Design and Implementation of a Green Light Signal Process for Regulatory PMO Team

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Abstract *— The Project Management Office (PMO) Regulatory Team, manages regulatory projects that include in the scope all countries globally that can import and distribute their products. The Master Regulatory Schedule (MRS) is prepared with the countries' outcome to provide visibility to the Franchise and Supply Chain (SC) of the projects that are in the process of being implemented. Challenges for Supply Chain to provide accurate data into the Master Regulatory Schedule and for countries to review the data provide and align dates have been evaluated to identify the risks for restricted countries that cannot receive the previous product after submitting or approving the new product. The main goal is to achieve supply continuity in all countries and avoid any disruptions in product supply by implementing a Green Light Signal. The Project Management Office team started gathering feedback to improve the process, reduce workload, identify priorities, and avoid and mitigate risks.*

Key Terms *— Green Light Signal, PMO, Restricted countries, Supply Continuity*

PROJECT DESCRIPTION AND OBJECTIVES

The PMO and SC are experiencing challenges with high inventory build ups due to lack of understanding and tracking of countries transition dates to the new product. PMO team discussed with the SC team the process and receive input regarding information that can be valuable for them to analyze better the information provided in the Master Schedule Report. The PMO team also provided feedback to the Supply Chain team on how to provide clearer feedback that could have been translated into "needed by" dates to the countries. Other improvements for traceability and prioritization and reduce manual work as well will be introduced to the scope of the project.

Project Objectives

One of the goals for the business is to avoid and mitigate the product supply gaps in the countries. In this type of project where all portfolio is impacted it is of high importance that all teams work together to meet the expectations so the project can be implemented successfully but there are multiple variables affecting the implementation of the project that ultimately add risks to the projects. The high volume of projects, countries and products makes the identification of risks a complex process. To achieve the goal of properly identifying the risks of supply chain gaps in the countries, PMO decided to map out the process and understanding the Supply Chain needs as well as their own needs to mitigate risks and identify new risks. The process of identification of risks and having alignment with Supply Chain and the countries will be called The Green Light Signal Process. During the Green Light Signal process, the feedback gathered by Supply Chain and the countries will be analyzed to define when there is alignment between Supply Chain and Countries and when there is no alignment and there are risks for countries that are restricted. Countries that are restricted are the ones that cannot receive the new product and the old product at the same time. When we refer to the new product, we refer to the product that will be compliant with the new regulation and the old product is the one the country is already receiving. When an alignment is reached will mean that the country estimated submission date and approval dates are aligned with supply chain dates or feedback, and Green Light Signal will be used for identification and tracking.

Process Description

The process starts with the Business decision of transitioning a project to PMO Team. The PMO team schedules a project kick off meeting with the countries in scope of the PMO Team. See Figure 1 for all countries in scope and their respective Region.

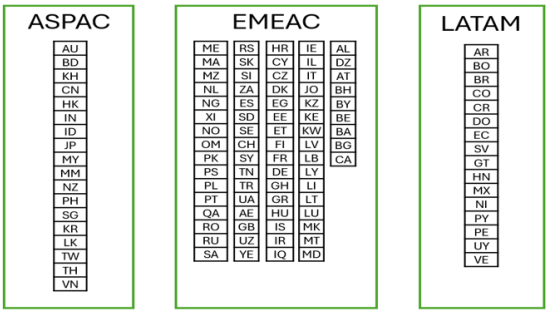

Figure 1
List of Countries in Scope of the PMO Projects

Information provided at this stage of the process used as input for the countries is listed in Figure 2, under Franchise Transition. Countries in scope of the project will assess the changes and report a country's outcome. The country assessments completed in the Regulatory Platform can be exported to excel for the planning team to start analyzing the data and calculating timelines. The Master Schedule Report includes 17 number of columns that are described in the next section that includes, project information, timelines, SC feedback, and Country feedback. Supply chain reviews the Master Schedule Report and provides feedback to PMO if they understand there are risks associated with the supply continuity of the product for either the old product or the new product. Supply chain needs to review the status of each country registration to maintain inventory numbers updated to satisfy countries demand as well as interpret country restrictions to understand the new product transition dates or the importation date of the new product by country to finally determine if the importation dates are aligned with the new product manufacturing readiness. The SC feedback is shared with countries for them to review and confirm by email or in the MRS Country feedback column if they can align their submission of the regulatory action with the SC proposed date or improve the submission based on the risks highlighted. The report is also reviewed by Franchise to document assessment outcome and highlight risks, if necessary. The new product refers to the product that will contain the changes implemented and old product refers to the product that is currently being received and distributed to the countries. The flowchart of the process depicts all stages of the process from project transition to PMO team to the SC review and feedback. The process, inputs and outputs are described in Figure 2.

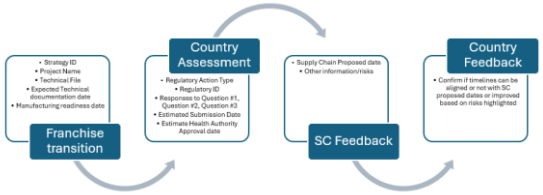

Figure 2
PMO Process Flowchart

Master Regulatory Schedule Report Columns and Columns Description

In this section all columns of the Master Regulatory Schedule are listed and described. The MRS file is available in Appendix A.

- Column A: Strategy ID
- Column B: Project Name
- Column C: Technical file (TF) name
- Column D: TF Description
- Column E: Expected technical documentation date
- Column F: Region
- Column G: Country
- Column H: Manufacturing readiness date
- Column I: Question #1) When the new version can be imported? –when the country can start receiving the new product.
- Column J: Question #2) After Regulatory Action, can countries receive both versions? –if country is allowed to receive both versions after the regulatory action specified on column I.

- Column K: Question #3) How long can country receive old version? – how long the country can continue to receive the old version of the product if the answer on column J was "Yes".
- Column L: Estimated Submission Due date
- Column M: Estimated Health Authority Approval due date
- Column N: Submission Actual
- Column O: Health Authority Actual
- Column P: SC feedback
- Column Q: Country Feedback

Supply Chain & PMO Team Challenges with The Master Regulatory Schedule and Input for Process Improvement

Supply Chain receives the Master Schedule Report by email, and they review the data and provide feedback in column P. They upload the Master Schedule Report to a SharePoint where countries go and review SC feedback and answer if they can improve or not their registration timelines to align with the SC feedback. From the PMO team perspective the volume of the projects has been increasing and it has been more difficult to receive feedback from SC ad hoc (no frequency required) and without any particular format. There is no harmonized SC feedback that can be communicated to the countries without PMO team having to go back to SC to ask and reconfirm what is their need. Also, SC misinterpret frequently the country answer to the questions in columns I and J or due to the high volume of columns in the file they filter incorrectly as well as input feedback in the incorrect row.

The SC feedback regarding the file is similar to the PMO observations. For example, the high volume of columns increases the probability of errors in the feedback input per row. To analyze, they need to do a high number of filters and that creates room as well for errors. The country responses to Questions #1, #2, and #3 are not harmonized, it can be tedious to interpret answers. Between Supply Chain and PMO Team we focused on providing solutions to those risks/issues.

LITERATURE REVIEW

Project in scope is the global implementation of the European Union Medical Device Regulation herein called MDR regulation. MDR goal is that products comply the highest level of quality for the safety of the patients for products produced or supplied to European union's countries (EU countries). The MDR was issued in 2017 and companies that produce and supply products to countries that are members of the European Union need to implement changes required by the regulation to continue to sell and distribute products to the EU countries [1]. The changes required by the regulation are being implemented to products that are also sold to non-European countries, which leads to a higher number of countries and regions in scope of the Regulatory PMO team projects.

MDR Regulation

MDR projects impact the entire portfolio of the Business and the strategy to reduce costs and gain efficiency implementing changes, the business decided to bundle the Main project with other projects impacting a high percentage of the Business portfolio. These bundled changes will add complexity to countries registrations. The complexity can be reflected in type of regulatory action, increase of time needed to prepare documentation for registration, increase in health authorities time of reviewal, and segregation of changes into multiple regulatory action.

Regulatory Impact on an Industry

The medical device industry needs to comply with the regulations and legislations of the governing bodies for the medical devices to assure the continuation of product distribution to the countries that buy and distribute their products. Changes in regulation or introducing a new regulation create a numerous number of activities in companies.

Companies need to assess the changes and understand how feasible is to produce products compliant with the new regulation requirements.

They need to evaluate the costs of making manufacturing changes for the product to be compliant versus costs of losing the markets that will not be able to sell the products without those new requirements [2]. The changes in regulation can impact the documentation as consequence of changes as simple as removing/adding symbols to instructions for use (IFU) and labels. These minor changes do not necessarily trigger a lot of regulatory activity within the countries even when there will be some that need to complete a minor regulatory activity. There can be changes in regulation that can be significant and trigger major regulatory activities within the countries, those are the regulatory activities that introduce higher risks to the supply continuity. Significant changes can be the implementation of a new regulation, changing Legal owner of the products, changing legal or manufacturing addresses (even a street number change), adding an alternative supplier or manufacturer, changing sterilization site, and multiple other changes. Interestingly, for the medical device industry regulation is key on when introducing innovative technology and the companies will need to reject innovative proposals or designs to keep compliant with the regulation since regulatory agencies will look after patient safety and not necessarily for new technology [3]. The difficulties introducing new technology can lead to multiple product quality issues and increasing manufacturing costs.

Regulatory Authorities

Almost all countries have their regulatory authority which ensures the product that will be marketed in the countries complies with the safety and quality required by the regulations [4]. The regulation seeks to require the manufacturers to produce a product that is safe and effective for its intended purpose. Not all regulatory agencies are as strict as others and can be differences on what evidence they need from the legal and physical manufacturers to allow the product to be approved for distribution in the country. It is perceptible that as stricter as the agency, less products are sale in the country with adverse events which increases the confidence of the consumers in the products.

Some regulatory authorities are for large markets:

- The Food and Drug administration (FDA) in US.
- The National Medical Products administration (NMPA) in China.
- The Therapeutic Goods Administration (TGA) in Australia.
- European Commission's MDR for EU countries.

METHODOLOGY

After understanding the challenges and issues that are being faced during the process and outcomes obtained it was decided to start gathering ideas using the Supply Chain Team and PMO team as clients. The process has always been improving, that is why we already know we will have to plan based on ideas, design what is needed, test the file to achieve the outcome desired, deploy for the clients, and finally review if it was successful.

- **Plan:** This first step of the project was focused on understanding the requirements from the SC team that is the end user with more challenges and the requirements from the PMO team since even though they are the owners, they also were experimenting challenges with the feedback received from Supply Chain team. The challenges exposed during the discussion between Supply Chain team and PMO team will be used as the base for new ideas to implement in the Master Regulatory Schedule. The resources to implement the ideas in the MRS were identified and timeline for the development and testing was defined during this phase. Goals will be established and divided into iterations with a respective timeline.
- **Design/Develop:** Based on the new ideas gathered, PMO team will define together with planning team what is needed to fulfill the requirements. The MRS will be modified to

include information, columns, formulas that will complement the information already in the file to reach the user requirements. In this step of the process, training forms were created to help guide the process to SC and the countries.

- **Test:** The test will incorporate the ideas by iterations. For the formulas that will be added by the planning team to the MRS, the PMO representative will be checking those formulas using tables with acceptance criteria predefined. For the Harmonized SC responses, countries will be trained and asked to update the system, that way for the next MRS released the new responses will show. The responses will be reviewed by PMO representative, and any corrections needed will be sent back to the countries for immediate correction in the system. The columns added that need SC input will be review by PMO team. This project is not restricted to one iteration, all feedback gathered from SC and PMO teams will be divided in iterations where changes will be implemented but will not interrupt the process.
- **Deploy:** Each iteration will be deployed to only one business unit, one planning representative and one PMO representative since the process is the same for all Business Units. Feedback will be gathered after each deployment and review if goals were fulfilled and will be documented as part of the results. The development (creating of formulas and internal discussion) of the next iteration will be done in parallel with the previous deployment. After reaching the last goal, the MRS will be deployed to all Business Unit and feedback will be gathered for future improvements but will not be part of the scope of this project.
- **Review/Results:** After each iteration, a goal must be met. It will be evaluated if more requirements need to be included in the next iteration based on the previous iteration results. Formulas will be reviewed and tested by PMO representative and the results obtained will be discuss during this section. PMO will also be responsible to review if the data obtained by the countries or SC is what was required and will be discussed during the results if data was deliver on time and in its entirety. All new columns need to work as intended and provide the information required.

RESULTS

In this section the results will be discussed by phase.

Plan

Feedback from SC was gathered during a lesson learned meeting during Q12024. The challenges and risks exposed by SC Team and PMO team are shown in Figure 3.

Challenges	Risks
Supply Chain Team Feedback	
1. Supply Chain questions #1, #2 and #3 have multiple answers that can be interpreted incorrectly. 2. To understand when countries can receive the new products, too many filters are needed. 3. No traceability of changes in documentation dates. 4. No record of alignment with specifically, restricted countries.	1. No clear visibility of countries aligned can lead to supply issues. 2. Inventory build ups are high due to tardiness in alignments or misalignments. 3. High volume countries and restricted countries end up with supply issues, and product blocks.
PMO Team Feedback	
1. Supply chain feedback need to be interpreted, long sentences, no specific dates provided, and no priorities provided. 2. Date aligned with country and SC has no traceability. 3. Countries responses to SC questions are not harmonized and introduce complexity when data needs to be analyzed. 4. Information for prioritization is needed.	1. Information provided to the supply chain team can lead to misalignments if it is not harmonized or simplified. 2. Information can be interpreted incorrectly by the countries if no specific dates are provided to them. 3. Date of importation alignments are in risk if there is no clear identification of restricted countries for SC and if no prioritization is defined.

Figure 3
SC and PMO Team Feedback

The solutions and ideas for the MRS were defined to mitigate the risks mentioned in Figure 3 and are detailed below. The roadmap of the project is shown in Figure 4. The roadmap was created to define the iterations, their timeline, goals and iteration description or features included in the MRS.

Figure 4
Project Roadmap

- **Harmonize SC responses:** SC responses can be harmonized by requesting the countries to restrict their answers using a specific answer list that are allowed. Re-train countries with a form with specific answers and provide them one week to update the responses. The MRS released after the responses are updated will be used for the other actions under iteration #1, see Figure 4: Project Roadmap
- **Importation date column:** The Importation date should be based on the first supply chain question. Automated column

Supply proposed dates columns: SC feedback will be divided into three columns where they can only include dates. See columns defined in Figure 5. Columns are input by SC.

Column Name	Column Purpose
Supply Chain Proposed Date	This is the base date of when SC prefer the country to start importing the new product.
Importation date not before	In this column SC inputs when is the earliest the country can start importing the product based on manufacturing readiness dates
Importation date not after	In this column SC inputs when is the latest the country can start importing the product based on manufacturing readiness dates.

Figure 5
Columns Added for SC Proposed Dates

- **Green Light Signal column:** This column will provide information as when there is alignment or not between countries and SC dates. Green Light Yes or No will be applied to countries restricted and Not Applicable to non-restricted. The column is input by PMO.
- **Green Light Date column:** To record the date when the alignment was reached and Green Light Signal changed to Yes. The column is input by PMO.
- **Forecast column:** Product Forecast will be used to prioritize. The column is input by SC.
- **Priority column:** If the country has forecast and is restricted, will be flag as priority. Automated column.
- **Country Importation date within SC proposed dates? Column:** This column will determine if registration dates are within, after or before SC dates. Automated column.
- **PMO quick check column:** This column will provide to PMO the action to take (No action, Change Green Light to Yes or Country to propose new dates) without having to do many filters. Automated column

Design/Develop

- **Iteration#1:** The Harmonized responses list was created by PMO Team as training material for countries to update them in the Regulatory Platform. Training material is showed in Figure 6. The Importation date column was added and formula can be seen in Table 1. The last part of iteration #1 was to add the three columns for Supply Chain proposed dates.

1) When the <u>new</u> version of the product can be imported?	Definition
After HA approval	Once HA approves submission or notification.
After Regulatory Action completion	Once internal activities or submission of notification is completed, but do not require HA approval.
Immediately after Changes Implementation	Once the new product with the changes is available, the country could receive it without the need of any action or HA approval.
3) How long can Country receive (import) <u>old</u> version?	**Definition**
Limited - X months	Until a specific period established by local HA. *(Specify # of months in comments)*
Limited - Dual License	Limited as both codes (old or new) are required to be in an active license.
Limited - Until Certs are valid	Until certificates validity. *(Specify which certificates are required to be valid)*
Not allowed	Old version not allowed due to local regulations.
Unlimited	No restriction on receiving old version of the product.
Limited - Other	Any other limitation in the country that is not specified in the other categories. *(e.g. Until hospital listing of products is changed to the new product, Until new MOH circular with enforcement date of new regulation.)*

Figure 6
Training Material to Harmonize SC Responses

- **Iteration#2:** For Iteration #2, the column Importation date within SC proposed dates? Was added and formula created as shown in Table 1. The Green Light Date and the Green Light Signal columns were added to the MRS.
- **Iteration#3:** The Forecast column was added to the MRS and formulas for Priority column and PMO quick check column created. The formulas are shown in Table 1.

Table 1

Formulas Developed for New Columns

New Column	Formula
Importation Date	=IF([@[Question '#1) When the new version can be imported?]]="Immediately after Changes Implementation",[@[Expected technical documentation date]],IF([@[Question '#1) When the new version can be imported?]]="After Regulatory Action completion",[@[Estimated Submission Due date]],IF([@[Question '#1) When the new version can be imported?]]="After HA approval",[@[Estimated Health Authority Approval due date]]," ")))
Importation date within SC proposed dates?	=IF([@[Importation Date]]<[@[Importation date not before]],"Before SC proposed dates",IF([@[Importation Date]]>[@[Importation date not after]],"After SC proposed dates","Within SC proposed dates"))
Priority	=IF([@Forecast]>0,"Yes","No")
PMO Quick Check	=IF([@[Question '#2) After Regulatory Action, can countries receive both versions?]]="No",IF([@[Importation date within SC proposed dates?]]="Before SC propose dates","Country to propose new dates",IF([@[Importation date within SC proposed dates?]]="After SC proposed dates","Country to propose new dates","Change Green Light to YES")),IF([@[Question '#2) After Regulatory Action, can countries receive both versions?]]="Yes","No actions",""))

Test

Columns added as part of the Iterations were recorded in different sheets of the MRS and identified by iteration number. Countries were notified that during four weeks we were going to implement the Green Light Signal Process and asked to the restricted countries to not submit until implementation was completed to avoid having more submissions that could be at risks.

- **Iteration#1:** As defined in Chapter 3 for Harmonized SC responses, after countries were trained, they updated the system and the MRS was released with the new updated responses in week 1. PMO verified the responses and 100% of responses were aligned to the defined Harmonized questions. The MRS of week 1 was used to include the formula for "Importation date". The formula was verified by PMO representative, and verification was performed as shown in Figure 7. The three columns for SC were added successfully. They had until end of the week 2 to input the information. At the end of week 2, PMO checked the information, and it was 100% input in the file.

Question #1) When the new version can be imported?	Expected technical documentation date	Estimated Submission Due date	Estimated Health Authority Approval due date	Acceptance Criteria	Formula	Pass/ Fail
After HA approval	21-Apr-2023	31-Oct-2024	31-Jan-2025	Importation date should be equal to 31-Jan-2025	31-Jan-2025	Pass
After Regulatory Action completion	21-Apr-2023	4-Apr-2024	4-Apr-2024	Importation date should be equal to 4-Apr-2024	4-Apr-2024	Pass
Immediately after Changes Implementation	21-Apr-2023	30-Nov-2024	30-May-2025	Importation date should be equal to 21-Apr-2023	21-Apr-2023	Pass

Figure 7

Importation Date Verification Columns

- **Iteration#2:** The MRS released in week #3 includes everything added during week 1 and 2, as verified by PMO representative. The formula for "Importation date within SC proposed dates?" was added and verified by PMO representative. The verification was performed as shown in Figure 8. Columns "Green Light Date" and "Green Light Signal" were added successfully. PMO Input the information manually.

Importation date - value Tested	Importation date not before	Importation date not after	Acceptance Criteria	Formula	Pass/Fail
14-Dec-23	13-Jan-2024	13-Mar-2024	Importation date within SC proposed date? should reflect "Before SC proposed date".	Before SC proposed dates	Pass
12-Feb-24	13-Jan-2024	13-Mar-2024	Importation date within SC proposed date? should reflect "Within SC proposed date".	Within SC proposed Dates	Pass
20-Apr-24	13-Jan-2024	13-Mar-2024	Importation date within SC proposed date? should reflect "After SC proposed dates"	After SC proposed dates	Pass

Figure 8

Importation Date Within SC Proposed Dates? Verification

- **Iteration#3:** The MRS released on Week 4 includes everything tested in Iteration #1 and

Iteration #2, as verified by PMO representative. SC needed to input the forecast into the file during the first half of the week. It was completed on time, as verified by PMO representative. The "Priority" formula was added and verified by PMO representative. The verification was performed as shown in Figure 9. The "PMO quick check" was added to the MRS and verified by PMO representative. The verification was performed as shown in Figure 10.

Forecast – Value tested	Acceptance Criteria	Formula Results	Pass/Fail
2524	Priority Column should reflect "Yes"	Yes	Pass
0	Priority Column should reflect "No"	No	Pass

Figure 9
Priority Column Verification

Importation date within SC proposed dates?	Country Response to Question #2	Acceptance Criteria	Formula Results	Pass/ Fail
Before SC proposed Dates	Yes	Action should be reflected in PMO quick check as "No actions"	No actions	Pass
Within SC proposed Dates	Yes	Action should be reflected in PMO quick check as "No actions"	No actions	Pass
After SC proposed Dates	Yes	Action should be reflected in PMO quick check as "No actions"	No actions	Pass
Within SC proposed Dates	No	Action should be reflected in PMO quick check as "Change Green Light to YES"	Change Green Light to YES	Pass
After SC proposed Dates	No	Action should be reflected in PMO quick check as "Country to propose new dates"	Country to propose new dates	Pass
Before SC proposed Dates	No	Action should be reflected in PMO quick check as "Country to propose new dates"	Country to propose new dates	Pass

Figure 10
PMO Quick Check Verification

Deployment

As explained before, the deployment of each iteration was performed to one business unit, one planning representative, SC representative for the business unit, and one PMO representative. This reduced the scope for the iterations in order to not overwhelm the project team deploying all changes at once.

Planning team was responsible to create the MRS and to create the formulas in excel for each column as defined. Supply Chain was able to provide all the information needed on time to continue with the iterations. The PMO representative was able to verify information provided by Countries, SC, and formulas integrated by planning representative. As part of the deployments, several meetings were held with the different teams to explain the new columns and the team responsible for input information on each of them.

All new columns and formulas were deployed on Week 5 to all the Business Units and feedback was collected for new improvements.

Review/Results

Goals were established by iteration; the goals and its fulfillment description will be detailed below:

- **Iteration#1:** Goal of having by week 1, harmonized SC responses was achieved a 100%. Countries understood the intend of harmonization of the responses and completed the system update using the responses in Figure 6: Training Material to Harmonize SC Responses.

  Having the responses harmonized made it possible to include the "Importation date" formula. Formula for "Importation date" was verified and worked as intended. This column was used to reduce filters and errors during the SC and PMO review of dates. SC was able to understand which date they needed to challenge by country. Supply Chain was able to understand the specific date when the country was able to import the new product and with that information, they were aware of risks and input information/dates based on risk mitigation and prevention of supply continuity of product.

  Also having a not before date and not after date will provide a tolerance for the countries to update their submission or registration without impacting the alignment reducing the workload every time the dates change.
- **Iteration#2:** The "Importation date within SC dates?" formula was verified and worked as intended. This formula provides a quick glance of the difference between SC proposed dates and the country importation date. It was also used as the base for the PMO quick check, reducing the time to define actions.

Once the SC proposed dates and importation date are identified, PMO was able to start analyzing the data and providing Green Light Signal "Yes" to countries. Countries with Green Light Signal "Yes" do not have any outstanding risk if submission is done as per dates aligned.

Providing visibility to the countries with Green Light Signal "No", was a main goal since these are the ones that are at risks of supply chain gaps for the new product. It is expected that the country with no alignment starts evaluating their options or strategies to align with SC dates. The summary of how many countries by strategy were provided with a "Yes" and "No" signal is shown in Figure 11. It can be noticed that we have 42 strategy/country combinations that are at risk with no alignment but on the other hand we have 91 strategy/country combinations that was granted the Green Light Signal "Yes"

Green Light Signal	Strategy ID	Count of Country
No	2888	7
No	4008	3
No	5058	2
No	5076	1
No	5078	1
No	6582	2
No	6583	2
No	6584	1
No	6599	5
No	6745	4
No	6754	1
No	6773	5
No	6913	1
No	6957	5
No	6999	2
No Total		**42**

Green Light Signal	Strategy ID	Count of Country
Yes	2888	1
Yes	3725	13
Yes	4008	4
Yes	5058	5
Yes	5076	3
Yes	5077	9
Yes	6121	1
Yes	6582	1
Yes	6583	4
Yes	6584	8
Yes	6599	8
Yes	6745	7
Yes	6754	1
Yes	6773	1
Yes	6774	6
Yes	6913	9
Yes	6955	4
Yes	6957	1
Yes	6999	5
Yes Total		**91**

Figure 11
Summary of Countries with Green Light Signal "No' at the Left and "Yes" at the Right

As shown in Figure 11, from not having traceability of which countries were at risks and which were not at risks, it was identified that 91 countries can submit for 19 strategies without any risk.

- **Iteration#3:** The "Priority" column formula was verified and worked as intended. The formula is useful to start providing visibility of priorities and reduce workload. This way the workload can be scheduled based on priorities.

PMO verified the "Forecast" column and it was filled out a 100% by SC. This column was used to assign priorities. All countries with no alignment, they need to prioritize using this column. The formula for "PMO quick check column" was verified and worked as intended. The formula helped PMO to identify the actions, reducing the time spent in the task. Identifying risks and reaching alignments will reduce risks and effort.

From not having any traceability of countries with or without risks we were able to identify that 42 strategy/country combination were at risk being a 4% of the total strategy/country combination, see Figure 12. From those 42 strategy/country combinations, 38 strategy/country combination have not started the submission process, see Figure 13. Those countries will have to align dates prior to complete their registrations to avoid risks. For the 4 strategy/country combination that already started their process of submission, PMO team will have to start the risk management process and provide visibility of the risks to the entire team. The 8% pertains to submissions with dates aligned with SC proposed dates, see Figure 12. Some of them have been already completed but no risk management is needed for them. From the 91 strategy/country combination, 54 strategy/country combination are submissions that can be completed as scheduled without any risks identified, see Figure 13.

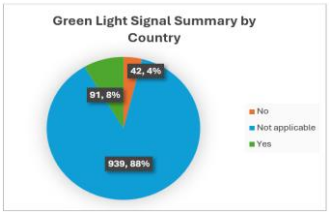

Figure 12
Green Light Summary by Country

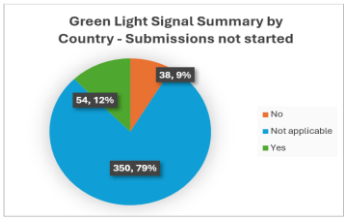

Figure 13
Green Light Signal Summary by Country - Submissions Not Started

CONCLUSION

The Green Light Signal Process Project Implementation and benefits will be summarized in this section. Companies require resources to achieve specific goals and learn from previous years of roadblocks and issues encountered. As part of lessons learned sessions, it was brought up as one of the significant risks to avoid and mitigate is Supply Continuity to the countries for the new product. In order to achieve supply continuity, the PMO team needed to identify areas of the process that could have been improved in order to provide visibility at a cross-functional level. The PMO team decided to improve the process by considering Supply Chain feedback since they are the key players in providing the information needed to identify all risks and priorities It was decided to include, by iterations, during a period of four weeks, important information that was used by the countries to align their priorities and that provided clarity on when it was needed from them to start or complete their registrations based on the importation date. All formulas incorporated in the MRS Excel file were tested and complied with their intended use. Those automated columns reduce the filtering time and errors caused by wrong filters. All goals established by iteration, as per Figure 3, were achieved. From having no traceability of risks, we were able to identify that, 91 strategy/country combinations with the Green Light Signal "Yes" leaving only 42 strategy/country combinations with risks identified as "No" in the Green Light Signal. The priorities were identified successfully with the forecast information, and countries can focus on reviewing for alignment only the ones identified as "Yes" in the Priority Column.

This Green Light Signal Process was deployed to all Business Units in Week 5, and even though the results are not within this project's scope, new ideas for improvements were received from SC and other countries. Since the number of strategies is high for all Business Units, even with priorities assigned, countries and SC need more time to review and provide their feedback. The next steps for the process are:

- To create a cycle of one month for this process where each team will have more time to evaluate and provide feedback.
- To reduce workload, include forecast value ($) to prioritize between Business Units.
- Use prioritization information to also assign priorities with the technical documentation team.
- Main goal is to have all countries aligned when this is reached only changes from one MRS to the next are needed to align.
- Create Forums for Risk Management with Global SC and Stakeholders to provide visibility of risks to receive the support needed in order to reach the alignment.

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