GHP Guild of Healthcare Pharmacists

25th July 2016

Innovative Medicines Initiative

Innovative Medicines Initiative (IMI) consultation
Facilitating the translation of advanced therapies to patients in Europe

Response from the Guild of Healthcare Pharmacists

Thank you for the opportunity to respond to this consultation. The Guild of Healthcare Pharmacists represents UK wide around 4,500 pharmacists including the majority of hospital pharmacists, pharmacists employed by NHS Primary Care organisations and pharmacists employed by other public bodies such as Prisons and the Care Quality Commission. The Guild is part of the health sector of the union Unite.

The European Association of Hospital Pharmacists (EAHP) has made the Guild of Healthcare Pharmacists (GHP) aware of their views on the IMI consultation and we wish to support these views and also endorse the answers to the consultation questions, as follows:

1. The mission of the hospital pharmacy profession will always be connected to ensuring patients can receive the treatments they require. The consultation is therefore timely and needed as it is clear that the translation of advanced therapy medicinal products (ATMPs) is not yet occurring at the ideal rate.

2. Hospital pharmacists are conducting a crucial role in supporting the present use of ATMPs, including taking responsibility for the governance of their safe use in the hospital sectors. The hospital pharmacy profession should be kept in mind as key stakeholders as IMI further develops projects and activities in this important area of public interest.

Question 1: Have the key challenges that can be addressed through collaborative, public private initiatives been properly identified?

Yes

Comment:
It is important that "communication to the general public" is conducted via independent, unbiased and creditable sources. This will avoid any unintended undermining of public confidence.

In respect to the comment "*Nevertheless, the growing number of unregulated application of Hospital Exemption (which does not require long and costly safety, quality and efficacy demonstrations) acts as a disincentive to small and big companies*", it should be borne in mind that hospitals across Europe operate to strict governance and supervision arrangements with regards to the oversight of medicines supply and use. In addition to this, Article 28 of the ATMP regulation sets out numerous conditions for operation of the hospital exemption, for example, in respect to professional supervision, traceability, pharmacovigilance and quality standards. For these reasons the term "unregulated application of Hospital Exemption" could give a false impression to a lay reader in respect to patient safety, which we do not believe the authors intended to convey. The term "unregulated" should therefore be removed as it does not provide an accurate representation of the manner in which the hospital exemption operates.

We feel that the statement "*the hospital exemption is acting as a disincentive to small and big companies*", is rather subjective. Within the hospital pharmacy sector there is both agreement and disagreement with this the statement and it is not supported by any evidence. We feel the sentence should be a conditional sentence i.e. "*it has been suggested by some within the ATMP stakeholder community as acting as an unintended disincentive*". There are compelling reasons for hospital exemption to authorise the use of custom-made ATMPs prepared on non-routine basis in the absence of a marketing authorisation, provided that the product is used for individual patients in a hospital and under the professional responsibility of a medical practitioner. The exemption exists as a tool for providing access to ATMPs where otherwise full marketing authorization requirement may have made the access unfeasible. Exemption may be improved by learning from best practices within certain EU member states in respect to oversight of the exemption, and how best to insure maintenance of manufacturing standards when operating the hospital exemption.

Question 2: Which of the proposed potential initiatives should be prioritized?

We support prioritisation of:

1. Addressing manufacturing knowhow.

Whilst we agree with the statement *"In general there is a lack of manufacturing knowhow, regulatory sciences and Current Good Manufacturing Practice (CGMP) related to ATMP usage",* it also states: "*Besides that, there is a shortage of well-trained engineers that understand the manufacturing processes and are capable to develop automated/robotic methods and common platforms."* We feel that it is incorrect to focus the manufacturing knowhow needs on the engineering profession alone. ATMP manufacturing knowledge is also a great need for the pharmacy profession, in hospitals and academia, and therefore should be better represented within the consultation document.

2. Access to early regulatory consultation

There is a need to make regulatory considerations in relation to the potential marketing authorisation application as early in the process as possible, ideally it should be prioritized at the preclinical development stage. Innovators and researchers need to understand the importance of quality by design thinking to develop their product in such a way that it facilitates an easier pathway through the regulatory pathway later. Pharmacy Quality Assurance and Regulatory colleagues may be able to help if innovation is occurring in a healthcare / academic setting.

Question 3: Are any areas missing?

We agree that the following areas as missing, or capable of further elaboration:

- Hospital facility needs/clinical site development
- Healthcare professional education needs in general

1. Hospital facility needs/clinical site development

Research and Development Teams within potential clinical sites for clinical trials should be prioritised. Clinicians in a variety of specialisms could be interested in being an investigator. Therefore, the Research and Development Teams in such prospective sites, including clinicians, research nurses and clinical trial

coordinators and pharmacy clinical trial staff, need to be trained. Attention must also be paid to any required upgrade to hospital site facilities, such as pharmacy production areas and associated training of staff.

2. Healthcare Professional education needs in general
There is the need to address healthcare professional education needs in respect to ATMPs from the hospital pharmacist perspective. This is not well represented within the document. If ATMPs are to be translated into patient access, healthcare professionals (prescribers, nurses, pharmacists) will be critical intermediaries, and must be knowledgeable enough about ATMPs to prescribe with confidence, advise the patient on use, and ensure correct governance around use and administration to underpin safe access. This challenge should be included within the priorities.

Question 4: What are the key European or national initiatives that IMI shall synergise with?

We agree that the following initiatives for IMI awareness and potential linkage are required:

- Efforts being undertaken by the European Medicines Agency (EMA) to facilitate greater uptake of ATMPs
- Projects underway to support the implementation of the European Statements of Hospital Pharmacy
- A forthcoming elaboration at the European level of a common training framework for the hospital pharmacy profession

Linkage with the European Medicines Agency
We are not clear as to the extent to which IMI initiatives on ATMPs are in linkage and synergy with similar reflections and debates on ATMP uptake being facilitated by the European Medicines Agency. Close linkage between IMI and EMA on this subject would seem sensible and appropriate, especially as the EMA links into interested stakeholder organisations that may be of benefit to IMI initiatives.

European Statements of Hospital Pharmacy, and their implementation
In respect to the development of hospital pharmacy services across Europe, the European Statements of Hospital Pharmacy will provide a useful resource and support to ATMP translation to patient access. These statements express commonly agreed objectives that every European health system should aim for, for example: "*Hospital pharmacists should have responsibility for all medicines logistics in hospitals. This includes proper storage, preparation, dispensing, distribution and disposal conditions for all medicines, including investigational medicines*" and "*Hospital pharmacists should be actively involved in clinical trials of medicines."*

Common Training Framework for hospital pharmacy in Europe
Another European initiative in the area of hospital pharmacy, with potential synergy to ATMP translation, is the current development of a common training framework for advanced practice in hospital pharmacy.

Question 5: Further comments

Consideration should be afforded to the document's reflection on 'pricing and reimbursement for ATMPs', with respect as to how the early investment made by hospital sites and academic centres into ATMPs, can be returned within pricing and reimbursement systems.

We hope these comments are of assistance. Our reply may be made freely available.

Yours faithfully

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