

# T-AP Conference

## Social *Pharmaceutical* Innovation (SPIN)



## For Unmet Medical Needs

**SOCIAL PHARMACEUTICAL  
INNOVATION**

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# The need for SI in rare diseases & our research questions

## Challenges:

- 7000 rare diseases only about 600 treatments (medical need, vulnerability)
- Clinical assessment of drugs for rare diseases (regulatory requirements because of the access, poor decisions)
- Price of treatments (amongst the most expensive)
- Tip of the iceberg (movement towards pharmaceutical system sustainability)

Douglas et al.  
*Orphanet Journal of Rare Diseases* (2022) 17:344  
<https://doi.org/10.1186/s13023-022-02476-6>

Orphanet Journal of  
Rare Diseases

## POSITION STATEMENT

Open Access

## Social pharmaceutical innovation and alternative forms of research, development and deployment for drugs for rare diseases



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### Abstract

A possible solution to these challenges: Our definition of “social pharmaceutical innovation” (SPIN)

“We understand SPIN as novel forms of collaborative processes, programs, policies, procedures and/or designs involving diverse sets of actors that break with conventional pharmaceutical innovation practices for the production of safe, effective, and accessible interventions that address unmet societal needs of rare disease patients and that are not primarily market driven.”

(Douglas, Aith, Boon, et al. 2022) <https://doi.org/10.1186/s13023-022-02476-6>

# Research questions

To address these challenges, alternative forms of pharmaceutical innovation are needed, which we call SPIN.

We study a diverse range of SPIN developed by a variety of actors across four national contexts - Brazil, Canada, France, the Netherlands - , with an aim at:

- (i) analyzing the changes they bring to pharmaceutical research, development and deployment of drugs, which is traditionally profit-driven;
- (ii) documenting the social, political, institutional and economic challenges and bottlenecks that these SPIN face throughout their lifecycle; and
- (iii) reflecting on the upscaling conditions of SPIN if we are to support their implementation.

# Kinds /forms of SPIN

- Novel/ improved R&D partnerships across the public, not-for-profit and private sectors.
- Alternative forms of provision and licensing.
- Alternative regulatory frameworks for coverage and licensing.

# Project Overview

WP2 - 'Mapping' the social, economic, political and regulatory contexts faced by SPINs

- Full report completed

WP3 - Case studies of SPIN

- 15 Case studies completed across Brazil, Canada, France and the Netherlands

WP4 - Development, organization, and hosting of outreach events

- Outreach event March 9<sup>th</sup> and 10<sup>th</sup>, 2023 in Utrecht, NL

WP1 - Project Coordination and Reporting

- 2 face-to-face meetings (Paris March 2020 and Paris May 2022) + ~10 number of virtual meetings
- Social innovation workshop (May 2021)

- Website (<https://www.socialpharmaceuticalinnovation.org/>) Twitter (@SPIN\_rare)

- LinkedIn (<https://www.linkedin.com/company/social-pharmaceutical-innovation-spin/>)

- ~50 blog posts

# *1. What is the upscaling potential of the innovation, and can it also apply to other fields and circumstances?*

- SPINs are underway across our constituencies & around the world
- There is significant variety in the form they take
- Some could be subject to upscaling, others might not (and remain local)
- Scaling usually means de-contextualizing and re-contextualizing (and not just large-scale diffusion)
- Local socio-political contexts must be taken into consideration when looking to apply experiences from abroad
  - Related: there is a need for legitimation and/or legalization
- Is it about upscale individual intervention, or create new innovation pathways and platforms for new –similar but not the same- products? (e.g. CAR-T, ultra-rare diseases, drugs for neglected diseases in low-income countries)
- Scaling within countries, between countries, and also between Global North and South has different dynamics and challenges

*Recommendation: Upscaling SPIN initiatives should carefully take local contextualization and legitimation into account.*

## *2. What were the specific context conditions that led to the innovation, and how did the process from some creative act to a social innovation process unfold?*

- Specific policies, legislation and regulation for drugs for rare diseases (for better or worse; e.g. Canada doesn't have any)
- Economic development, pharmaceutical industrial park and pharmaceutical markets
- Innovation environment (universities, private industries, start ups, public investments on innovation and science, level of higher education).
- Robust democratic institutions and organized civil society
- Advocacy capabilities, and the role of patient organizations and access to medicines movements.
- Public budget reserved for coverage

### *Recommendation:*

- 1. Enhance States and NGOs institutions and capabilities to address rare diseases pharmaceutical issues*
- 2. Create cooperative paths between the actors involved, in a global perspective, to ameliorate the innovation environment for clinical trials, license, coverage and industrial production of drugs for rare diseases.*

### *3. What role did entrepreneurs (social, political, economic, cultural) play in bringing about the innovation?*

- Desire to work towards a higher social good (not only profit)
- Importance of social-driven investment
- Importance of patient advocacy and patient voices
- Importance of clinical-research expertise (blurred boundary)
- Collaboration is key (across groups and sectors: public, private, not-for-profit), nothing is achieved alone
- International connections is critical for rare diseases (so few patients)

*Recommendation: create a network of like-minded entrepreneurs who can learn from each other and collaborate (that is part of our role and part of what we are doing)*



#### *4. What was the particular “social” aspect of the innovations, and what sets it apart from other kinds of innovations?*

- New forms of collaboration that are uncharacteristic of how pharma R&D is normally carried out.
- Desire to work towards a higher social good (not only profit), address unmet needs / vulnerability.
- Interest in supporting healthcare system sustainability (as a public good)
- Innovation takes place not only just in early phases of research, but also in the manufacturing process, the accessibility of drugs for those in need, etc.
- SPIN take place in the form of products **and** processes.

*Recommendation: Support SPIN through investments in infrastructures and policies that facilitate public sector pharmaceutical research, development, and deployment (a la vaccine sovereignty)*

# Looking Forward

- Outreach event March 9<sup>th</sup> and 10<sup>th</sup>, 2023 in Utrecht
- Project report
- New projects: from studying to intervening

# Thanks to you, to the SPIN Team, Questions?

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