Avibela Harmonized Labeling Initiative

Final Brief – Nonconfidential Version

January 2022

IMPACT™ RH360

fhi360
THE SCIENCE OF IMPROVING LIVES

WCG
EMPOWER EDUCATE ENABLE

Abbreviations

AE	Adverse Event
CARPHA	Caribbean Public Health Agency
CRS	Caribbean Regulatory System
EAC-MRH	East African Community Medicines Regulatory Harmonization
LMICs	Low- and Middle-Income Countries
MAH	Marketing Authorization Holder
PIL	Patient Information Leaflet
PV	Pharmacovigilance
NMRA	National Medicines Regulatory Authority
PANDRH	Pan American Network for Drug Regulatory Harmonization
SKU	Stock Keeping Unit
SME	Subject Matter Expert
SmPC	Summary of Product Characteristics
SRA	Stringent Regulatory Authority
UNFPA	United Nations Population Fund
USAID	United States Agency for International Development
ZaZiBoNa[1]	Southern Africa harmonized regulatory initiative

1 The acronym ZaZiBoNa was derived from the first two letters of the founding countries (Zambia, Zimbabwe, Botswana, Namibia), although the initiative has expanded beyond these four countries.

Acknowledgements

The LEAP Initiative – which stands for Learning about Expanding Access and Potential of the LNG-IUS – is funded by the Bill & Melinda Gates Foundation and is led by FHI 360 in partnership with PSI, WCG Cares, Society for Family Health, and Impact RH360 (the latter being a subsidiary of Medicines360). The contents of this report are the sole responsibility of Impact RH360, FHI 360, and WCG Cares.

Executive Summary

- Harmonizing pharmaceutical product labeling (i.e., using identical labeling across multiple countries) can create time and cost efficiencies that benefit stakeholders across the value chain. Not surprisingly, the two largest global contraceptive procurers, USAID and UNFPA, strongly prefer that manufacturers supply products with harmonized labeling. Despite the clear benefits, there is little publicly available information for manufacturers and suppliers who want to pursue harmonized labeling of their products.
- Under the LEAP Initiative, Impact RH360, WCG Cares, and FHI 360 developed a strategy to implement harmonized labeling for the hormonal IUD, Avibela[1]. The project team is disseminating the learnings from this project to enable other suppliers to implement harmonized labeling for their products, if desired.
- The project team conducted extensive desk research on the labeling requirements issued by regulators in 21 LMICs and conducted 12 interviews with SMEs from procurement agencies, donors, manufacturers of similar products, and independent global regulatory consultancies.

1 Avibela is a registered trademark of Medicines360 in select LMICs.

Executive Summary, continued

- Key findings from desk research and interviews included:
  - Some level of harmonization is possible for the majority of the 21 countries assessed.
  - The approved harmonized labeling of similar products sometimes deviates from the guidelines published by regulators.
  - While label harmonization requires negotiation with individual regulators, proactive engagement with the regulators (i.e., before submission of revised labeling) appears to have little value.
  - In discussions with the regulators, it is crucial to have a clear value proposition for the product. Regulators are more willing to make allowances for products that are readily available, inexpensive, and respond to critical health needs.
  - While large global procurers like USAID and UNFPA prefer multi-language harmonized labeling, other long-acting reversible contraceptives (LARCs) have been procured in large volumes with single-language harmonized labeling.
  - Local contact information for PV reporting appears to be less of a priority for regulators and procurers compared to other requirements.
- These findings led Impact RH360 to develop a phased strategy for harmonized labeling for Avibela, in order to benefit from some level of harmonization in the relative short-term while allowing adequate time for the more extensive changes required for multi-language harmonized labeling.

TABLE OF CONTENTS

Introduction & Overview

The Case for Harmonized Labeling

- When pharmaceutical manufacturers and suppliers seek to distribute a drug product in a country, they must first receive authorization from the National Medicines Regulatory Authority (NMRA). Typically, the NMRA publishes specific guidelines outlining the requirements for a regulatory submission, and nearly always these guidelines include requirements for pharmaceutical product labels that vary in content and format.
- Harmonizing pharmaceutical product labeling (i.e., using identical labeling across multiple countries) can create time and cost efficiencies that may benefit stakeholders across the value chain. These efficiencies may result from several factors:
  - reductions in human and capital resource requirements for label creation, printing, and packaging since the same label is used for many countries,
  - more flexibility in the supply chain: manufacturers, procurers, and distributors can deploy the same stock to numerous destinations, including countries using different languages,
  - decreased risk of labeling inconsistency and errors, and
  - less wastage (some packaging printers require minimum order quantities, which can be challenging to achieve with country-specific labeling, especially during the early stages of product introduction).
- Not surprisingly, the two largest global contraceptive procurers, USAID and UNFPA, strongly prefer that manufacturers supply products with harmonized, multi-language labeling.

Key Challenges

- Despite these clear benefits, there is limited publicly available information for manufacturers and suppliers who want to pursue harmonized labeling of their products.
- One element of labeling that the team believed would pose a particular challenge to harmonization is pharmacovigilance reporting information (i.e., the process through which healthcare providers and patients/clients can report suspected adverse drug reactions). Typically, NMRAs request that the label include contact information for the manufacturer's local technical representative or distributor and the national regulatory authority.
- In addition, when a product supplier makes changes to a product approval, NMRAs must typically approve any resulting label changes. Since review timelines can vary significantly by country, even a previously harmonized label may no longer be identical across all relevant countries for extended periods of time.

Project Goals

01 Develop a strategy to implement harmonized labeling for Avibela

02 Disseminate learnings to enable other organizations to implement harmonized labeling for their products

Method Overview

- The hormonal IUD was developed by the Population Council and was first approved in Finland in 1990. The method was approved in the U.S. in 2000, and use has steadily grown, leading to a revitalization in the IUD market. Unfortunately, the method has not been available at scale in any FP2020 focus country, largely due to the upfront product cost of the innovator product.[1]

- In 2015, the nonprofit pharmaceutical organization Medicines360 received SRA approval of their hormonal IUD. The relative low price of this product created momentum around the consideration of the hormonal IUD as a viable contraceptive option for women in LMICs. In the same year, the WHO added the hormonal IUD to the model Essential Medicines List and released an Expression of Interest for Pre-Qualification of the method.

> ***"In 2015, there was of course a new Stringent Regulatory Authority-approved product that was approaching a price point that was feasible for [LMIC] introduction. And so there was a convening of a global working group that was established to evaluate this potential to expand access of the hormonal IUS..."***
>
> – Tabitha Sripipatana, Deputy Division Chief, USAID's Office of Population and Reproductive Health[2]

- This newly formed working group developed a global learning agenda for the hormonal IUD. Its members conducted eight pilot studies from 2017-2020. The results showed an unmet need for the hormonal IUD and high user satisfaction and continuation rates.[3]

- In 2020, this working group, now called the **Hormonal IUD Access Group**, supported the acceleration of hormonal IUD introduction in LMICs, including developing a global forecast for hormonal IUD demand and scale-up in LMICs. In 2021, USAID and UNFPA added the hormonal IUD (Avibela and Mirena®) to their product catalogs.

1. Rademacher KH, Sripipatana T, Pfitzer A, et al. A global learning agenda for the levonorgestrel intrauterine system (LNG IUS): addressing challenges and opportunities to increase access. Glob Health Sci Pract. 2018;6(4):635-643. https://doi.org/10.9745/GHSP-D-18-00383
2. Sixth International Symposium on IUDs: Event 3: Programs Increasing Access to IUDs and IUSs in the US and Lower- and Middle-Income Countries, January 27, 2021
3. "Hormonal IUS: Five Key Questions". Kate Rademacher (FHI 360), Kendal Danna (PSI), Deborah Sitrin (Jhpiego), Aurelie Brunie (FHI 360). June 24, 2020.

Product Overview

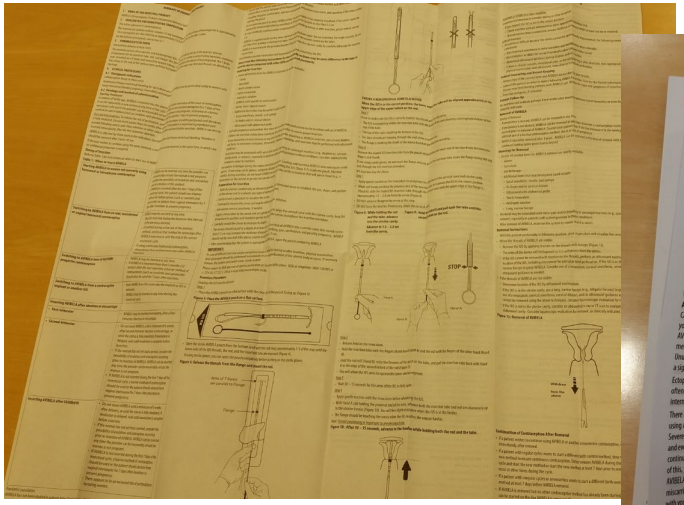
- The nonprofit pharmaceutical company, Medicines360, was founded in 2009 to bring an affordable hormonal IUD to market in the U.S. Medicines360 sourced a 52 mg hormonal IUD in development in Europe and conducted a large Phase 3 clinical trial in the U.S. This product, under the brand name Liletta®, was initially approved by the U.S. FDA in 2015 for contraception for up to 3 years of use and the product has received subsequent U.S. FDA approvals for up to 4, 5, and 6 years of use.
- In 2014, Medicines360 created Impact RH360, a wholly owned subsidiary, to focus on introducing their hormonal IUD in LMICs. Impact RH360 began efforts to register Avibela in 2015. As a small non-profit organization with no prior experience registering products in LMICs, Impact RH360 believed it was necessary to strictly adhere to NMRA labeling guidelines, resulting in unique labeling for each country. As the number of Avibela registrations and orders grew, the country-specific labeling, coupled with a small average order size, resulted in multiple inefficiencies. When the Impact RH360 team started exploring labeling harmonized across multiple markets, they realized that many pharmaceutical companies used harmonized labeling (particularly when supplying global procurers), but there was no publicly available information about how they were able to secure NMRAs approval of labels that did not follow their country-specific guidelines.
- At the time of this writing, Avibela is approved in six sub-Saharan African countries with additional approvals pending. Now that Avibela is in the USAID and UNFPA catalogs, Impact RH360 is accelerating registration activities. Impact RH360 works with global NGOs and pharmaceutical companies with local infrastructure to make the product available to women who want it.

Avibela Labeling Components (for the two-handed inserter product)

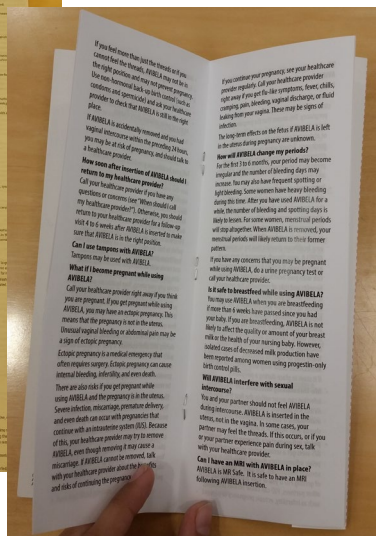
Component[1]	Description
Pouch Label	• Affixed to the primary packaging (sterile pouch)
Summary of Product Characteristics (SmPC)	• Audience: Healthcare providers • Contains instructions for use, including the insertion and removal procedure
Patient Information Leaflet (PIL)[2]	• Audience: Patients • Contains instructions for use, including what to expect when using the product, like bleeding patterns and common side effects
Unit Carton	• Secondary packaging for Avibela • Each carton contains one unit in a sterile pouch, along with the SmPC and PIL

1 One additional labeling component, the directional sticker, was excluded from our analysis. It consists of an arrow and the text "Open Here".
2 The PIL consists of two labeling components – the cover artwork and the leaflet text. For the purposes of this report, we will refer to them as a single component.

Summary of Product Characteristics

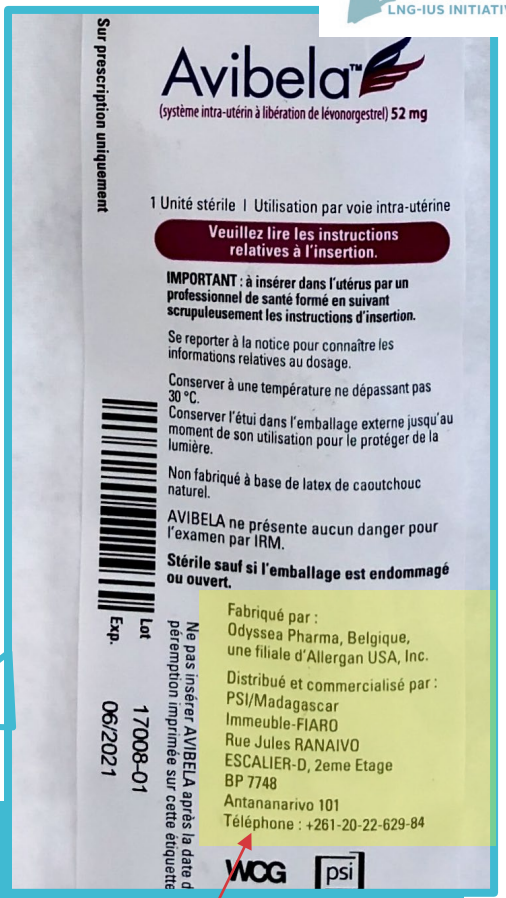


Patient Information Leaflet



Sterile pouch

Unit Carton



Country specific information

Example: Avibela Labeling for Madagascar

Key Project Activities

From November 2020 to October 2021, the team implemented two main workstreams:

Desk review: The project team conducted extensive desk research on the labeling requirements of regulators in 21 countries.

SME Interviews: Conducted 12 interviews with subject matter experts from procurement agencies and donors, other manufacturers of similar products, and independent global regulatory consultancies.

After the desk review and SME interviews were completed, Impact RH360 developed a short- and long-term labeling strategy and drafted the first version of the harmonized labeling for Avibela.

Desk Review Process

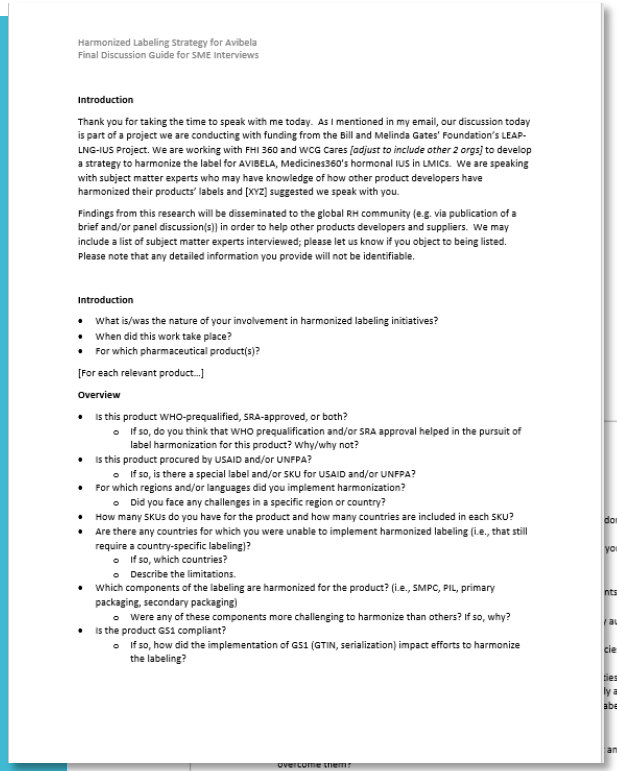
- Impact RH360 selected 21 countries[1] to include in the harmonized labeling assessment for Avibela
- Countries were selected based on current approvals, pending approvals, and planned countries for registration. Criteria for prioritization include:
  - Hormonal IUD Access Group prioritization (which is based on country interest in the product, and their readiness to introduce it)
  - Participation in WHO Collaborative Registration Procedure (CRP)
  - Existing and potential distributor interest
  - Internal tiering system, which considers a number of factors including donor interest, FP2020/2030 commitments, number and proportion of women with unmet need for modern contraception, and proportion of women using IUDs
- Impact RH360 and WCG Cares conducted a thorough review of labeling guidance[2] published by local regulatory agencies, as it applied to the Avibela labeling components
- The project team also gathered examples of harmonized labeling for contraceptives and other products in many LMICs. These examples helped the team understand the precedent for harmonized labeling approved by specific NMRAs as well as the harmonization strategy of other suppliers.

1 Bangladesh, Cambodia, Cote D'Ivoire, Democratic Republic of Congo (DRC), Ethiopia, Ghana, Kenya, Madagascar, Malawi, Malaysia, Mali, Nigeria, Rwanda, Senegal, South Africa, Sri Lanka, Tanzania, Uganda, Vietnam, Zambia, and Zimbabwe.
2 Labeling guidelines for the DRC and Mali were not available online. Guidelines were requested from the regulators with no response.

SME Interview Process

The project team solicited feedback from key stakeholders involved in the provision of pharmaceutical products in LMICs. For this reason, it was a priority for the team to interview the largest global procurers of global health products, USAID and UNFPA, as well as manufacturers who supply similar products.

At the start of this project, the “why” of harmonized labeling was clear, so in discussion guides, the team focused primarily on “how” harmonized labeling has been achieved for other similar products. Interviews with current and former supplier representatives were particularly instrumental in developing the harmonized labeling strategy for Avibela.



Harmonized Labeling Strategy for Avibela
Final Discussion Guide for SME Interviews

Introduction

Thank you for taking the time to speak with me today. As I mentioned in my email, our discussion today is part of a project we are conducting with funding from the Bill and Melinda Gates' Foundation's LEAP-LNG-IUS Project. We are working with FHI 360 and WCG Cares *[adjust to include other 2 orgs]* to develop a strategy to harmonize the label for AVIBELA, Medicines360's hormonal IUS in LMICs. We are speaking with subject matter experts who may have knowledge of how other product developers have harmonized their products' labels and [XYZ] suggested we speak with you.

Findings from this research will be disseminated to the global RH community (e.g. via publication of a brief and/or panel discussion(s)) in order to help other products developers and suppliers. We may include a list of subject matter experts interviewed; please let us know if you object to being listed. Please note that any detailed information you provide will not be identifiable.

Introduction

- What is/was the nature of your involvement in harmonized labeling initiatives?
- When did this work take place?
- For which pharmaceutical product(s)?

[For each relevant product…]

Overview

- Is this product WHO-prequalified, SRA-approved, or both?
  - If so, do you think that WHO prequalification and/or SRA approval helped in the pursuit of label harmonization for this product? Why/why not?
- Is this product procured by USAID and/or UNFPA?
  - If so, is there a special label and/or SKU for USAID and/or UNFPA?
- For which regions and/or languages did you implement harmonization?
  - Did you face any challenges in a specific region or country?
- How many SKUs do you have for the product and how many countries are included in each SKU?
- Are there any countries for which you were unable to implement harmonized labeling (i.e., that still require a country-specific labeling)?
  - If so, which countries?
  - Describe the limitations.
- Which components of the labeling are harmonized for the product? (i.e., SMPC, PIL, primary packaging, secondary packaging)
  - Were any of these components more challenging to harmonize than others? If so, why?
- Is the product GS1 compliant?
  - If so, how did the implementation of GS1 (GTIN, serialization) impact efforts to harmonize the labeling?

don't provide local

you described?

nts with regulatory

authorities in this

cies in SSA and/or

ties?

y around PV reporting

abel)?

and how did you

overcome them?

- What have been the biggest benefits to harmonizing the labeling for this product?
- Have there been any unintended negative consequences and/or drawbacks to harmonizing the label that you did not foresee?
- Are you able to send us example(s) of the harmonized labeling for this product/these products?
- Is there anything else that you want to add that you think is important to consider as part of our strategy to harmonize Avibela labeling?
- Is there anyone else you recommend we speak with?

Dissemination of Findings

- Do you have any suggestions for how we could best disseminate the findings from our research (e.g., format, setting, etc.)?
- Are you interested in contributing to the dissemination of the findings from our research?

Key Findings

Desk Review Findings

- The team compiled the labeling requirements from 19 of the selected countries, with a particular focus on country-specific variable information and local language requirements, as these are the main barriers to label harmonization (see summary table on next slide).
- The team also gathered examples of harmonized labeling for other products approved in multiple LMICs, including Implanon®, Nexplanon®, Levoplant®, Jadelle®, and Mirena®.

Labeling Component Requirements

Component	Country-Specific Variable Information Required	Languages Required in 21 Countries Assessed
Pouch Label	MAH name and address, local registration number, registration number in the country of origin, scheduling status, requirement for "generic name to be more prominent on the label than trade name"	• Afrikaans[1] (South Africa) • Bahasa (Malaysia) • English – 13 countries (Bangladesh, Cambodia, Ethiopia, Ghana, Kenya, Malawi, Nigeria, Rwanda, Sri Lanka, Tanzania, Uganda, Zambia, Zimbabwe) • French – 5 countries (Cote d'Ivoire, DRC, Madagascar, Mali, Senegal) • Vietnamese (Vietnam)
Summary of Product Characteristics	MAH name and address, contact info for AE reporting, registration number, scheduling status, date of first authorization & renewal. Note: format requirements also vary slightly	• Afrikaans[1] (South Africa) • English – 14 countries (Bangladesh, Cambodia, Ethiopia, Ghana, Kenya, Malawi, Malaysia, Nigeria, Rwanda, Sri Lanka, Tanzania, Uganda, Zambia, Zimbabwe) • French – 5 countries (Cote d'Ivoire, DRC, Madagascar, Mali, Senegal) • Vietnamese (Vietnam)
Patient Information Leaflet	Local registration number, scheduling status. Note: required format also varies slightly	• Afrikaans[1] (South Africa) • Bahasa (Malaysia) • English – 12 countries (Bangladesh, Cambodia, Ethiopia, Ghana, Kenya, Malawi, Nigeria, Rwanda, Tanzania, Uganda, Zambia, Zimbabwe) • French – 5 countries (Cote d'Ivoire, DRC, Madagascar, Mali, Senegal) • Sinhala, Tamil (Sri Lanka) • Vietnamese (Vietnam)
Unit Carton	MAH name and address, and local registration number	• Afrikaans[1] (South Africa) • English – 14 countries (Bangladesh, Cambodia, Ethiopia, Ghana, Kenya, Malawi, Malaysia, Nigeria, Rwanda, Sri Lanka, Tanzania, Uganda, Zambia, Zimbabwe) • French – 5 countries (Cote d'Ivoire, DRC, Madagascar, Mali, Senegal) • Vietnamese (Vietnam)

1 Or any of South Africa's other 12 local languages

SME Interview Findings

- Harmonized labeling is preferred by all stakeholders, as it increases efficiencies by reducing lead times and costs (e.g., manufacturing, stockkeeping).
- However, achieving and maintaining harmonized labeling across many markets is complex and resource-intensive. “Over-harmonization” (i.e., having too many countries under the same SKU) can result in diminishing returns. That is, a change required by one NMRA requires a change to the labeling for all other countries under the same SKU.
- SMEs do not believe there is an advantage to proactive engagement with NMRAs but do believe a strong value proposition (e.g., low-cost product, fills an unmet need) is needed to advance regulatory approval of standard labeling.
- The country-specific variable data requirements that make label harmonization difficult were put in place by local regulators under advisement of WHO to reduce the risk of fraudulent/diverted product making its way into the market and this risk must be considered in harmonization efforts.
- Pharmacovigilance reporting contact information does not, in fact, represent a significant barrier to label harmonization as there is already a precedent for the acceptability of global (vs. local) contact information.
- WHO pre-qualification of products is helpful for harmonization as local regulators generally accept the standard labeling approved by the WHO.

Global Procurement Agencies

- The procurers we spoke with indicated a strong preference for labeling that is applicable to as many markets as possible (i.e., multi-language harmonized labeling) to decrease lead times and allow stockkeeping of product. It is common for suppliers to only have 1 or 2 SKUs for the major global procurers.
- Historically, specific obstacles to harmonizing labeling have not been well characterized. Therefore, these obstacles may not be clear to procurers.
- Procurers are in ongoing discussions with manufacturers and regulators to encourage consolidation of labeling requirements.
- Procurers also noted that it is important to engage with Medicines Regulatory Harmonization initiatives such as EAC-MRH and ZaZiBoNa in Africa and PANDRH, CRS and CARPHA in Latin America.

Manufacturers & Suppliers

- The suppliers interviewed shared that they achieved harmonized labeling in the vast majority of LMICs.
  - They primarily harmonize labeling by language, followed by region. Some suppliers use single-language labeling while others have implemented dual-language labeling (primarily English/French). Some suppliers note that multi-language labeling sometimes requires artwork redesign and validation of new label sizes which can be a barrier to harmonization.
  - It is best to harmonize at the component level and it is most critical to harmonize the pouch label, since the pouch label typically has the biggest impact on manufacturing efficiencies and minimum order quantities.
  - Suppliers confirm that harmonized labeling deviates from local regulatory guidelines in many instances and should be negotiated during the review process.
  - Some suppliers have told regulators that approving harmonized labeling is a requirement to be eligible to receive product from global procurement agencies.
  - Several also noted that regulators are more willing to make allowances for products that are readily available, inexpensive, and respond to critical health crises (e.g., antiretrovirals).
- Some suppliers allow distributor requests for specific packaging for the private sector, but the cost of producing the specialized labeling is passed on to the purchaser.

Outcomes & Next Steps

Avibela Labeling Harmonization Plan

Short-Term

- Single language labeling
- Does not require the manufacturer to validate new labeling sizes
- Allows Avibela to achieve some level of harmonization in the relative short-term

Long-Term

- Explore potential for multi-language labeling (would require redesign of the artwork and validation of new labeling sizes for some components)
- To be aligned with future label changes
- Potentially allows Avibela to achieve further harmonization

Country SKU Proposal for Harmonized Labeling

Group 1: English Harmonized v1

Bangladesh, Cambodia, Ethiopia, Ghana, Kenya, Malawi, Nigeria, Rwanda, Tanzania, Uganda, Zambia, Zimbabwe

Group 2: English Harmonized v2

Malaysia, Sri Lanka

Group 3: French Harmonized

Cote D'Ivoire, DRC, Madagascar, Mali, Senegal

Pharmacovigilance Reporting

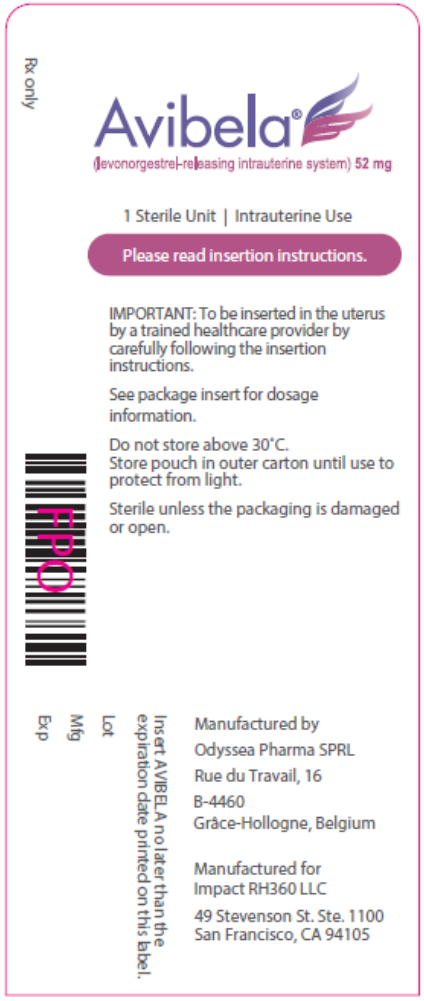
Currently, the country-specific labeling for Avibela contains local contact information for pharmacovigilance reporting. Based on learnings from this initiative, our planned solution is to build a webpage (accessible at avibelapv.net, avibelapv.com, and avibelapv.org) that includes current contact information for all local distributors and/or local technical representatives for each country where Avibela is distributed. This webpage also includes the contact information for the local regulatory authority in each country. In addition, RH360 created a QR code which opens this URL upon being scanned by a smartphone (try it!). A QR code is an innovative, novel approach that has not yet been submitted to or approved by any NMRA for this product.

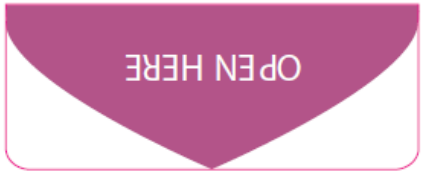
Harmonization Strategy for English Labeling Components

Component	Harmonization Proposal
Pouch Label	• Variable info: MAH (Impact RH360)
Summary of Product Characteristics	• Variable Info: MAH and address • Format to be aligned with EU labeling • PV: A URL will be provided for a webpage where contact info can be found
Patient Information Leaflet	• Variable info: MAH and address • Format to be aligned with EU labeling • PV: Patients will be referred to their HCP for reporting of suspected adverse reactions
Unit Carton	• Variable info: MAH and local registration number for all markets

Harmonized English

Pouch Label & Directional Sticker





- ***Removed distributor information***
- ***Removed product registration numbers***

Harmonized English

Patient Information Leaflet

- ***Removed patient consent form and follow-up card***

- ***Removed in-country distributor information and left manufacturer and MAH information:***

Manufactured by:
Odyssea Pharma SPRL
Rue du Travail, 16
B-4460
Grâce-Hollogne, Belgium

Manufactured for
Impact RH360 LLC
49 Stevenson St. Ste. 1100
San Francisco, CA 94105

- ***Removed local PV contact info and replaced with guidance for patient to contact HCPs about side effects:***

Reporting of side effects
If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your healthcare provider.

Harmonized English

Summary of Product Characteristics

➢ ***Removed distributor information***

7. SUPPLIER AND MANUFACTURER

Supplied by:
Impact RH360 LLC
49 Stevenson St., Suite 1100
San Francisco, CA 94105
Telephone: 1-415-951-8700

Manufactured by:
Odyssea Pharma SPRL
Rue du Travail, 16
B-4460
Grâce-Hollogne, Belgium

Date of revision of the text: 17/05/2021

➢ ***Removed local PV contact info and added global URL and QR code***

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system or to the local partner. Patients are encouraged to call their healthcare provider if they have any concerns about AVIBELA and patients may also report any suspected adverse reactions via the national reporting system or to the local partner. Contact information for the national reporting systems and local partners can be found at www.avibelapv.com.

Marketing authorization number(s):

Kenya: H2019/CTD5856/1070ER
Zambia: 125/010
Nigeria: NAFDAC REG. NO. 03-7235
Tanzania: TAN 21 HM 0241
Rwanda: TBD
Uganda: NDA/MAL/HDP/9791

➢ *Added all current product registration numbers (instead of listing only a few on pouch label)*

➢ *Removed local distributor information*

Harmonized English

Unit Carton

Manufactured by
Odyssea Pharma SPRL
Rue du Travail, 16
B-4460
Grâce-Hollogne, Belgium

Manufactured for Impact RH360 LLC
49 Stevenson St. Ste.1100
San Francisco, CA 94105

Next Steps

- Impact RH360 is in the process of submitting post-approval variations to achieve regulatory approval of the new harmonized labeling in countries where Avibela is already approved, combining with other updates such as manufacturing changes and extensions of shelf-life and duration of use.
- To date, the French harmonized labeling for Avibela has been approved by the Direction de l'Agence du Médicament de Madagascar and the English harmonized labeling has been approved by the Pharmacy and Poisons Board in Kenya.
- The Spanish harmonized label will be used for the first time for an order of Avibela for a Latin American country in 2022.

Appendix

Project Team

Andree Sosler, MBA
Former Sr. Director, Impact & Global Access, Impact RH360

Kelly Dannucci
Sr. Manager, Global Access
Impact RH360

Mark R. Busch, PhD
SVP, QA & Product Safety
Impact RH360

Emily Morris, MS, RAC
Associate Director, RA
Impact RH360

Tracey Brett, MCIPS
Supply Chain & RA Consultant, DKT, FHI 360

Kate Rademacher, MHA
Sr. Technical Advisor
FHI 360

Wilberto Robles, MS
Sr. Director, Global RA/QA
WCG Cares

Courtney Stachowski, MPH
Program Manager
WCG Cares

Mbavhalelo Jade Tshikosi, MS
Global RA Consultant

Markus Steiner, PhD
Sr. Epidemiologist, Product Dev/Introduction, FHI 360

Selected Organizations Interviewed

- AbbVie Inc
- Bill & Melinda Gates Foundation
- DDReg Pharma Regulatory Solutions
- FHI 360
- Gynuity Health Projects
- International Planned Parenthood Federation
- Organon
- Partnership for Supply Chain Management
- Zwiers Regulatory Consultancy