[FREE TRANSLATION]

OPINION N°2024-AO-02 OF MARCH 20, 2024

ON A DRAFT LAW OF THE COUNTRY MODIFYING THE DELIBERATION AMENDED N° 88-153 AT OF 20 OCTOBER 1988 RELATING TO CERTAIN PROVISIONS CONCERNING THE PRACTICE OF PHARMACY

Polynesian Competition Authority,

Considering the letter dated March 7, 2024, registered on March 8, 2024, under number 24/0008 A, by which the President of French Polynesia referred to the Polynesian Competition Authority (hereinafter the "**Authority**") for an opinion on a draft law of the country amending deliberation no.
no. 88-153 AT of October 20, 1988, as amended, relating to certain provisions concerning the practice of pharmacy;

Having regard to the Polynesian Competition Code, and in particular Article LP. 620-2, III ;

Having regard to the other documents in the file;

The Deputy General Rapporteur, the General Rapporteur and representatives of the Secrétariat Général du Gouvernement (hereinafter "**SGG**") heard on the basis of the provisions of article LP. 630-5 of the French Competition Code at the meeting of March 20, 2024;

Is of the opinion to respond to the request presented in the sense of the following observations:

INTRODUCTION

1. The draft text submitted for the Authority's consideration aims to change the regulatory framework for the practice of pharmacy, in particular by modifying the criteria to be taken into consideration when authorizing the creation or transfer of a pharmacy. To this end, it amends deliberation no. 88-153 AT of October 20, 1988.

2. Following a presentation of the general framework for the pharmaceutical retail distribution sector in French Polynesia and the main provisions of the draft law (**I.**), the effects of the new provisions on competition will be examined, and the Authority will make any proposals for improvement (**II**.).

I. FINDINGS

3. The draft law submitted for the Authority's consideration is part of a recent history marked by a reflection on the necessary evolution of the regulations governing the practice of pharmacy and the location of pharmacies, as well as those governing the distribution and pricing of medicines.

4. Before describing the draft law of the country which is the subject of this opinion and the context of the referral (**B**.), it is necessary to describe the operation and regulation of the pharmaceutical distribution sector (**A.**).

A. THE PHARMACEUTICAL RETAIL DISTRIBUTION SECTOR IN FRENCH POLYNESIA

5. Medicines and other pharmaceutical products sold in pharmacies are produced by pharmaceutical laboratories, which do not operate in French Polynesia.

6. They are then imported into French Polynesia by sea or air, depending on the type of product, its weight, volume, value and the urgency of supply[1] . Drug imports are mainly carried out by wholesaler-distributors[2] , who account for around 85% of annual drug imports by value, exclusively from mainland France. In the case of reimbursable drugs, industry players report that imports are carried out almost exclusively by wholesaler-distributors. For non-reimbursable medicines, imports may be carried out by dispensing pharmacies, either directly or *via* their associations, in addition to wholesaler-distributors. These products are then resold to pharmacies, according to their daily needs, and finally to patient-clients.

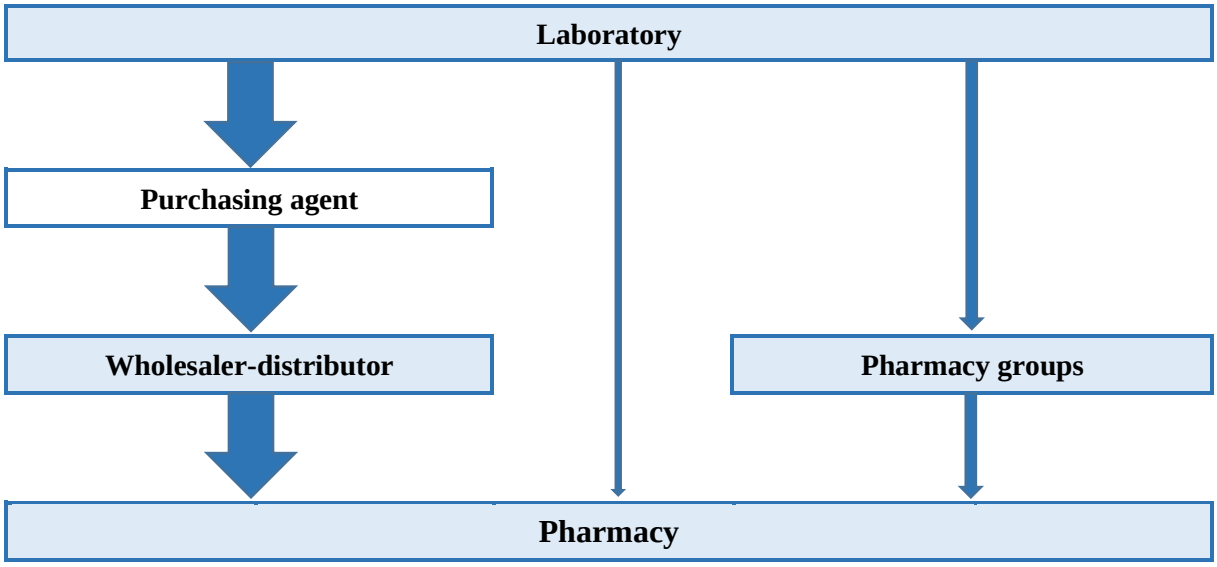
7. The prescriber plays an indirect but important role in drug distribution. Although he is not a link in the distribution chain, he is the actor who initially determines the treatment to be delivered to the patient. And yet, at least for prescription-only medicines, it is the prescription

[1] Wholesalers report a proportion of 60% for sea freight and 40% for air freight (by value).

[2] Wholesaler-distributors use the services of a purchasing agent. Representing the wholesaler-distributor in mainland France, he or she is in charge of logistics, in direct contact with the laboratories.

that determines the dispensing by pharmacies; and it is the demand sent by pharmacies to wholesalers that determines the supply by wholesalers.

The drug distribution chain in French Polynesia



8. The practice of the profession of pharmacist and the procedures for setting up pharmacies are governed primarily by deliberation no. 88-153 AT of October 20, 1988. The draft law submitted to the Authority for consideration amends certain provisions of this deliberation. It is therefore necessary to present the details of this regulation, before examining the modifications made by the draft text.

9. The pharmacist's main mission is to dispense medicines. Article 1-4 of the aforementioned Deliberation no. 88-153 AT stipulates that pharmacists are responsible for "*dispensing to the public the medicines, products and articles mentioned in 1°, 2° and 3°*". The dispensing of medicines is therefore the responsibility of the pharmacist, who checks the internal consistency of prescriptions and has "*the obligation to substitute the prescribed speciality with a speciality from the same generic group [...] provided that the prescriber has not excluded this possibility*"[3] . Pharmacists also provide a guarantee of safety for patients, insofar as they have a duty to advise them. This advisory role is specified in article 48 of Deliberation No. 97-107 APF of July 10, 1997 on the code of ethics for pharmacists in French Polynesia, which stipulates that: "*the pharmacist must carry out the entire act of dispensing the drug, associating with its delivery:*
1- Pharmaceutical analysis of the medical prescription, if available;
2- Preparing the doses to be administered;
3- Providing the information and advice required for proper use of the drug.
They have a special duty to advise when dispensing drugs that do not require a medical prescription. By providing appropriate advice within the scope of his or her competence, he or she must participate in supporting the patient".

10. In French Polynesia, the retail distribution of prescription medicines is entrusted exclusively to pharmacists who own a dispensary. In return for this legal monopoly, strict rules governing access, operations and the location of pharmacies have been laid down.

[3] Article LP 12 of French law no. 2013-1 of January 14, 2013 relating to the control of expenditure on health products and reimbursable products and services.

1. THE MONOPOLY OF PHARMACISTS AND PHARMACIES

11. Under article 1-4 of deliberation no. 88-153 AT of October 20, 1988, pharmacists have a monopoly on the preparation and sale of medicines, extended to a number of other items.

12. The monopoly covers the preparation and sale of medicines intended for use in human medicine, dressings and all articles presented as complying with the pharmacopoeia, insecticides and acaricides intended for application to humans, products for the care or application of contact lenses, generators, kits or precursors. The sale of certain medicinal plants listed in the pharmacopoeia, certain essential oils, as well as milk-based dietary foods for infants and dietary foods for infants (under four months of age) is also subject to the monopoly of pharmacists[4] .

13. Furthermore, according to article 23 of the aforementioned deliberation no. 88-153 AT of October 20, 1988, a dispensary is defined as "*the establishment used for the retail dispensing of the medicines, products and articles mentioned in article 1-4, as well as for the preparation of magistral or officinal preparations*". The sale of these products must therefore take place within the pharmacy network. In particular, all medicines, whether or not reimbursed by the Caisse de Prévoyance Sociale (hereafter "**CPS**"), may only be sold within a pharmacy operated by a qualified pharmacist registered with the Ordre des pharmaciens de la Polynésie française.

14. However, there are certain exceptions to the pharmacy monopoly:

- delivery outside the pharmacy (to customers' homes, for example) is possible in the form of a sealed package "bearing the customer's name and address"[5] ;
- the distribution of medicines on the public highway is forbidden, except in the context of "public health initiatives aimed at improving the health of the population, undertaken by the Health Department"[6] ;
- distribution by doctors on islands without pharmacists or by the Institut Malardé[7] ;
- the possibility of creating restricted drug depots, as defined in article 17 of decree no. 55-1122 of August 16 1955, as amended: "In cases where the density of open pharmacies is insufficient to meet the needs of the population, personal authorizations to open drug depots may be granted to non-pharmacist traders by order of the head of the territory, on the proposal of the director of the Agence de régulation de l'action sanitaire et sociale, after consulting the pharmacy inspector and the delegate of the subsection of the Ordre des pharmaciens"[8] . In this case, the medicines must be separated from the rest of the products sold and packaged or prepared in advance by a pharmacist. Merchants authorized to open restricted depots are therefore only drug dealers, it being understood that "the regular opening of a pharmacy automatically renders null and void any authorization to open a drug depot within a radius of twenty kilometers".

15. Consequently, in towns and cities, with the exception of derogations, only pharmacists with a dispensary can sell medicines and the aforementioned products to end consumers. It is therefore possible to distinguish between a monopoly linked to the function or profession (pharmaceutical monopoly) and a monopoly linked to the place where products are sold (pharmacy monopoly).

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[4] Eye lens care products can also be sold to the public by opticians.

[5] Article 43 of deliberation no. 88-153 AT cited above.

[6] Article 45 of the above-mentioned resolution.

[7] Articles 48, 49 and 51 of the above-mentioned resolution.

[8] Since 1997, 7 restricted drug depots have been authorized (including 4 in the Tuamotu archipelago) and 5 requests have been refused (4 in the Tuamotu and 1 in the Australes).

16. The pharmacist's code of ethics requires them to ensure that the public has no direct access to medicines. In practice, this means that medicines must be stored behind the sales counter and dispensed by the pharmacist to the customer.

2. TERRITORIAL DISTRIBUTION OF PHARMACIES

17. The location of pharmacies must meet the health needs of the Polynesian population. Article 25 of the aforementioned Deliberation No. 88-153 AT stipulates that "*the creation and transfer of pharmacies open to the public must enable the best possible response to the medication needs of the population living in the areas where these pharmacies are located*". In particular, "*the creation and transfer of pharmacies open to the public may only be carried out in a location that guarantees permanent public access to the pharmacy and enables it to provide a satisfactory on-call and emergency service*". Since 1983, the establishment of pharmacies in French Polynesia has been limited according to population thresholds[9] .

18. The opening of a pharmacy is thus subject to obtaining a license issued by a decree issued by the President of French Polynesia, after consulting the regulatory commission. This commission, created by deliberation no. 2002-50 APF of March 27, 2002, gives an opinion on the request for the creation of a pharmacy "*with regard to compliance with legal and regulatory provisions, the needs of the population and public health, and the organization of access to pharmaceutical services*" (article 62-1 of deliberation no. 88-153 AT cited above). It is made up of the Director of Health (Chairman), the Chairman of the French Polynesian Order of Pharmacists (hereinafter referred to as "**COPPF**") (Vice-Chairman), the Chairman of the Order of Physicians (local section), two persons appointed by the presidents of the representative pharmacy unions, a person appointed by the President of the Government for his or her expertise, a territorial representative appointed by the Assembly of French Polynesia, and a representative of users' interests appointed by the Council of Ministers. The license thus issued specifies the location where the pharmacy will be operated.

19. In addition, a minimum distance may be imposed between a new pharmacy and the nearest existing pharmacy, which must be greater than that stipulated in article 26 of the aforementioned deliberation no. 88-153 AT. A particular sector of the commune may also be designated for the installation of any new dispensary, "*with a view to ensuring optimum service to the population*" (article 25 of the aforementioned deliberation no. 88-153 AT).

20. Licensing criteria are defined in article 26 of the aforementioned deliberation no. 88-153 AT:

- in communes with a population of less than 5,000, no more than one pharmacy license may be issued;
- in communes with a population of over 5,000, a second license may be issued when the population reaches an additional whole block of 5,000; additional dispensaries may continue to be created at the rate of one authorization per additional whole block of 7,000 inhabitants, with the exception of the commune of Papeete ;
- in the commune of Papeete, the opening of a new pharmacy may be authorized by the creation of one new dispensary for each additional whole block of 3,000 inhabitants registered in the commune.

21. The distance between an existing and a new pharmacy is set at 300 meters in the commune of Papeete, 650 meters in the communes of Mahina, Arue, Pirae Faa'a, Punaauia and 1,000 meters

[9] This is also the case in mainland France: Directive 85/432/EC of December 16, 1985 gave Member States the option of establishing such a system, based on demographic criteria.

in other communes. The latter distance must also be respected in relation to a pharmacy already established on the territory of the neighboring commune.

22. As of March 13, 2024, there were 48 pharmacies in French Polynesia, including 37 in the Windward Islands (34 in Tahiti and 3 in Moorea) and 11 in the other archipelagos (see maps in Appendices).

3. THE PRINCIPLE OF INDIVISIBLE OWNERSHIP AND OPERATION OF PHARMACIES

23. Article 28 of deliberation no. 88-153 AT stipulates that "*the pharmacist must be the owner of the pharmacy of which he is the proprietor*". This article also specifies the legal form that the entity operating the pharmacy may take. It is thus possible for pharmacists to form "*a general partnership for the purpose of operating a pharmacy". Pharmacists are also authorized to form a limited liability company to operate a pharmacy, provided that the company owns only one pharmacy, regardless of the number of pharmacists associated with it, and that one or more of the associated pharmacists is responsible for managing the pharmacy*". Lastly, "*a pharmacist may only be the owner or co-owner of a single dispensary*". Consequently, only qualified pharmacists may operate and own one (and only one) pharmacy.

24. Joint practice is possible for several pharmacist associates, under a number of legal forms, in particular the general partnership (société en nom collectif), the liberal practice company (hereafter "SEL") and the limited liability liberal practice company (hereafter "SELARL"). In an SEL, a pharmacist can be a minority shareholder in 2 pharmacies, in addition to the one he or she owns[10] .

25. In addition, article 25 of the aforementioned deliberation no. 88-153 AT stipulates that "*except in the case of force majeure, as determined by the Council of Ministers on the recommendation of the Director of the Agence de Régulation de l'Action Sanitaire et Sociale after consulting the President of the Conseil de l'Ordre des Pharmaciens de la Polynésie Française, a newly-created dispensary may not be sold in whole or in part before ten years have elapsed, nor may it be transferred before five years have elapsed, starting from notification of the license decree*".

4. CONDITIONS FOR PRACTICING AS A PHARMACIST

26. Pharmacists are subject to a strict legislative and regulatory framework. In particular, all pharmacists owning a dispensary must be registered with the Ordre des pharmaciens de la Polynésie française (French Polynesian Order of Pharmacists), which was created by Resolution no. 2003-149 APF of September 9, 2003, as amended. Previously, under the aforementioned deliberation no. 88-153 AT, the profession was represented by Section F of the Conseil national de l'ordre des pharmaciens, dedicated to practice in the French Overseas Territories.

27. Once registered with the Order, pharmacists must practice their profession in accordance with the rules set out in the Pharmacists' Code of Ethics.

28. Among the rules of conduct imposed on pharmacists by deliberation no. 97-107 APF of July 10, 1997 on the code of ethics for pharmacists, some directly concern their presence in the

[10] Arrêté n°1206 DRCL du 10 novembre 1992 portant promulgation du décret n° 92-909 du 28 août 1992 relatif à l'exercice en commun de la profession de pharmacien d'officine sous forme de société d'exercice libéral et modifiant le code de la santé publique (deuxième partie : Décrets en Conseil d'Etat).

distribution market, as well as the nature and degree of competition they may face. The code of ethics includes:

- rules governing pharmacists' relations with their customers. In particular, all pharmacists must respect the freedom with which patients choose their pharmacist (article 21). They are also *"forbidden to solicit customers by means and procedures contrary to the dignity of the profession*" (article 22);

- advertising rules. Article 30 stipulates that "*all information or advertising, when authorized, must be truthful, fair and formulated with tact and moderation"*. In addition, drug advertising is governed by the aforementioned deliberation no. 88-153 AT and by decree no. 610 CM of May 9, 1989, as amended. Thus, advertising is only possible for drugs not subject to compulsory medical prescription and not reimbursed by the CPS. In this case, advertising is subject to authorization by the Minister of Health, who issues a visa after consulting the territorial public health council[11] . This approval "*is granted for a period not exceeding five years*"[12] . The same conditions apply to drug advertising by pharmacies themselves[13] ;

- rules of confraternity and non-competition. Article 34 of deliberation no. 97-107 APF stipulates that "*all pharmacists registered with the Order owe each other mutual aid and assistance in the performance of their professional duties. In all circumstances, they must show loyalty and solidarity with one another*". In addition, article 36 of the aforementioned decree prohibits pharmacists from *"inciting any colleague to terminate his or her employment contract*". Finally, article 37 stipulates that pharmacists are subject to a non-competition obligation limited to two years with regard to colleagues whom they have replaced, assisted or seconded (either during or after their studies) for a minimum period of 6 months.

29. In conclusion, Polynesian regulations governing the practice of pharmacy are relatively strict compared to other countries. It combines strict control over the establishment of pharmacies (with population and distance thresholds, and criteria for length of presence in the territory) and an extensive pharmacy monopoly, with its corollary, the indivisibility of ownership and operation of the pharmacy by the pharmacist. These strict regulations, largely inspired by rules in metropolitan France (except for installation criteria), ensure a high level of security in the distribution of medicines in French Polynesia, and thus a high level of public health protection.

B. THE DRAFT LAW OF THE COUNTRY SUBMITTED FOR EXAMINATION

30. The purpose of the draft law submitted to the Authority for consideration is to amend the aforementioned Deliberation No. 88-153 AT, mainly in order to :

- modify the criteria to be taken into consideration for the geographical location of a pharmacy within a commune, in light of case law, and in particular taking into account the changing role of pharmacists in the healthcare system (**a.**); and

[11] Article 20 of order no. 610 CM of May 9, 1989, as amended.

[12] Article 23 of order no. 610 CM of May 9, 1989, as amended.

[13] Article 34 of order no. 610 CM of May 9, 1989, as amended.

- to introduce concordance measures, particularly in view of certain terminological changes (**b.**).

The project consists of two articles.

a) MODIFICATION OF THE CRITERIA DEFINING OPTIMAL DRUG SUPPLY AND ACCESS TO PHARMACEUTICAL SERVICES

31. Article LP 1, 13°, of the draft country law modifies the criteria defining the optimal nature of the supply of medicines and access to pharmaceutical services in order to "*place the pharmacy at the heart of the population's center of life*", taking into account "*not only the resident population but also* [...] *the transient and seasonal population*". The previous criterion of "*population residing in the host districts*" would no longer meet current needs.

32. In particular, the explanatory memorandum notes that taking into account the surrounding healthcare offer is no longer a "*relevant [...] criterion*" since the pharmacist's missions were extended by French law no. 2022-34 of August 23, 2022 to make him or her a fully-fledged healthcare player, participating in particular in primary care and prevention.

33. In order to assess the "*optimal nature of the pharmaceutical supply*", the text also incorporates into the law of the country several criteria originally taken from decree no. 610 CM of May 9 1989, as amended. These criteria are intended to guide the regulatory commission in formulating its opinion on applications for authorization to set up or transfer a pharmacy. In particular, the country's draft law states that the optimal nature of the pharmaceutical supply is assessed in the light of all the following criteria:

    - the location of the pharmacy, "taking into account the surrounding administrative, educational, commercial, port, airport, sports, tourist, cultural and religious infrastructures";
    - accessibility of the pharmacy, "taking into account geographical constraints on travel, the availability of public transport and parking";
    - pharmaceutical services offered by the pharmacy; and
    - opening hours.

34. The explanatory memorandum stresses that the administrative courts have been able to set aside these criteria, which were derived from the amended decree no. 610 CM of May 9, 1989 . By incorporating them into the loi du pays, these criteria will be elevated to a higher legal status, obliging the administrative courts to take them into account. On the other hand, the criteria relating to "*the size of the population served by the dispensary in relation to the resident and seasonal population*", "*the health care offer in the commune*", "*the anteriority of the centers of material and moral interests*" and "the *mastery and understanding of a Polynesian language*" will remain at the level of the decree. The regulatory commission may, however, take them into account to distinguish between two files.

35. Article LP 1er , 13°, also provides for priority to be given, in the event of equivalent applications, to pharmacists who have received an enhanced grant as provided for in Order no. 366 CM of April 13, 2006, as amended, regulating French Polynesia's allowances for higher education.

36. Lastly, article LP 2 stipulates that the draft country law will apply to requests for authorization "*filed prior to its effective date and which have not yet given rise to an authorization or refusal*" .

b) TERMINOLOGY CHANGES

37. The draft loi du pays makes a number of terminological changes to deliberation no. 88-153 AT of October 20, 1988, including the following:

- Article LP 1er , 2° which changes the terminology "*biomedical research*" to "*research involving the human person*" to bring it into line with the vocabulary used since Ordinance no. 2016-800 of June 16, 2016 on research involving the human person, extended and adapted to French Polynesia by Ordinance no. 2023-285 of April 19, 2023 extending and adapting various legislative provisions relating to health to French Polynesia, New Caledonia and the Wallis and Futuna Islands;
- articles LP 1er , 4° and 8°, which delete the reference to the Conseil Supérieur de Santé Publique since it was abolished by deliberation no. 2018-92 APF of November 15, 2018 creating the Polynesian Health and Social Council; and
- rectification of references to opinions from the Chairman of COPPF in deliberation no. 88-153 AT of October 20, 1988, when it is the COPPF, and not just the Chairman, who is asked for an opinion.

II. COMPETITIVE ANALYSIS

38. When it is asked to give an opinion on a draft text, the Authority endeavors to assess the extent to which the text's provisions restrict or improve the competitive operation of the sector. As the Autorité has already had occasion to point out, "*a competitive market optimally allocates available resources, maximizes consumer welfare and boosts the competitiveness of the sector concerned, by encouraging innovation, lower prices, diversification of supply and higher quality goods and services. Competition is a factor of productive and allocative efficiency*"[14] . Nevertheless, competition is not an end in itself; it is a tool in the service of this economic efficiency.

39. Normative texts very frequently respond to concerns of general interest that go beyond competition, and involve intervention by public authorities that has an impact on the functioning of the economy. In such circumstances, the role of the Autorité is to inform the government and the Assembly of French Polynesia of the effects on competition of the planned public intervention, and to recommend to them, where appropriate, the measures to be taken to reconcile general interest objectives and economic efficiency.

40. In this case, the draft law submitted to the Authority amends a number of provisions relating to the establishment of pharmacies in French Polynesia. While the changes are designed to open up the sector, the draft law nevertheless raises questions about its impact on the pharmacy sector.

A. HEALTH PROFESSIONS AND COMPETITION

41. Extensive regulation of the pharmaceutical distribution sector restricts the commercial autonomy of players in the drug distribution chain. While these constraints are essentially justified by public health requirements and the need to balance social accounts, they cannot lead to the exclusion of all forms of competition. In its opinions no. 2018-AO-01 of April 24, 2018[15] and no. 2018-AO-02 of July 13, 2018[16] , the Autorité specified that although "*competition and healthcare seem to belong to spheres that are foreign to each other*", healthcare, envisaged "*as a sector grouping together healthcare service activities and the sale of healthcare products, [it] cannot be excluded from the economic field*"[17] . Health-care and health-product distribution activities are indeed economic in nature. Even if supply and demand are specific to the sector, "*these elements cannot (...) conceal the reality of the existence of a demand, in terms of healthcare services or healthcare products, whose meeting with supply is remunerative for suppliers. A market exists when demand meets supply. Competition is intended to govern any activity carried out on a market (...), and is therefore applicable, even if the specific nature of healthcare missions prevents competition law from becoming the sole regulator*"[18] .

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[14] Opinion no. 2016-A-03 of December 9, 2016 on the draft law of the country regulating professional activities related to the production and marketing of pearl and mother-of-pearl products in French Polynesia; opinion no. 2017-A0-02 of June 19, 2017 on the draft law of the country regulating the activity of private road transport with driver using vehicles with fewer than ten seats.

[15] Opinion No. 2018-AO-01 of April 24, 2018 on the draft law of the country regulating the profession of speech therapist.

[16] Opinion n°2018-AO-02 of July 13, 2018 on the draft law of the country modifying the conditions for the creation of pharmacy dispensaries and certain provisions relating to the practice of pharmacy.

[17] See, for example, Opinion n°2018-AO-02, paragraph 59.

[18] Quotations from Conseil de la concurrence, *Rapport annuel 2008, étude thématique, "Droit de la concurrence et santé".*

42. In addition, regulatory constraints have been relaxed in French Polynesia with regard to non-reimbursable drugs, whose price is now free, as are the margins of those involved in their distribution. As a result, the profession of pharmacist is in reality both a health profession (pharmacists dispense medicines) and a commercial profession (pharmacists are remunerated by a commercial margin on products sold to the public).

B. ANALYSIS OF THE PROVISIONS OF THE DRAFT LAW OF THE COUNTRY SUBMITTED FOR EXAMINATION

43. The explanatory memorandum states that the purpose of this draft law is to amend Deliberation No. 88-153 AT of October 20, 1988, "*mainly in order* to *modify the criteria to be taken into consideration when authorizing the opening of a pharmacy, in light of case law, and in particular taking into account the evolution of the missions and role of pharmacists in the healthcare system*".

44. Accordingly, article LP 1er ,13° proposes to rewrite article 25 of the aforementioned deliberation no. 88-153 AT, so that the creation or transfer of a pharmacy is no longer examined solely on the basis of the drug needs of the "*resident population*" in the areas where the pharmacies are located, but on the basis of a criterion relating to the drug needs and access to pharmaceutical services of the "*resident, seasonal and transient population*". The notion of *a* "pharmacy *district*" has disappeared from the new version of the text proposed by the country's bill.

1. GENESIS OF THE DRAFT TEXT

45. The current reform of deliberation no. 88-153 AT follows a previous review of the text in 2018, which had already given the Authority the opportunity to rule on the conditions for setting up pharmacy dispensaries and certain provisions relating to the practice of pharmacy in 2017 and 2018[19] . In its opinion 2018-AO-02, the Authority welcomed a number of provisions in the country's draft law that "move *in the direction of greater market openness, greater competition and greater market transparency*"[20] , thanks in particular to the abolition of the system for creating pharmacies by derogation, the reduction in population quotas and minimum distances between pharmacies.

46. The reasons for this new reform of deliberation no. 88-153 AT of October 20, 1988 lie mainly in the repeated censures handed down by the administrative courts against orders authorizing the opening of a second pharmacy in Bora Bora. These legal proceedings have given rise to extensive media coverage.

47. As a reminder, Mr. X has been seeking authorization to set up a second pharmacy in the associated commune of Nunue in Bora Bora since 2021. Mr. X has submitted four successive applications for authorization, which have been accepted by the Pays but also systematically contested by Mr. Y, the island's only pharmacist, before the administrative courts[21] . Mr. Y

[19] Opinion no. 2017-A-03 of November 6, 2017 on the operation of competition in the pharmaceutical distribution sector and opinion no. 2018-AO-02 cited above.

[20] Opinion no. 2018-AO-02, paragraph 153.

[21] See, for example, the article in Polynésie la 1ère, *Bora-Bora : Teano Cojan, the island's new pharmacist singled out by his only competitor*, December 12, 2023. https://la1ere.francetvinfo.fr/polynesie/tahiti/polynesie-francaise/bora-bora-teano-cojan-le-nouveau-pharmacien-de-l-ile-conteste-par-son-unique-son-concurrent-1450343.html.

considers that the proposed location for the second pharmacy does not optimally meet the needs of the population, as it concentrates healthcare provision in the associated commune of Nunue.

48. The Administrative Court of French Polynesia ruled in favor of Mr. Y, twice censuring these authorizations on the grounds of manifest error of assessment. In particular, the Court ruled that the choice of location for Mr. X's pharmacy could not be considered to optimally meet the medication needs of the population of Bora Bora, particularly in view of "*the low volume of the population domiciled in the area hosting the disputed project or which resides there on a stable basis*"[22] .

49. In particular, the Tribunal considered that the proximity of the second pharmacy to a secondary school and hotels was not relevant in quantifying the resident population's need for medicines. The Paris Administrative Court of Appeal confirmed the Tribunal's reasoning in a ruling dated October 20, 2023. In all, this dispute over the opening of the second pharmacy in Bora Bora has generated twelve legal proceedings, five of which are still pending before the Paris Administrative Court of Appeal and the Conseil d'Etat.

50. The explanatory memorandum states that the government wished to take note of the interpretation of the criteria for the creation or transfer of pharmacy dispensaries by the administrative courts, as well as "*the evolution of the missions and role of the pharmacist in the healthcare system*", by revising deliberation no. 88-153 AT. As the SGG, co-sponsor of the text with the Agence de Régulation de l'Action Sanitaire et Sociale (hereafter "**ARASS**"), pointed out at the hearing: "*All these court decisions interpret the regulations in a uniform manner, resulting in the cancellation of the authorization to open a second pharmacy in Bora Bora. The political authorities considered that it had become necessary to modify the regulatory framework governing the opening of pharmacies in order to make it easier to set up a pharmacy in French Polynesia*".

2. THE CONTENT OF THE DRAFT TEXT

51. The Autorité notes that most of the changes introduced by the draft law have little impact on competition in the sector. For example, the draft law confers a higher legal value on a certain number of criteria, taken from decree no. 610 CM of May 9, 1989, as amended, and used to assess the relevance of opening a pharmacy. These include criteria relating to the location of the pharmacy, its accessibility and the pharmaceutical services it offers. The aim here was to prevent these criteria from being easily dismissed by the administrative judge in the event of a dispute.

52. The draft country law refrains from giving higher legal value to some of these criteria, such as those relating to "*prior centers of material and moral interests*" and "*mastery and understanding of a Polynesian language*", due to the excessive risk of censure by the administrative courts on the basis of potentially discriminatory criteria.

53. On the other hand, the change in the criterion for authorizing the creation or transfer of a dispensary from the drug needs of the resident population to the needs of the "*resident, seasonal and transient population*" in the present draft law is likely to have an impact on the operation of the pharmaceutical retail distribution sector.

54. As indicated *above*, the government has taken note of the administrative courts' interpretation of the criteria for the creation or transfer of pharmacies by reforming the notion of "*resident population*" in the area where the pharmacy is located.

[22] Note from the SGG dated March 13, 2024 to the attention of the President of the Polynesian Competition Authority.

55. This change is made in accordance with the law as it stands, as the draft text retains the conditions relating to the number of pharmacies per inhabitant and the minimum distance between pharmacies. As a reminder, article 26 of deliberation no. 88-153 AT of October 20 1988 makes the creation or transfer of a pharmacy subject to minimum distances between two pharmacies[23] and population thresholds per commune[24] . As a result, this project will not allow the opening of more pharmacies per commune, but will allow greater flexibility in terms of location.

56. In the aforementioned opinion no. 2018-AO-02, the Autorité noted that "*while the [pharmacy] network undeniably presents elements of rationality and geographical equity, it seems relatively sparse and disparate*"[25] . Indeed, with one pharmacy for every 6,270 inhabitants, the density of pharmacies in Polynesia is more than half that in mainland France (one pharmacy for every 3,019 inhabitants[26]). It is also much lower than in the French overseas departments (excluding Mayotte) and New Caledonia. Consequently, in order to improve the territorial coverage of drug distribution outlets, the Autorité recalls the possibility, under certain conditions, of opening secondary establishments in places where opening would not be permitted due to demographic criteria.

57. From a legal point of view, article LP 1er , 13° of the draft country law significantly broadens a central concept used to justify the location of a pharmacy, by referring to the drug needs of three types of population (resident, seasonal and transient) as opposed to the needs of the resident population alone.

58. In particular, the Authority emphasizes the particularly broad nature of the notion of "*transient*" population introduced in the draft. In fact, article LP 1er , 13°, a, I. of the draft country law states that "in *particular, the surrounding administrative, educational, commercial, port and airport, sports, tourist, cultural and religious infrastructures*" will be taken into account when examining the location of the pharmacy. This list therefore encompasses a multitude of activities that could justify consideration under the heading of transient population.

59. In addition, the Authority notes that the draft country law no longer refers to the "*pharmacy reception area*", which made it possible to establish a geographical perimeter within which the needs of the resident population could be assessed. The absence of a geographical reference perimeter in the draft law appears to add a further factor of uncertainty to the interpretation to be given to the text.

60. Given the particularly wide range of parameters that can be taken into account when deciding where to locate a pharmacy, it would appear that the various resident, seasonal and transient populations could encourage a discretionary interpretation by the administration, by referring to a multitude of population flows present in a given territory to justify the choice of where to locate a pharmacy.

61. The Authority notes that, at this stage, the authorities themselves do not appear to have the data needed to assess these different flows of "*transient*" or "*seasonal*" populations, and therefore the potential impact of this reform on the sector.

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[23] 300 meters in Papeete, 650 meters in the communes of Mahina, Arue, Pirae, Faa'a, Punaauia and 1,000 meters in the other communes.

[24] The first population threshold is set at 5,000 inhabitants per commune, and a second license may be issued when an additional whole block of 5,000 inhabitants is reached. Additional pharmacies may continue to be created at a rate of one authorization per 7,000 inhabitants.

[25] Opinion no. 2018-AO-02, paragraph 72.

[26] CNOP data, March 2017.

62. The AMF stresses the importance of ensuring that the draft text does not have undesirable effects on territorial coverage, for example by concentrating pharmacies in the most economically attractive areas of towns and cities, to the detriment of less well-endowed areas.

63. In the aforementioned 2018 opinion, the Autorité noted that "*the need to guarantee the population sufficient access to medicines and therefore the need to present a harmonious network of pharmacies means that this barrier should not be lifted without measuring the effects of this provision on the said network. As pharmacists themselves acknowledge, if freedom of establishment is granted, pharmacies will locate in areas deemed to be the most profitable, thus confirming the economic and commercial orientation of their activity. Such a situation could lead to a phenomenon of geographical concentration of pharmacy activity which, while desirable for the competitive animation of the sector and the selection of the most efficient companies, risks being contradictory to the public health imperative of access to medicines*"[27] .

64. Particularly in the case of urgent referrals, the Authority regrets the failure to produce maps showing the locations concerned by the creation or transfer of a pharmacy as a result of the reform of the population needs criterion.

65. In this respect, the Autorité regrets not having been able to accurately assess the impact of the reformed population needs criterion on the pharmaceutical retail distribution sector. To do so, it would have been necessary to create maps, modelling existing pharmacy locations on isochronous maps[28] , and to identify possible locations for the various criteria for creating or transferring a pharmacy.

66. The Authority has produced an initial map of pharmacies in Polynesia (see Appendix). However, this mapping does not allow us to model the impact of the reform on the Polynesian territory with any precision, as a true mapping, based on an isochronic model, of existing and possible pharmacy locations is incompatible with the situation of an emergency referral to the Authority. It should also be pointed out that the data required to produce these maps is not readily available. The Authority therefore recommends that these projections be carried out before the text comes into force.

67. While the Authority understands the need for urgent referrals, it regrets in this case that the dossier is very thinly supported, making the Authority's work considerably more complex in such a tight timeframe. Generally speaking, the Authority believes that the tighter the timeframe for issuing an opinion, the more complete the dossier submitted by the government must be in order for the opinion to be as well-informed as possible.

Recommendations:

The Authority makes the following recommendations:

1. In terms of optimal pharmaceutical supply, the criterion relating to the needs of the resident, seasonal and transient population should be better defined, to ensure equitable treatment of applications for the creation or transfer of a pharmacy;
2. Create maps of existing and planned pharmacies, as well as all attached healthcare professionals, based on an isochronous model, which would make it possible to

[27] Opinion no. 2018-AO-02, paragraph 100.

[28] An isochronous map is a tool used in particular in the context of merger control or the control of retail floor space, to delimit a theoretical geographical area, calculated on the basis of a given travel time around a given outlet (the so-called "isochronous" area), from which the bulk of the outlet's clientele is presumed to come.

anticipate the impact of modifying the criterion relating to the needs of the population; and

3. Publish these maps, including potential locations eligible to open a pharmacy, to guarantee equal access to information for those wishing to open a pharmacy.

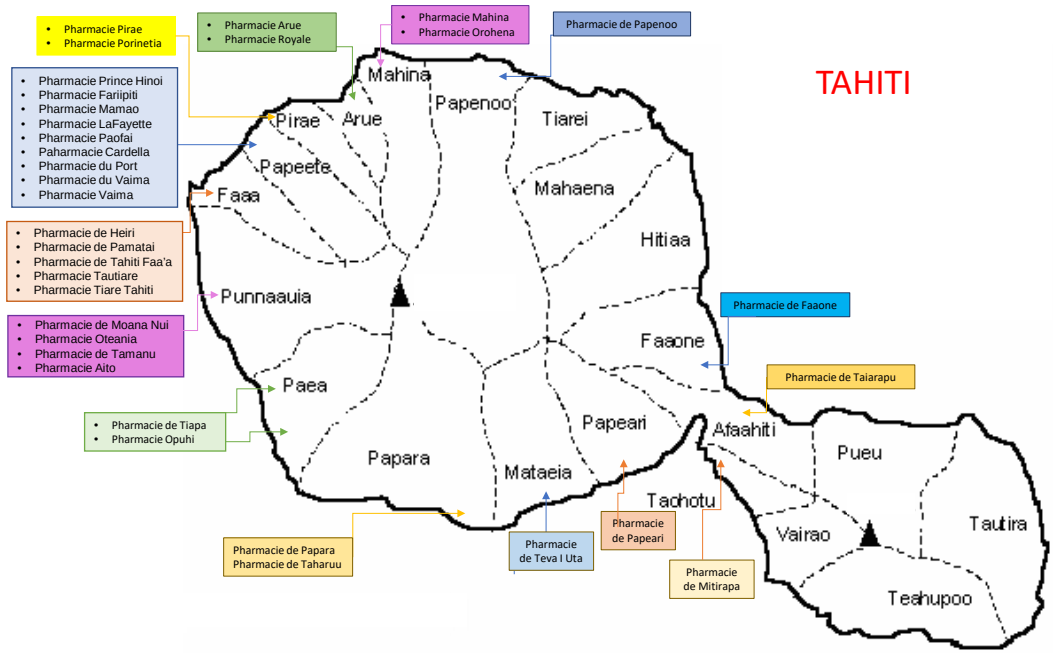
Deliberated on the report by Frédéric Paillusson, *Deputy General Rapporteur*, and the intervention of Sophie Bresny, *General Rapporteur*, by Enzo Silvestro, *Chairman of the meeting*, Ingrid Izquierdo and Pierre Frébault, *full members*.

The Chairman

Enzo Silvestro

III. APPENDIX: MAPS OF PHARMACIES IN FRENCH POLYNESIA

A. TAHITI ISLAND



Commune	Population
PAPEETE	26 654
FAAA	29 826
PUNAAUIA	28 781
PAEA	12 756
PAPARA	11 743
MATAIEA	5 391
PAPEARI	5 446
TOAHOTU	3 925
AFAAHITI	6 829
FAAONE	2 170
PAPENOO	3 900
MAHINA	14 623
ARUE	10 322
PIRAE	14 068
TOTAL TAHITI	196 21

Source: ISPF - https://www.ispf.pf/publication/1396

B. HUAHINE ISLAND

Commune	Population
FARE	1 600
TOTAL	6 325

Source: INSEE 2022
https://www.insee.fr/fr/statistiques/3294364?sommaire=2122700

HUAHINE



C. BORA BORA ISLAND

Commune	Population
ANAU	1 905
FAANUI	3 312
NUNUE	5 541
TOTAL	10 856

Source: INSEE 2022
https://www.insee.fr/fr/statistiques/3294364?sommaire=2122700

BORA BORA



D. ISLANDS OF RAIATEA AND TAHAA

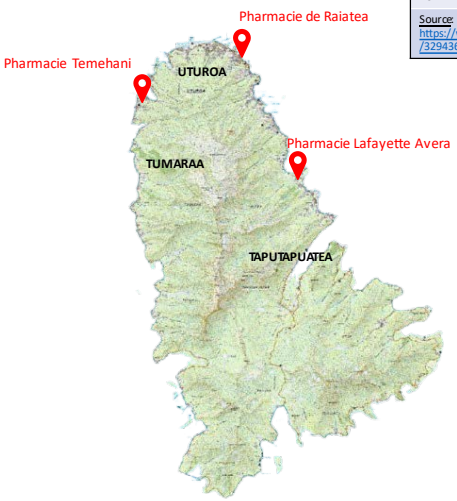
TAHAA



Île	Population
TAHAA	5 365

Source: INSEE 2022
https://www.insee.fr/fr/statistiques/3294364?sommaire=2122700

RAIATEA



Commune	Population
TUMARAA	3 760
UTUROA	4 064
TAPUTAPUATEA	5 039
TOTAL	12 863

Source: INSEE 2022
https://www.insee.fr/fr/statistiques/3294364?sommaire=2122700

E. RANGIROA ISLAND

RANGIROA

Île	Population
RANGIROA	3 904

Source: INSEE 2022
https://www.insee.fr/fr/statistiques/6690032?sommaire=2122700



F. ISLANDS OF HIVA OA AND NUKU HIVA

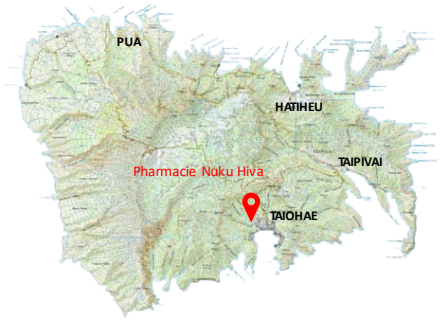
Îles	Population
HIVA OA	2 514
NUKU HIVA	3 161

Source: INSEE 2022 https://www.insee.fr/fr/statistiques/6690032?sommaire=2122700

HIVA OA



NUKU HIVA

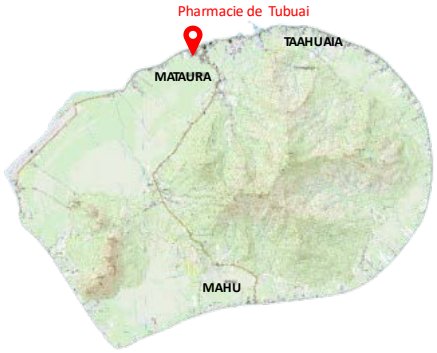


G. ISLANDS OF TUBUAI AND RURUTU

île	Démographie
TUBUAI	2 285
RURUTU	2 250

Source: INSEE 2022
https://www.insee.fr/fr/statistiques/6690032?sommaire=2122700

TUBUAI



RURUTU

