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AN EXPLORATORY ANALYSIS ON THE INVOLVEMENT OF EUROPEAN ORGANISATIONS IN THE FIELD OF BIOMEDICAL INNOVATION

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INTRODUCTION AND METHODOLOGY

Many actors influence the framing of EU legislation and regulation applicable to gene and cell therapy. Nevertheless, one can wonder how much their activity is focusing on gene and cell therapy or whether it is part of a wider set of activities taking place in the more general theme of biomedical innovation. Biomedical innovation has been considered widely as a set of processes and products based on biological elements of human or animal origin intended to generate both improvement in health and economic competitiveness.

From an identification of the actors involved in the public consultation process of adoption of European Regulation n°1394/2007 on Advanced Therapy Medicinal Products, of guidance applicable to ATMPs and adopted either by the European Medicines Agency or by the European Commission, and on the Proposal for a European Regulation on substances of human origin, and of guidance applicable to ATMPs, a few of them have been selected in order to conduct more specific analysis. Our selection process for this pilot analysis included the following criteria: European level organisation, degree of the involvement in the above-mentioned consultation processes, combination between organisations the names of which imply either a very specific or a general remit. Another choice has been to include European organisations particularly relevant for pharmacists, as professionals involved all along the medicinal products' life cycle.

It resulted in a set of 13 European organisations including 5 business associations, 2 professional organisations, 4 learned societies, 1 research institution taking the form of European project, 1 European network based on national medicines agencies.

Then, in depth research has been conducted by pharmaceutical sciences students between January and April 2023 on the website of each organisation in order to identify their activity within and beyond gene and cell therapy regarding biomedical innovation in general. First, we analysed their structure, governance, typology and possible name changes or mergers over time. Second, we collected the occurrences of general and specific keywords relating to biomedical innovations both through an exploration of the tabs dedicated to their production and by using the "search" function when it exists on the websites of the studied organisations.

Beyond "biomedical innovation" itself, the general keywords used were: therapeutic innovation, innovative medicine, regenerative medicine, biotechnology, advanced therapies, nanomedicine, organoid. The specific keywords used were: biological medicine, orphan medicine, advanced therapy medicinal products, gene therapy, cell therapy, tissue engineering, genome editing.

This analysis is considered to be exploratory as a limited number of organisations has been studied from the interests of the pharmaceutical sciences students involved and the feasibility required a limited number of keywords to be searched for. Terms that are similar to our keywords may have been mentioned on the websites of the organisations studied although we have not searched for them. For instance, "genome editing" and "cell therapy" were searched for but not "gene editing" and "cellular therapy". Nevertheless, some of these similar keywords have been identified when they appeared in the names of working groups of the organisations studied.

Type and date of creation of every organisation

ORGANISATION	TYPE	CREATION DATE
European Federation of Pharmaceutical Industries and Associations (EFPIA)	Business association	1978
The European Association for Bioindustries (Europabio)	Business association	1996
European Biopharmaceutical Enterprises (EBE)	Business association	2000
European Confederation of Pharmaceutical Entrepreneurs (EUCOPE)	Business association	2008
MedTech Europe	Business association	2012
European association of tissue and cell banks (EATCB)	Learned Society	1949
European group for Blood and Bone Marrow Transplantation (EBMT)	Learned Society	1974
European Eye Bank Association (EEBA)	Learned Society	1989
European Society of Gene and Cell Therapy (ESGCT)	Learned Society	1992
European Industrial Pharmacists Group (EIPG)	Professional organisation	1966
European association of hospital pharmacist (EAHP)	Professional organisation	1969
European Network for the Advancement of Clinical Gene Transfer & Therapy (CLINIGENE)	Research Project	2006-2011
European Innovation Network (EIN)	European Network	2015

RESULTS

Main elements of structure

Mergers among 2 business associations studied

MedTech Europe is a 2021 merger of EDMA and Eucomed. EFPIA & European Biopharmaceutical Enterprises (EBE) collaborated for a long time (common members, papers,...) until EBE has become a specialized group of EFPIA.

Changes of names of 2 learned societies

Working Group on Human Gene Transfer and Therapy (EWGT) > 1998: European Society of Gene Therapy (ESGT) > 2007: European Society of Gene and Cell Therapy (ESGCT)
European association of tissue banks (EATB) > 2016: European association of tissue and cell banks (EATCB)

Reading grid

Not often/rarely (<25%)
Slightly often (≥25%)
Fairly often (50%)
Very often (≥75%)
Always (100%)

Groups targeting biomedical innovations in the organisations studied in 2023



Each of the organisation studied has its own structure, and is composed of groups whose titles refer to therapeutic areas and/or regulatory issues.

Occurrences of general terms within the production of the organisations

	Biomedical innovation	Therapeutic innovation	Innovative medicine	Regenerative medicine	Biotechnology	Advanced therapies	Nanomedicine	Organoid
European Federation of Pharmaceutical Industries and Associations (EFPIA)	7%	4%	7%	7%	14%	14%	0%	0%
European Associations for Bioindustries (Europabio)	5%	5%	14%	32%	23%	45%	0%	0%
European Confederation of Pharmaceutical Entrepreneurs (EUCOPE)	0%	0%	23%	14%	0%	23%	3%	0%
Med Tech Europe	0%	0%	50%	50%	50%	50%	0%	0%
European association of tissue and cell banks (EATCB)	50%	75%	50%	75%	100%	75%	0%	50%
European Society for Blood and Marrow Transplantation (EBMT)	0%	6%	3%	9%	9%	20%	0%	0%
European Eye Bank Association (EEBA)	50%	50%	0%	50%	50%	50%	0%	0%
European Society of Gene and Cell Therapy (ESGCT)	0%	0%	9%	9%	0%	18%	0%	0%
European Industrial Pharmacists Group (EIPG)	0%	0%	50%	50%	50%	50%	0%	0%
European association of hospital pharmacist (EAHP)	50%	83%	50%	0%	50%	50%	0%	0%

MAIN RESULTS

- ❖ **"Advanced therapies"** is the most used term. It is the only one that has been used by every organisations in our study, whatever their typology. However, its use has been quantitatively various ranging from not often/rarely (<25%) to very often (≥75%) without obvious result linking the quantity of use of this term to the type of organisation using it.
- ❖ **"Regenerative medicine"** and **"innovative medicine"** have been very used by the studied organisations (9 out of 10 in both cases). Nevertheless, the use of "innovative medicine" appears much more contrasted (being either not often/rarely or very often) than the use of "regenerative medicine" that appears all along our gradation scale of use.
- ❖ **"Biotechnology"** has also been very used (8 out of 10 organisations). Its use has been less clearly contrasted than for "innovative medicine" but also slightly less gradated than for "regenerative medicine".
- ❖ **"Therapeutic innovation"** and **"biomedical innovation"** have been used respectively by 6/10 and 5/10 organisations. Their use has been quite equally contrasted (Not often or rarely used by half of the organisations and fairly often or more for the other half). However, contrary to "biomedical innovation", "therapeutic innovation" has been used very often by 2/3 of the organisations that used this term.
- ❖ **"Nanomedicine"** and **"organoid"** have been the less used terms. They are the only terms that have been mentioned only by one organisation (respectively <5% EUCOPE as a business association, and 50% EATCB as a learned society) among the 10 studied.
 - The results underline that nanomedicine and organoids are still relatively untapped by the studied organisations, notably business associations.
 - The only occurrence of the term "organoid" comes from the EATCB, with a high frequency (50%), which indicates a significant interest on the part of this learned society in this emerging topic.

Occurrences of specific terms related to gene and cell within the production of the organisations

	Biological medicine	Orphan medicine	Advanced therapy medicinal product	Gene therapy	Cell therapy	Tissue engineering	Genome editing
European Federation of Pharmaceutical Industries and Associations (EFPIA)	11%	29%	4%	14%	11%	0%	0%
European Associations for Bioindustries (Europabio)	0%	9%	45%	45%	32%	5%	50%
European Confederation of Pharmaceutical Entrepreneurs (EUCOPE)	0%	0%	100%	0%	0%	0%	0%
MedTech Europe	0%	0%	50%	50%	50%	50%	50%
European association of tissue and cell banks (EATCB)	100%	25%	100%	75%	100%	100%	25%
European Society for Blood and Marrow Transplantation (EBMT)	6%	0%	14%	23%	69%	9%	9%
European Eye Bank Association (EEBA)	50%	0%	50%	0%	100%	100%	0%
European Society of Gene and Cell Therapy (ESGCT)	9%	0%	9%	82%	45%	9%	27%
European Industrial Pharmacists Group (EIPG)	0%	0%	100%	0%	0%	0%	0%
European association of hospital pharmacist (EAHP)	17%	33%	50%	0%	0%	0%	0%

MAIN RESULTS

- ❖ **Advanced Therapy Medicinal Product:** This specific term is the most frequently found in our analysis, regardless of the type of organisation studied. It has been found on every organisations' websites. It should be noted that the term does not appear frequently on the ESGCT website although we have not searched for the acronym (ATMP), which may be more frequently used.
- ❖ **Cell Therapy** is the second most frequently used term among the keywords we researched. There is a strong representation of learned societies. All of them have used it frequently.
- ❖ **Tissue engineering, Gene therapy and Biological medicine** have been found in the same number of websites (6/10) among the studied organisations. They have been particularly used by learned societies.
- ❖ **Genome editing** has been used by half of the organisations we studied. This specific term is over-represented by the 2 business associations that have mentioned it.
- ❖ **Orphan Medicine** is the most underused specific term among the selected keywords. It has been mentioned by 4/10 organisations only and quite rarely regardless of the type of organisation studied.

CONCLUSION

- Half of the organisations we studied have one (or more) specific working Group/Committee/Council (hereafter groups) targeting biomedical innovations regarding our keywords and related terms. When these groups exist, they are more frequently found in learned societies (4/5). Among these groups, all have titles closer to our specific keywords than to our general ones.
- Using groups targeting biomedical innovations enabled us to minimise any bias and limits we might have introduced through our choice of keywords : for EUCOPE, no occurrence of "orphan medicine" have been found in our study, but there is a group which targets this type of medicines. Its involvement in this therapeutic area is therefore confirmed.
- The appearance of the term "genome editing" mainly for business associations suggests that this is a subject of interest for the industrial field.
- Although we have considered the EIPG to be a professional organisation representing industrial pharmacists, our study shows many points of convergence with MedTech Europe. This can be explained by the industrial aspect of this organisation.
- Among the learned societies, the 2 associations of banks (EATCB & EEBA) have been the most active. EATCB appears clearly has the organisation using the most our selected keywords among all the organisations studied. EBMT & ESGCT have used quite similarly our keywords with only one significant difference: the emphasis is on gene therapy for ESGCT while it is on cell therapy for EBMT. In our study, the term "gene therapy" occurred 1.8 times more frequently than "cell therapy" for the ESGCT.
- EBMT, ESGCT and EAHP distinguish themselves from the other organisations studied by their number of groups.
- The EBMT and the ESGCT appear to be the two learned societies with the closest links in their areas of interest.

Despite changing its name to include cell therapy, the ESGCT remains more active in the field of gene therapy, which is confirmed by the titles of its working groups.