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Review Article

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Comparative Evaluation of Regulatory Registration & Approval Pathways for Semaglutide 14 mg Tablet in Emerging South American Markets: Chile, Peru and Bolivia

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Abstract

The regulatory registration and approval processes for semaglutide tablets 14 mg in Chile, Peru, and Bolivia—three developing South American markets—are compared in this paper. Regulatory bodies, dossier specifications, submission processes, review schedules, labelling requirements, and post-approval variances are all examined in the analysis. The results show that the three nations' technical documentation, GMP certification standards, language requirements, and approval procedures differ from one another. Bolivia retains a more administrative and mostly offline submission method, whereas Chile and Peru adhere to more structured regulatory frameworks with components that are in line with international norms. In order to facilitate effective market entrance planning and compliance in developing South American pharmaceutical markets, this comparison offers key regulatory insights.

Conclusion: The investigation reveals significant variation in Chile, Peru & Bolivia s Semaglutide market Regulatory Frameworks, particularly with regard to documentation, submission process & Compliance Bolivia has a more Manual Method Whereas Chile and Peru adhere to more Standarized, globally aligned systems. For an efficient registration Strategy and seamless market entry, these distinctions are essential.

Keywords: Semaglutide Tablet 14 mg, Regulatory Approval Pathways, Pharmaceutical Registration, Emerging South American markets; Chile, Peru and Bolivia, Comparative Regulatory Analysis

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1. Introduction

Semaglutide tablet14 mg, a glucagon like peptide-1 (GLP-1) Receptor Agonist, are one of the novel oral antidiabetic treatments that are in high demand due to the growing incidence of type 2 diabetes mellitus worldwide. It is therefore essential for pharmaceutical companies to comprehend the regulatory registration and approval processes unique to each country as they enter emerging markets in order to ensure timely market access and compliance.

However, in terms of dossier criteria, submission processes, and review dates, regulatory registration and approval methods vary greatly among nations like Bolivia, Peru, and Chile. For effective market entry and compliance, a comparative grasp of various regulatory regimes is necessary. The approval processes for 14 mg semaglutide tablets in various developing markets are assessed and contrasted in this study.

2. Global Market for Semaglutide 14 mg Tablets

The size of the global semaglutide Market was estimated at USD 28,429.9 million in 2024 and is expected to increase at a compound annual growth rate (CAGR) of 10.2% from 2025 to 2035, reaching USD 93,598.8 million. The growing incidence of type 2 diabetes and obesity, the need for GLP-1 receptor agonist, and the expanding use of weight-loss therapies are the main factors propelling the global Semaglutide market. (1)

From 2025 to 2035, the global semaglutide market is projected to develop at a compound annual growth rate (CAGR) of 10.5% from its estimted USD 28,429 million in 2024 to USD 93,598.8 million. The primary drivers of the global semaglutide market are the rising prevalence of type 2 diabetes and obesity, the need for GLP-1 receptor agonist,and the increased usage of weight-loss treatments. (2)

Figure 1. Semaglutide Market Size of 2018-2035 (1)

2.1 Major Market Players for Semaglutide tablet 14 mg

The major Players like Novo Nordisk , Eli Lilly , and other pharmaceutical companies are actively engaged in research and development , launching new formulation and exploring broader indications for oral semaglutide . This competetive environment will likely drive innovation and further market expansion. (3)

3. Introduction to Type-2 Diabetes

The most prevalent kind of diabetes, type 2, is brought on by an excessively high blood glucose, or blood sugar, level. Your Primary energy source, Blood glucose,is mostly derived from the food you eat. Your body either produces insufficient insulin or uses it poorly if you have type 2 diabete. Then, not enough glucose enters your cells and too much remains in your blood. (4) Although it is more common in middle-aged and older adults, type-2 diabete is also beginning more prevalent in young people. Initially, your beta cells compensate by producing more insulin. As time passes, your pancreas becomes unable to produce enough insulin to maintain normal blood glucose levels. (5)

3.1 What Causes of Type-2 Diabetes

Your pancreas, an organ located behind your stomach, helps your body retain and use sugar from food while you're healthy by releasing insulin. Diabetes is brought on by one or more of the following:

- It is not your pancreas that produces insulin.
- Insulin is not produced by your pancreas very often.
- Insulin does not have the desired effect on your body. (6)

3.2 Symtoms of Type-2 Diabetes

Type 2 diabetes symptoms frequently appear gradually. In actuality,person with type 2 diabetes may go years without realizing it.when symptoms are present,they could consist of as follows

- More thrist
- More Urination
- Frequuently hunger
- Wightloss (7)
- Dark Skin patches
- Dry Mouth
- Itchy Skin
- Nerve pains (8)

3.3 Traetement of Type-2 Diabetes

Oral Semaglutide Therapy :

- The active ingredient in Rybelsus 14 mg Tablets is semaglutide, a GLP-1 Receptor Agonist that is used to treat adult type 2 diabetes. (9)
- Before increasing dosages to 7 mg once daily,oral semaglutide therapy should begin at 3mg once daily for a month. After one Month of maintenance, the Dosage can be raised to 14mg once daily if needed Food and increased fluid intake might influence bioavailability, thus it is best to take this formulation on an empty stomach and wait 30 Minutes before eating or taking other drugs to maximize absorption. (10)
- Patients With type 2 diabetes who are at high risk for heart attacks, strokes, or death can also use this medication to reduce their risk. A glucagon-like peptide-1(GLP-1) receptor agonist is semaglutide.
- For patient with at least one weight-related medical problem, semaglutide is also used in conjunction with diet and exercise to help them lose weight and maintain it off. (11)

3.4 Semaglutide (Ozempic) Injection as an Intravenous Treatment option for Type-2 Diabetes

- The prescription medication Ozempic 1mg Injection is a member of the GLP-1 receptor agonist class. It functions similarly to a hormone that the body naturally produces to control blood sugar, hunger, and digestion. It is most effective when paired with regular exercise and a nutritious diet. (12)

- Ozempic injection beneath the skin of your upper arm, stomach, or thigh. It is administered once every seven days, or once a week. The preparation and administration of this drug will be taught to you. Use precisely as instructed. Take your prescription drug on a regular basis. Avoid taking it more frequently than prescribed. (13)

Table 1. Drug Profile of Semaglutide tablet 14 mg (14-16)

Sr no	General Drug Characteristics	Description
1	Brand Name	Rybelsus
2	Generic Name	Semaglutide
3	ATC Code	A10BJ06 (14)
4	Molecular Weight	4114gm/mol (15)
5	Molecular Formula	$C_{187}H_{291}N_{45}O_{59}$
6	Physiochemical Properties	White Hygroscopic Powder
7	Pharmacokinetics	Following oral Rybelsus treatment, food decreases the absorption of semaglutide, which has a low bioavailability (~1%) in the stomach. Within an hour, concentration reaches its peak, and it takes four to five weeks to achieve a steady level. It is mostly removed by urine and faces, is strongly protein bound (>99%), and is broken down by proteolysis and beta-oxidation. One week or so is the half-life.
8	Pharmacodynamics	By decreasing fasting and postprandial glucose levels, raising insulin production, and decreasing glucagon in a glucose-dependent manner without raising the risk of hypoglycaemia, semaglutide 1 mg subcutaneous injection enhances glycaemic control. Additionally, it lowers levels of very low-density lipoprotein (VLDL) and triglycerides and delays the emptying of the stomach.
9	Route of Administration	Oral
10	Dosage Strength	14g

4. Drug Profile of Semaglutide Tablet 14 mg

5.Semaglutide Tablets 14 mg are Falls Under NDA Application in Chile, Peru and Bolivia

- Semaglutide tablet 14 mg are Approved in USA and Europe so Registartion Route for Seamaglutide 14 mg are as Follows

Table 2. Type of Application Submission Route

Sr no	Country	Registartion Route
1	Chile (ISP)	Simplified Registartion
2	Peru (DIGEMID)	Category-II
3	Bolivia (AGEMED)	Verified Route

6. Preclinical and Clinical Requirements for Semaglutide tablet 14 mg

Semaglutide tablet 14 mg are alredy approved by FDA and EMA

- Instead of submitting the complete preclinical and clinical study reports, only the reference country's assessment report is submitted to the drug regulatory authorities of Chile (Instituto de Salud Publica de Chile),peru (Dirección General de Medicamentos, Insumos y Drogas), and Bolivia (Agencia Estatal de Medicamentos y Technologias en Salud) .(17)

7. Regulatory Requirement For Registartion of Semaglutide Tablet 14 mg in Chile

Chile Regulatory Authority : Public Health Institute (El Institute de Salud Publica de Chile))

- The first step in the registration process is to request admissibility using either the standard or simplified procedure. This step entails the initial assessment of the information and documents included in the dossier. After completing the Admissibility application form and providing the necessary regulatory information, the applicant must pay the fees.
- The admissibility application and fees are submitted by the applicant.

Reviewing the application form formally to ensure it is complete. In this case, ISP has ten days.

- If ISP issued Favourable decision towards completeness, a decision of admissibility is granted
- If Inadmissibility observed then applicant gets maximum period of 5 working days to solve the queries
- Again, a second evaluation has been conducted by ISP and decide whether admissibility shall grant or not
- In the second stage, known as the assessment stage, numerous factors, including as stability studies, FPS, validation of analytical techniques, and therapeutic equivalency, formulation raw

materials, GMP, etc. The product is registered with a unique identification number following a successful evaluation. The registration application may be denied if significant flaws are found during review. Products that successfully register are granted sanitary registration, which is good for five years after the date of issuance.

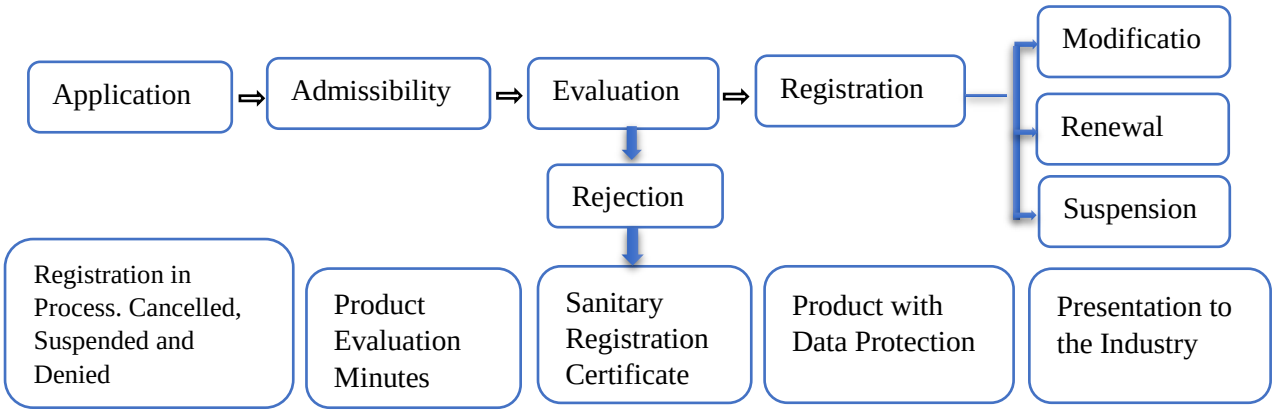

Figure 2. Flow Diagram of Sanitary Registration procedure (18)

8.Registartion Requirement of Semaglutide Tablet14 mg in Peru

Regulatory Authority : Genral Directorate of Medicine Supplies and Drug (DIGEMID)

- **Law No. 29459** : In Peru is regulated by Supreme Decree No. 016-2011-SA, which establishes comprehensive implementation guidelines and specifications for pharmaceutical registration, marketing authorization, quality standards, and regulatory supervision within the national drug regulatory framework. (19)

- **Types of Registartion Application**

Table 3. Different Categories for Drug Registration Application (20)

Category I	Category II	Category III
API of the product is present in the national petition for essential Medicines (PNME)	API of the product is not listed in PNME, and which are registered in France, Holland, UK, USA, Canada, Japan, Switzerland, German, Spain, Italy, Belgium, Sweden Norway, Australia and Denmark	The product whose API is not in categories I II, Comes Under the Category III

- **Procedure for Online Application Submission**

- The Application is made through an online portal known as **VUCE System (Single Window for Foreign Trade)** Which is governed by the Ministry of Foreign Trade (MINCETUR)Peru to apply through the VUCE System, Applicant must have

  a. Current health authorization as pharmaceutical establishment (Laboratory or Drugstore) which is granted by DIGEMID

  b. User ID & Password issued by MINCETUR

- The RUC number and access key (Password) is obtained from an official web portal called as **National Superintendency of customs and tax administration -SUNAT,** under operation Option (SOL) After apply through SUNAT they issued a SOL key/ Access key to applicant in sealed envelope then application is submitted. (21)

9. Bolivia Regulatory Registartion Process for Semaglutide tablet 14 mg

Regulatory Authority : State Agency for medicine and health tachnologies (Agencia Estatal de medicamentis y Technologies en Salud)

- Bolivia's national drug regulating body is called the Agencia Estatal de medicamentis y Technologias en Salud (AGEMED). It functions under The Ministry of health and is in charge of overseeing, regulating, and managing the nation's pharmaceuticals and medical technology.

- In addition to monitoring Good Manufacturing Practices (GMP), conducting pharmacovigilance, and ensuring adherence to quality, safety, and efficacy requirements, AGEMED is in charge of the sanitary registration (marketing authorization) of pharmaceutical goods. Its main goal is to safeguard the public's health by making sure that medications sold in Bolivia adhere to legal standards. (22)

Steps involed in Registration Procedure

The steps that combined comprise the semaglutide tablet 14 mg Registration process are as follows

A. Payment for Health Registration Service: Make a bank transfer to Account 3G-300, Ministry of Health and Sports, at the Central

Bank of Bolivia, in accordance with the costs of the Health Registration evaluation.

B. Issuing a Payment Order: At the counter, ask for the appropriate payment order (one for each product) using the bank deposit slip.

C. File Reception: Send the complete file, along with the sample and green copy of the payment order, to the Directorate of Medicines and Health Technology's archive window in compliance with the regulations.

D. File Evaluation: After the file is submitted, the requirements will be checked, and the submitted sample and documentation will be assessed. One of the following outcomes could happen:

- Approved
- Observation
- Rejected

E. Approved: The Evaluation and Registration Area will develop and sign the Health Registry, and the Directorate of Medicines and Health Technology will endorse it if all specified parameters and conditions are fulfilled.

F. Observation: A letter outlining any correctable technical, quality, efficacy, or safety observations will be provided to the relevant party. The interested party has 30 calendar days to rectify them by sending the relevant paperwork together with the Directorate of Medicines and Health Technology's remark. Only in extraordinary circumstances and upon written request may the file be given back to the interested person for this reason.

G. Rejected: The Directorate of Drugs and Health Technology's archive will return the file containing the rejection opinion to the interested party if the application is rejected because of significant observations, noncompliance with regulations, or a lack of any of the requirements listed in Chapter IV of Supreme Decree No. 25235 Regulations to the Drug Law. Within a maximum of 30 calendar days, a rejected file may be re-entered for a second evaluation with a copy of the second evaluation's payment order attached

H. Delivery of health Registration Certificate: The original Health Registration Certificate, along with the right to two free legalized copies, will be delivered within 30 business days of the date of entry to the Directorate of Medicines and Health Technology upon delivery of the invoice and bank deposit or check endorsed in the name of INLASA corresponding to the first post-marketing quality control. Copies of the obtained certificates must be signed by the Pharmaceutical Regent or an authorized representative.

I. Post-Marketing Quality Control and filling: As specified in Annex No. 10 Sampling and Quality Control, the Ministry of Health and Sports' Directorate of Medicines and Health Technology and the Medicines and Toxicology Quality Control Laboratory (CONCAMYT) will conduct the appropriate post-registration sampling and quality control analysis of the product. (23)

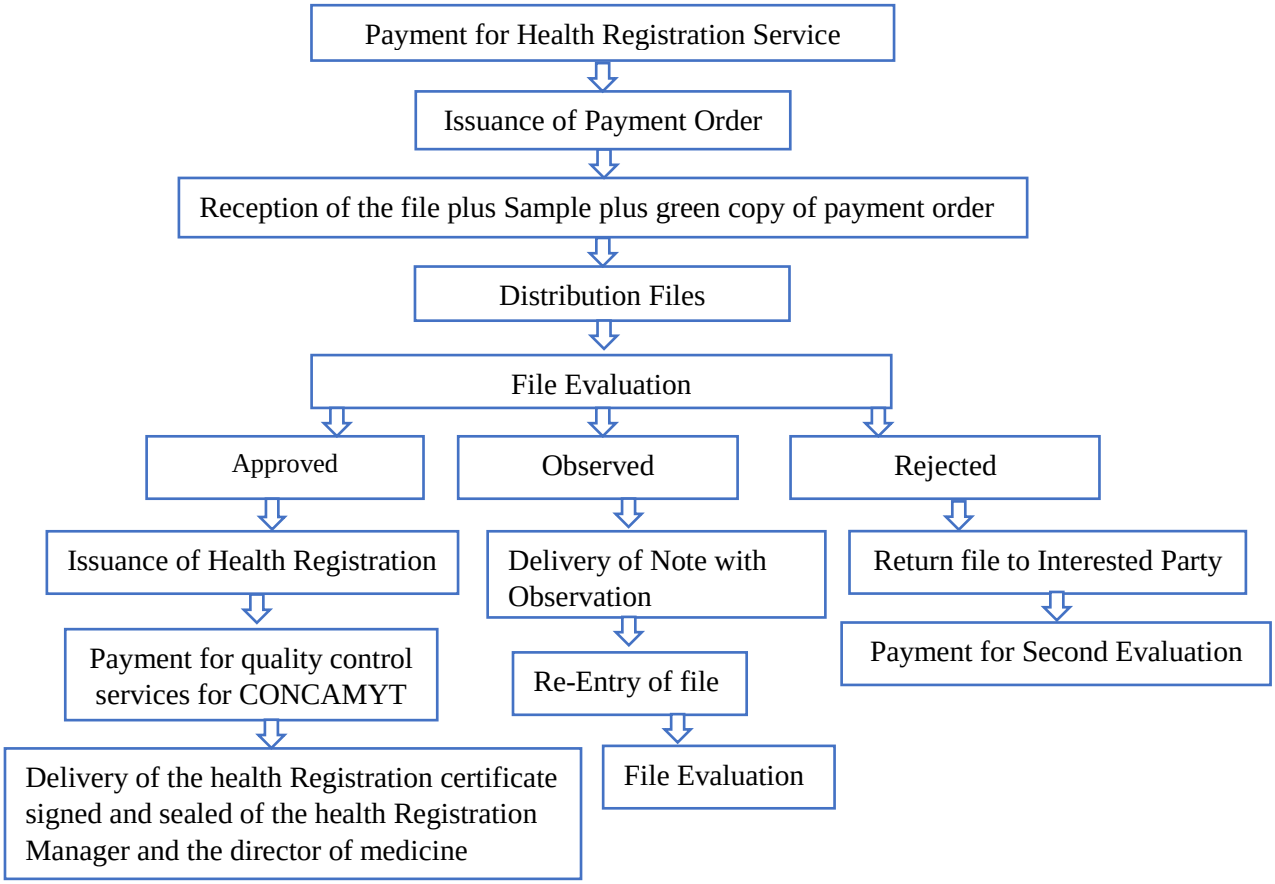

Figure 3. Flow Chart for Registration of Semaglutide 14 mg Tablet in Bolivia (24)

10. Comparative Overview for NDA Registartion Pathways for Semaglutide tablet 14 mg

Table 4. Regulatory Comparison of NDA Submission Routes for Semaglutide tablets 14 mg (25)

Sr no	Parameters	Chile (ISP)	Peru (DIGEMED)	Bolivia (AGEMED)
1	Regulatory Authority	Public Health Institute of Chile (ISP)	General Directorate of Medicines Supplies and Drugs (DIGEMED)	State Agency of Medicine and Health Technologies (AGEMED)
2	Drug Registration Act	Supreme Decree No.03/2010	Supreme Decree No. 016-2011-SA	Supreme Decree No. 25235
3	Application type	Simplified	Category II	Verified
4	Submission Format	CTD or eCTD	Country Specific	Country Specific
5	Supporting Regulatory Authority	National Medicine Agency (ANAMED)	National Institute of Health	Ministry of Health and Sports
6	Local Agent Requirement	Yes	Yes	Yes
7	Duration of Drug Product Registration	Ordinary Procedure: **180 Days** Simplified Procedure: **150 Days** Abbreviated Procedure: **120 Days**	Category I: 45 to 60 days Category II: 45 to 90days Category III: Up to 12 Months	Full Registration: 18-24 Months Homologation Route:**9-12 Month**
8	Online portal use for Submission of application	GICONA System	VUCE System	Offline Submission No Portal is there
9	Stability Zone	Zone- II	Zone-Iva	Zone-IVb
10	Validity of Registration	5 Year (renewable)	5 Year (renewable)	5 Year (renewable)
11	Labelling Requirement	Must be in Spanish	Must be in Spanish	Must be in Spanish
12	Electronic Submission	CTD or eCTD	Paper based	Paper Based
13	Regulatory Authority Website	https://www.ispch.cl/	https://www.digemid.minsa.gob.pe/webDigemid/	https://www.agemed.gob.bo/
14	GMP Certificate	Required	Required	Required
15	CPP Certificate	Required	Required	Required

11. Conclusion

While preserving national procedural differences, the regulatory processes for Semaglutide 14 mg tablets in Chile, Peru, and Bolivia show conformity with worldwide CTD-based standards. While Agencia Estatal de medicamentos y technologias en salud mostly uses a complete evaluation model, the Instituto de salud Pública and Direccion General de medicamentos, Insumos Y Drogasoffer more structured or reliance-based procedures that can enable expedited approvals. Therefore, to guarantee effective approval and a successful market debut in these developing South American markets, a carefully thought-out, nationally tailored regulatory approach is necessary.

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Conflict of Interest

The authors declare that there is no any Conflict of interest regarding publishing this article.

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