application stage.

Negotiation with EFPIA companies is also made more difficult by opaque management layers of those companies, considerable staff turnover, and little experience amongst EFPIA staff of dealing with IMI or similar research projects. The existence of two managing entities contributes to the general confusion as to who is responsible for what.

Conclusions

IMI shows how a private-public partnership should not be set up. The combination of disadvantageous financial and intellectual property rules represents a double negative when it comes to academic or SME participation. The EC and EFPIA should not expect their 'partners' to accept rules, by which they basically give away all their IP for free and do not even receive full funding for their research activities. As a consequence, several LERU members and other research institutions have implemented stringent procedures for scientists who wish to participate in an IMI proposal, with the effect that most of them withdraw before submission because academic participation is just not feasible.

Universities can expect - even in a PPP - that if they receive funding from FP7, the terms and conditions should be very similar to standard FP7 rules, as agreed by all stakeholders prior to the launch of FP7. It cannot be that with each Joint Technology Initiative (JTI), of which IMI is only the first one, the academic stakeholders have to submit to a multitude of different IP and

financial regimes, dependent on the goodwill of the industrial partners who do not even fund the academic participation. If universities and research centres are to participate in JTIs, publicly funded from the European Union budget, they should be able to expect the same terms and conditions from the EC as for comparable projects, and not be subjected to severe shortfalls in funding or inadequate or unattractive IP provisions.

This is even more important now with a view to FP8. If IMI is to serve as a model for more PPPs in FP7/FP8 and provide a best practice structure, it is absolutely imperative to sort out these issues now before they become set in stone for all future JTI programmes. The result would likely be mediocre science not worth the public funding at all.

It also seems questionable that the EC talks about simplification and consistency across programmes when at the same time promoting more and more diverse funding mechanisms. This does not further the understanding of the rules or participation in the Framework Programme, neither amongst academic partners nor with SMEs. For a full statement on simplification of Framework Programme funding conditions, see the LERU advice paper "Towards an effective 8th Framework Programme for Research".

http://www.leru.org/files/publications/LERU_Advice_paper_FP8_final.pdf

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