Observatoire
de la transparence
dans les politiques
du médicament

Local production of essential medicines: in Brazil and Europe: lessons and future directions

Pauline Londeix, *Observatoire de la transparence dans les politiques du médicaments* (OTMeds)

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GLOBAL HEALTH CENTRE

Who are we?

Observatoire
de la transparence
dans les politiques
du médicament

- OTMeds (Observatory on drug transparency) was launched in June 2019, after the adoption by WHO member States of a resolution on transparency :

« *Improving the transparency of markets for medicines, vaccines, and other health* products »

https://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_ACONF2Rev1-en.pdf

(Launched by Jérôme Martin and Pauline Londeix, two access to medicines advocates in France, but also very involved on this issue in other countries)

- Transparency seemed critical to us : as we noticed that many decision makers are designing public policies without having all the cards in hands, therefore the transparency angle seemed relevent to us.
- We wanted to seize the momentum to have more debates at the French level on the deficiency of the medicines development and production system and its consequences in the right to health (in the France, on the sustainability of the health system)
- We do not receive any funding from the industry, not from the States (except for this report, by the European Parliament)

World Health Organization

SEVENTY-SECOND WORLD HEALTH ASSEMBLY
Agenda item 11.7

A72/A/CONF./2 Rev.1
28 May 2019

Improving the transparency of markets for medicines, vaccines, and other health products (FOOTNOTE)

Draft resolution proposed by Andorra, Brazil, Egypt, Eswatini, Greece, India, Italy, Kenya, Luxembourg, Malaysia, Malta, Portugal, Russian Federation, Serbia, Slovenia, South Africa, Spain, Sri Lanka, Uganda

The Seventy-second World Health Assembly,

PP1 Having considered the Report by the Director-General on Access to medicines and vaccines[1] and its annex "Draft Road Map for access to medicines, vaccines, and other health products" and the Report by the Director-General on Medicines, vaccines and health products, Cancer medicines (document EB144/18), pursuant to resolution WHA70.12;

PP2 Recognizing the critical role played by health products [FOOTNOTE:] and services innovation in bringing new treatments and value to patients and health care systems around the world;

FOOTNOTE: For the purposes of this resolution, health products include medicines, vaccines, medical devices, diagnostics, assistive products, cell- and gene-based therapies, and other health technologies.

PP3 Recognizing that improving access to health products is a multi-dimensional challenge that requires action at, and adequate knowledge of, the entire value chain and life cycle, from research and development to quality assurance, regulatory capacity, supply chain management and use;

PP4 Seriously concerned about the high prices for some health products, and the inequitable access within and among Member States as well as the financial hardships associated with high prices which impede progress towards achieving Universal Health Coverage;

PP5 Recognizing that the types of information publicly available on data across the value chain of health products, including prices effectively paid by different actors and costs, vary among Member States and that the availability of comparable price information may facilitate efforts towards affordable and equitable access to health products;

[1] Document A72/17.

Genesis of the report

- In August 2021, a group of Members of the European Parliament (MEPs) from the left wing, asked us to conduct an independant report looking at the possibilities of relocating the pharmaceutical production in Europe.
- Since the beginning of COVID pandemic, in Europe and in particular in France, there has been a debate on « relocation of medicines production in France and Europe », and some political parties have denounced the dependency of these countries to Asian producers (for most of the API and different steps of medicines production).
- Emmanuel Macron has increased the incensitve to support Sanofi facilities on French territory.

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RELOCALISATION
DE L'INDUSTRIE PHARMACEUTIQUE
EN EUROPE
ET DANS LES ÉTATS MEMBRES

1er Octobre 2021

Ce rapport a été réalisé avec le soutien de :

GUE/NGL
LA GAUCHE
AU PARLEMENT EUROPÉEN

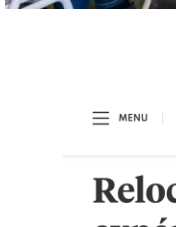
Methodology

- Research conducted from August 2020 to September 2021
- The report was directed by Pauline Londeix and Jérôme Martin, with the help of two consultants : Morgane Ahmar and Khaoula Hajarabi
- Several phases : during the first phase, we organized interviews with different key stakeholders in the field of pharmaceuticals
- In parallel we conducted a literature review on the topic
  - Morgane Ahmar coordinated the literature review
- After this first phases, we started the analysis and to write the conclusions of the study

People interviewed for the report

- **Economists** (mapping of the market and market dynamics)
- **Economists of health** (mapping of the market and sustainability of the public health systems)
- **Former directors of medicines agency** (France and Italy – sustainability of the public health systems and managing/anticipation of stock-outs)
- **Pharmo-scientists and experts in the API** production (API production, interdependence of countries, health security, managing/anticipation of stock-outs)
- **Bio-enginers** at Sanofi and members of the trade-union of workers at Sanofi (industry point of view)
- **Representative of generic medicines association** at the European level (industry point of view)
- **Experts and key stakeholders** in the industrial production strategy in Brazil (policy makers and academic point of view and analysis)
- **Experts in intellectual property and neglected diseases** (price negotiation, patent barriers, technology transfer and priority medicines)
- **Experts in bio-similar production** (scope of the report and alternative models) and small volume insulin production (alternative models)
- **Experts in the "generic" in-vitro diagnostic production** (scope of the report)

Launch of the report in Paris, *1st October 2021*



Context of this report?

- Dynamic of **increase of the medicines prices** in France and Member States, jeopardizing the sustainability of the public health system
  - From 40 000€, to 100K€, and 2 millions€ (per treatment from 2014 to 2019)
- Context of **cuts in funding/austerity measures** on public health system in France
- **Lots of public funding** invested in the development of health products
- Increasing number of the **structural shortages**/stock-outs (reported by ANSM)
- **Conjunctural shortages/stock-outs** during the COVID's first wave, with very serious consequences for patients
  - Stock-outs of medicines used in emergency room facilities, palliative care, etc.
  - Incapacity of the health authorities in France to be reactive and produce locally/in hospitals the missing medicines (cf. social security bill for 2022)

Why relocating ? And does « relocating » reply to it?

- The concept of relocating has been very present in media, with different meanings

E.g. : to **relocate** in order to protect health systems, patient security, for medicines prices to weight less on public systems, for principles of national sovereignty and self-sufficiency

- Does ”relocating” replies to these needs ?
- It depends on the conditions of “relocation”

Defining the object and the frame of relocation – general remarks

- Difficulty to have access to information, even of Members of the Parliament – mapping what we know exist

  (no mapping of the local production at the european level and member States)

- Lack of transparency (on the production and supply chains)
- Thus, difficulty for States to take the right decisions and to be reactive, with a will from them to let « the market » regulate itself (e.g. France), which has conducted to an incapacity to be reactive during when some problems occur (e.g : drug shortage, very high price asked by companies)

Defining the object and the frame of relocation – main questions & focus of the report

- Which health products are we talking about it ?
- Relocating under the « supply and demand » rule ?
- Production to supply the totality of the market, or strategic production ?
- Which steps of the production are talking about ?
  - The API production consideration
- Studying alternative systems (examples of hospitals in the Netherlands, OpenInsulin, military production, and the Brazilian policy)
- Articulating this production with intellectual property laws, market exclusivities, data exclusivity, trade secrets

Defining the object and the frame of relocation – mapping several alternative examples

We looked at different examples to try to better understand what were their purspose, to what problem they replied to, what were their scope

- Hospitals in the Netherlands (using the production strategically in the negotiation prices)
- OpenInsulin (addressing the problem of high prices of insulin in the U.S.)
- Military production (being reactive, production in emergency contexts if needed)
- The Brazilian public production (supplying public hospitals, ensuring the right to health)
- Production in French public hospitals?

RÉPUBLIQUE FRANÇAISE

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Ministère des Solidarités et de la Santé

AVANT-PROJET DE LOI
DE FINANCEMENT DE LA SÉCURITE SOCIALE
POUR 2022

Exposé des motifs

Lors de la crise, les établissements publics se sont mobilisés avec des sous-traitants privés pour produire en urgence des médicaments critiques (cisatracurium, atracurium) en appui des actions engagées par ailleurs. Deux difficultés restent cependant à lever afin de faciliter une telle démarche : prévoir l'autorisation d'une telle production normalement limitée à des produits pour lesquelles les fournisseurs ne prévoient pas de mise sur le marché, et identifier un modèle économique qui sécurise les établissements de santé au-delà du seul remboursement entre établissements des préparations hospitalières.

L'article propose donc de lever ces deux difficultés :

Main conclusions

- The industrial policies on pharmaceutical should be at the service of health policies, in the hierarchy of States
- Complete opacity on the actors and who is producing what, which leads to difficulties for policy makers to take the right decisions
- A production strategy should be articulated with a sanitary needs strategy, and it’s usually not the case, or with no anticipation
- A rule of at least 3 facilities (at least) located in different countries producing the same product should be compulsory to ensure safety/security (BCG vaccine, Rifapentine, and emergency rooms medicines)
- It would not be a problem to have an overlapping of some key essential drug production, if it ensures patient safety
- Public production should be put in place for all the essential medicines that face regularely stock-outs
- Public production should be also used strategically to enable the States to have more power in the prices negotiation process with originator companies, it should also allow export to LMICs when needed
- There is a need to have better training and managments of stocks in countries
- This debate should be an opportunity to address the question of the production of API (ethical & ecological aspects)

10 measures to be put in place at the European level and by member States

1. To implement **transparency** to better assess and guide the industrial policies
2. To make a **mapping of the national and European production** of pharmaceutical products in Europe and in EU member States
3. To **map the investments made** by Member States, the European Union, and the private sector to **evaluate the balance in terms of investments** made for each marketed health product
4. To **evaluate the contribution and the tax avoidance** of pharmaceutical companies to better stem it
5. To **define a production policy**, and the medicines concerned by it and **to better manage stocks** of medicines
6. To put in place an **industrial policy ethical and ecological production of API**
7. To reform **patentability criteria** in the European patent convention and implement TRIPS agreement flexibilities in Member States
8. To defend **ethical and pro health positions** in multilateral and international organizations and through bilateral agreements
9. To put in place different trainings for civil servants, policy makers, and in administration, **for a better understanding of the issues and to stem conflict of interests and revolving doors**
10. To promote **“health democracy”**

Bibliography

- Report on « relocation of pharmaceutical companies in Europe and Member States », OTMeds, October 2021

French – to be published, October 27th 2021 - English version November 2021, will be available from :

  - https://blogs.mediapart.fr/edition/transparence-dans-les-politiques-du-medicament
  - ResearchGate -> author: Pauline Londeix

Literature review available in the report

- « 10 measures for a pragmatic policy in the service of the right to health » (already available in French from: https://static.mediapart.fr/files/2021/10/03/10-mesures-prod-pharma-ue.pdf)
- Transparency check-list (OTMeds, 2019), available in English from:

https://blogs.mediapart.fr/edition/transparence-dans-les-politiques-du-medicament/article/010919/launch-transparency-check-list

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Twitter :

@OTMeds

Pauline Londeix : @londeixp

Jérôme Martin : @PeabodyJoshua