

# USER MANUAL

# for

# **EVERS** Portal



## Everest Minds for digital transformation

February 2, 2023

## Contents

1 Introduction					
	1.1	Project Scope Overview	3		
	1.2	Intended Audience and Reading Suggestions	3		
2	Con	ipany Interface	4		
	2.1	Portal overview	4		
		2.1.1 Login Page	4		
		2.1.2 Work-list	5		
		2.1.3 Notifications	6		
		2.1.4 New Request	7		
		2.1.5 Draft	15		
		2.1.6 Submission Details page	17		
		2.1.7 Final approval	22		
	2.2	Re-uploading Documents	22		
	2.3	Naming process	26		
		2.3.1 Line extension	26		
		2.3.2 Normal name list	26		
	2.4	Start soft file	28		
	2.5	Start hard file	29		
	2.6	Modifications	30		
	2.7	Status List	32		
		2.7.1 Screenshots for the status names	33		





## 1 Introduction

## 1.1 Project Scope Overview

The registration process of veterinary products currently operates its submissions using a manual non automated process and due to the large amount of in-person submissions and the back-and-forth feedback appointments between the EDA team and the Applicants in a single submission, this hectic process takes a long time to be reviewed and approved.

The EVERS Project is a web portal that helps ease the process of veterinary products registration.

The system will also manage the task distributions and will help in the process of decision making and limits the back and forth communication between both parties.

## 1.2 Intended Audience and Reading Suggestions

The document addresses The Companies that are going to be using this system. Also EDA users who are going to deal with the system. Basically, anyone who is going to use the EVERS Portal should read this user manual first before login as to make the experience smooth and easy.





# 2 Company Interface

## 2.1 Portal overview

The main goal of this project is to facilitate and enhance communication between companies and EDA team during the registration process of veterinary products.

### 2.1.1 Login Page





This is the first page the user encounters once he opens the portal, all the applicants should choose to login as a company which will then direct them to the company login page







Figure 2.2: Second Login page

Companies can only login to the Portal from the Company Login page, Login will be through company account created in EDA company profile. EDA is responsible to provide each company a user name and a password for login.

user-170 USER						لَقَالِالْفِينَةِ (٣)	(٢٠٩) هَيْنَةُ
Navigation	My As Applicati	signed <sup>(1)</sup> My Assigned Applicat ons (New) (resume)	ion <sup>99</sup> My Assi Modifica	gned <sup>1</sup> ations A	Ongoing <sup>(3)</sup> Ongoing <sup>(3)</sup> Applications Modifications	Completed <sup>29</sup> Completed <sup>29</sup> R Applications Modifications Mo	equested <sup>0</sup> difications
Notifications	ID,Applicat	ion,Company,Trade Name,Trade Code,In	gredient Name,Step		Q	▼ Filter Results	filter
Requests	Application	Trade Name	Registration Type	Marketing Typ	e Ingredients	Dosage form	Assig
New Request	NT-326		Toll	Local	ACETYLCYSTEINE	Absorbable Screw	Jan 24, 20
New Modification     Draft	NT-337	Notification 1	Toll	Export	BISACODYL	Absorbable Suture	Jan 25, 2(
	NT-247	Ethostatvest Premix	Local	Local	AMPROLIUM-Ethopabate	Premix	Dec 8, 20
	NT-248	Spectradox 50%	Local	Local	DOXYCYCLINE	Powder for use in drinking water / milk replace	er Dec 8, 20
	NT-249	Fluralaner 250 mg–Eva Pharma	Local	Local	Fluralaner	Chewable Tablet	Dec 8, 20
	NT-251	Fluralaner 1000 mg–Eva Pharma	Local	Local	Fluralaner	Chewable Tablet	Dec 8, 20
	NT-255	L-Spectin Forte	Local	Local	LINCOMYCIN-SPECTINOMYCIN	Water Soluble Powder	Dec 8, 20
	NT-256	Oxytetrex 50% Powder	Local	Local	OXYTETRACYCLINE	Powder for use in drinking water	Dec 8, 20
	NT-257	Respotulathril plus	F-toll	Local	Tulathromycin -KETOPROFEN	Solution for injection	Dec 8, 20
	NT-258	Marbofloxacin -Mapco	F-toll	Local	Marbofloxacin	Solution for injection	Dec 8, 20
-€[]						Activate Window 1-10gf & Settings to active	5 ite Window}!

#### 2.1.2 Work-list







Once the user logs in he will land on this page: "My Work-list" which is the main page for managing his work, user can find 3 different tabs to do so:

My Assigned Applications (New): This tab contains all the new submissions or tasks that the user must take an action upon.

My Assigned Applications (Resume): This tab contains all the resumed submissions or tasks that the user must take an action upon.

My Assigned Modifications: This tab contains all the modifications that the user must take an action upon.

**Ongoing Application**: This tab contains all the submissions or tasks the user has already worked on to be able to track the progress of his work and at this point the user can't take any actions on the submission but just view them.

**Ongoing Modification**: This tab contains all the submissions or tasks the user has already worked on to be able to track the progress of his work and at this point the user can't take any actions on the submission but just view them.

**Completed Application**: This tab shows only the finished submissions either the ones who completed the workflow and got accepted or the ones who got rejected or canceled.

**Completed Modification**: This tab shows only the finished modifications either the ones who completed the workflow and got accepted or the ones who got rejected or canceled.

**Requested Modification** This tab shows the requested modification, modification still waiting either to be accepted or rejected.

#### 2.1.3 Notifications

USER		الم
Navigation Home Worklist Notifications	From To Apply Filters mm/dd/yyyy a mm/dd/yyyy Notifications:	Clear All
Requests	1/30/2023, 112118 PM       Modification Request [Name change after Sc. Committee Approval] on Submission (NT-299) has been [Accepted]         1/30/2023, 112118 PM       Modification Request [Name change after Sc. Committee Approval] on Submission (NT-299) has been [Accepted]	
<ul> <li>New Modification</li> <li>Draft</li> </ul>	1/30/2023, 11:21:18 PM Modification Request [Name change after Sc. Committee Approval] on Submission (NT-299) has been [Accepted]	
	1/30/2023, 1121:18 PM Modification Request [Name change after Sc. Committee Approval] on Submission (NT-299) has been [Accepted]	
	1/30/2023, 11:14:35 PM       Your Modification Request with name (Name change after Sc. Committee Approval) [NT-299] has been Started	
	1/30/2023, 11:04:10 PM Modification Request [Name change after Sc. Committee Approval] on Submission (NT-299) has been [Accepted]	
	1/30/2023, 10:58:11 PM 🕥 Your Modification Request with name ( Name change after Sc. Committee Approval ) [ NT-299 ] has been Started	
	1/30/2023, 10:55:35 PM	
-[]		Activate Windows Go to Settings to activate Windows.

#### Figure 2.4: Notifications

From the side navigation bar you can access the notifications that are sent to you whenever an action regarding your application occurs or they can be accessed from the top right notification icon. Also, the company will receive an email as a notification each time the submission requires their attention or at the company's side.





Page 7  $\,$ 

#### 2.1.4 New Request

user-170 USER				مَنْ مَنْ الْمُوْلُوْ الْمُوْلُوْ الْمُوْلُوْ الْمُوْلُوْ
Navigation				
🖽 Worklist				
Notifications	Please	e select the reques	st type	
Requests			51	
E New Request				
New Modification			1	
Draft			R.E	
	REQUEST INQUIRY	FAST TRACK	RE-REGISTRATION	
				Activate Windows
		Everest Minds © everestminds.com		

Figure 2.5: Request Inquiry

The company can start a new Inquiry Request from the New Request Tab in the side navigation bar, then they will be able to choose either Local or Export Requests as shown.

διτεκs User-170 USER Ο			الم عبتة الدَّاء المُوَتِد ٢
Navigation Home Worklist Notifications Request New Request New Modification Draft	<ol> <li>Application Type</li> <li>Active Ingredient</li> <li>Product Information</li> <li>Inquiry Attachments</li> </ol>	<b>1.1 Application Type 1.1 Type of Marketing</b> Local       Export         Une Extension	☐ Save as draft
÷Ű		Everest Minds © everestminds.com	Activate Windows Go to Settings to activate Windows.

Figure 2.6: Type of Marketing

Then company will be able to choose either Local or Export Requests as shown.





user-170 USER ●			٢
Navigation Marking Morklist Notifications Requests New Request New Modification	Application Type     Active Ingredient     S     Product Information     Auguity Attachments	1.1 Application Type 1.1 Type of Marketing (e) Local () Export	Save as draft
Draft		I.2 Type of Registration  I.0 Registration Category*   Local/F-Toll  Toll  T	
		Local     F-toll     Iam Still Under Construction	
+[]		1.4 Manufacturers Information Manufacturer Name *	Activate Windows Go to Settings to activate Windows.

Figure 2.7: Type of Registration

After choosing the type of marketing, you should choose the registration category in the type of registration (Local or Toll). Then you can choose whether the type of registration is Local or F-toll. You should tick the checkbox if you're still under construction.

Please note that each entry affects the required inquiry attachments later on.

user-170 O USER			المعنى المؤالي المعني المعنى
Navigation	1 Application Type	11 Application Type	Save as draft
Notifications	2 Active Ingredient	1.1 Type of Marketing	
Hequests           Image: New Request           Image: New Modification           Image: New Modification           Image: Draft	<ul><li>3 Product Information</li><li>4 Inquiry Attachments</li></ul>	Local     D Export     Line Extension	
		1.2 Type of Registration	
		10 Registration Category*	
		1.2 Type Of Registration*	
		1.4 Manufacturers Information	
		Manufacturer Name *	Anthony Manufacture
÷[]			ACTIVATE WINDOWS Go to Settings to activate Windows.

Figure 2.8: Registration category





#### Depending on the type of registration, you'll be guided through Manufacturer's information.

GNTAS USER O					ال
Navigation	3 Product Information	1.1 Type of Marketing			
☆ Home ₩orklist	3 Produce information	Local     C Export			
Notifications	4 Inquiry Attachments	Line Extension			
Requests					
New Modification		1.2 Type of Registration			
Draft		1.0 Registration Category*			
		C Local/F-Toll C Toll Imported/Under-license			
		1.2 Type Of Registration*			
		Under License     Imported Bulk     Imported			
		Trade Name			
		1.4 Manufacturers Information			
		Manufacturer Name *	V	Country Of Origin *	~
		License Holder *	~	Country Of Origin *	v
		Marketing Authorization Holder *	~	Country Of Origin *	v
t]		Manufacturer Name In Egypt *	~	Country Of Origin *	Activate Windows Go to Settings to activate Windows.



Products with imported as registration type will allow you to enter the trade name as this submission will skip the naming process.

The manufacturer's information change according to the type of registration.

USER				٢
Navigation	1	.2 Type of Registration		
Notifications	١	0 Registration Category*		
Requests	C	Local/F-Toll O Toll Imported/Under-license		
New Modification	1	2 Type Of Registration*		
Draft	(	Under License   Imported Bulk Imported		
		Trade Name		
	ı	.3 This Application Concern		
	١	0 This Application Concern*		
	(	Innovator Product Generic Products		
	1	.4 Manufacturers Information		
		Manufacturer Name *	Country Of Origin *	~
		License Holder *	Country Of Origin *	×
		Marketing Authorization Holder *	Country Of Origin *	Activate Windows
÷[]				Go to Settings to activate Windows.
		Manutacturer Name In Egypt *	Country Of Origin *	×







Please note that the red asterisk means that this file is mandatory which means that you could not submit unless you upload all the mandatory files.

6vos USER			ميتة الدواد المولية
Navigation	O Under License O Imported Bulk O Imported Trade Name		
Requests	1.3 This Application Concern		
New Modification Draft	10 This Application Concern*     O Innovator Product     O Generic Products		
	1.4 Manufacturers Information		
	Manufacturer Name *	Country Of Origin *	~
	License Holder *	Country Of Origin *	~
	Marketing Authorization Holder *	Country Of Origin *	~
	Manufacturing of the finished product v	Country Of Origin	
	Manufacturing of the accessories	Country Of Origin	~
	Packager v	Country Of Origin	
	Batch Release site	Country Of Origin	Activate Windows
<u>]</u> +	Manufacturer of primary packaging $\vee$	Country Of Origin	Go to Settings to activate Windows.

Figure 2.11: Imported as the registration type

Please note that the red asterisk means that this file is mandatory which means that you could not submit unless you upload all the mandatory files.

user-170 در USER	Contexes #GBDar Application Type		٢
Navigation	2 Active Ingredient	1.1 Application Type 1.1 Type of Marketing	
Notifications	3 Product Information	O Local ( Export	
E New Request	4 Inquiry Attachments	Line Extension	
Draft		1.2 Type of Registration	
		L0 Registration Category*       Image: Cocal/F-Toil       Image: Cocal/F-Toil   Toil	
		1.2 Type Of Registration*	
		Trade Name	
		1.4 Manufacturers Information	
₽		Manufacturer Name *	Activate Windows Go to Settings to activate Windows.

Figure 2.12: Export as type of marketing





Once the application is filled successfully and all the mandatory fields are filled the user can then submit his application and he will then get the following message notifying him that the application is now submitted as shown.

در user-170 USER			الم
Navigation          Navigation         Image: Control of the second secon	<ol> <li>Application Type</li> <li>Active Ingredient</li> <li>Froduct Information</li> <li>Inquiry Attachments</li> </ol>	2.1 Active Ingredient         Name of Active Ingredient *         Salt         Salt         Unit         Add	Save as draft
40			Activate Windows Go to Settings to activate Windows.
		Everest Minds © everestminds.com	

Figure 2.13: Active ingredient

Use the drop down list to choose your active ingredient and salt.

user-170 USER				٢
Navigation	Application Type	21 Active Incredient		Save as draft
Notifications	2 Active Ingredient	Name of Active Ingredient *		
Requests	3 Product Information	Salt		
Draft	4 Inquiry Attachments	Salt	Strength	
		Salt		
		Salt	Strength	
		Unit 🗸		
		Add		
		Add 🚦		4
				Activate Windows
€		Back Next		Go to Settings to activate Windows.

Figure 2.14: More than one Salt





There is an option where you can add or remove more than one salt.

6vus user-170 USER O	Application Type		الم
Navigation	2 Active Ingredient	2.1 Active Ingredient     Name of Active Ingredient *	
<ul> <li>Notifications</li> <li>Requests</li> <li>New Request</li> <li>New Modification</li> <li>Draft</li> </ul>	3 Product information 4 Inquiry Attachments	Salt   v Strength	
		Add  Active Ingredient (2) Name of Active Ingredient *	
		Salt Virength Strength	
٠Ľ		Add  Add Add	Activate Windows Go to Settings to activate Windows.

Figure 2.15: More than one Active ingredient

There is an option where you can add or remove more than one active ingredient.

user-170 USER				فيتةالقر الفراي (
Navigation	1 Application Type 2 Active Ingredient	3.1 Product Information		Save as draft
Requests	3 Product Information	Dosage Form * v Reference Country * v		
Draft	4 Inquiry Attachments	Concentration Active Ingredient:		
		Strength Concentration Active ingredient:	Unit	×
		Strength	Unit	<b> </b> ~
				streene
щ		Back Next		Activate Windows Go to Settings to activate Windows.



The product information like the dosage form, reference country, concentration, etc associated with each active ingredient. For each active ingredient there should be a corresponding product information



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User-170			الله الم
Navigation Morklist Notifications Requests New Request New Modification Tofft	Application Type       Active ingredient       Product information       Inquiry Attachments	A.1 Inquiry Attachments Scientific reference/pharmacopeia for composition*          Inquiry Receipt (Fee = 1000)*         Tename       0%         Receipt Number *       0%	Save as draft
-1		Translation of scientific reference/pharmacopela	Activate Windows Go to Settings to activate Windows.

Figure 2.17: Inquiry attachments

After filling all the data and pressing next the user will be asked to upload a list of files some of them are mandatory and some are optional as shown.

The company should only upload PDF files, other types of files will be rejected by the portal and this message should appear "please check files extensions". Also, encrypted PDF files won't be accepted.

The company can use the multiple uploads feature. This means the company can upload more than one file under each attachment request. There is a difference between the multiple upload feature and the single upload feature. Multiple uploads feature does not have a load bar, while the single upload feature has a load bar. Moreover, the button for multiple upload feature says "Upload Files", while the single upload feature says "Upload".



Figure 2.18: Extra attachments

Extra attachments option is available. If the company uploaded all the required attachments and also wanted to attach more PDF files to the submission.

user-170 USER				1000 - 1000 - 1000 - 1000 - 1000 - 1000 - 1000 - 1000 - 1000 - 1000 - 1000 - 1000 - 1000 - 1000 - 1000 - 1000 -	الم منت المعالم الم الم
Navigation	and mounty Attachments	Inquiry Receipt (Fee = 1000)*			
ሰ Home		Test PDF.pdf		Upload	Preview
🗄 Worklist					
Notifications		4574567456745674567	457rturturtyurtu56786758568564		
Requests		Desidents Lint			
🔲 New Request		Test PDE odf		Unload	Transform
New Modification				100%	
Draft Draft					
		Registration certificate /			
		Test PDF.pdf		Upload 100%	Preview
		Translation of scientific r			
		file name	Your application has been sent	Upload 0%	
		Extra Attachment	successfully!		
			Ok		
					SCR
		Back	Submit		nrec
~					Activate Windows
<b>₩</b>			Everest Minds © everestminds.	s.com	Go to Settings to activate Windows.

Figure 2.19: Submit message

After the company entered all the mandatory data and uploaded all the obligatory PDF files. There is a message ensuring that you filled all the mandatory fields successfully.





#### 2.1.5 Draft

USER	Collapse sidebar			(m) مَيْتَةُ الْمُزَاءِ الْجِنِيَّةِ (m)
Navigation	1 Application Type			Save as draft
Worklist Notifications Requests New Request	2 Active ingredient 3 Product Information	3.1 Product Information 3.1 Dotage Form* Blood bag \v	1241234 X	
New Modification In the second sec	4 Inquiry Attachments	MHRA (UK) ~	] ×	
		Active Ingredient: CIMETIDINE	3.2 Unit	
		Add	C.F.U. v	×
		Back Noxt		screenter
ť.		Everest Minds © everestmind	ls.com	Activate Windows Go to Settings to activate Windows.

Figure 2.20: Draft

While filling the application the user will have the ability to save the application as a draft from the button at the top right corner "Save As Draft"

user-170 USER			الم
Navigation More Worklist Notifications Requests New Request New Modification	Application Type     Active Ingredient     Product Information     Inquiry Attachments	3.1 Product Information 3.1 Desage Form*  Elood bag 3.3 Reference Country*  MHRA (UK)	ane as dat
Dat		Concentration Active Ingredient: CIM  IZ342I34  Active Ingredient: CIM  Active Ingredient: CIM  Cancel  C.F.U.  Active Ingredient: CIM  Active Ingredi	×
ΨĹ		Back Next	Activate Windows

Figure 2.21: Draft 1

The user will then be asked to confirm his choice and press save as shown.





فاتلغ user-170 USER					الم عيْدَةُ الدَّانِ الْمُوْتِةِ ٢
Navigation          Navigation         Image: Address of the second secon	<ol> <li>Application Type</li> <li>Active Ingredient</li> <li>Product Information</li> <li>Inquiry Attachments</li> </ol>	3.1 Product Infor 3.1 Desige Form* Blood bag 3.3 Reference Country* MHRA (UK) Concentration Active Ingredient: CIM 12342134	rmation	X X 3.2 Unit C.F.U.	Save as draft
		Back	Next		Activate Windows
۹U			Everest Minds © everestminds.c	om	



The submission should be saved as draft for the company to resume working on it.

مەنغە user-170 USER			المعنى من المقالة الموالي المعنى
Navigation	Drafts		
🔃 Worklist	ID,Application,Applicant,Company	Q	♥ Filter Results ♥ Clear Filter
Notifications	Submissions count	Date	FF
Requests	1	2023-02-01T05:43:29.000Z	NT-DI
New Modification			1-1 of 1  < < > >
Draft			
			8
			reenre
			Activate Windows
		Everest Minds © everestminds.com	Go to Settings to activate Windows.



The company can find the saved as draft submission by clicking on the "Draft" section in the navigation side bar.





#### 2.1.6 Submission Details page

Once the user submits his application he can then find it inside the ongoing tab, and he can press on it to open the submission details page.

δντεκ user-170 USER Ο						للقراء الحيرية	فيَنَهُ
Navigation	My As Applicati	signed <sup>(1)</sup> My Assigned Applicat ons (New) (resume)	tion <sup>(1)</sup> My Assig Modifica	gned <b>O</b> tions Ap	Ongoing <sup>(1)</sup> Ongoing <sup>(1)</sup> oplications Modifications	Completed <sup>10</sup> Completed <sup>10</sup> R Applications Modifications Mo	equested <b>0</b> difications
Notifications	ID,Applicat	ion,Company,Trade Name,Trade Code,In	gredient Name,Step		Q	V Filter Results	ilter
Requests	Application	Trade Name	Registration Type	Marketing Type	Ingredients	Dosage form	Assig
🗐 New Request	NT-326		Toll	Local	ACETYLCYSTEINE	Absorbable Screw	Jan 24, 20
New Modification Draft	NT-337	Notification 1	Toll	Export	BISACODYL	Absorbable Suture	Jan 25, 2(
	NT-247	Ethostatvest Premix	Local	Local	AMPROLIUM-Ethopabate	Premix	Dec 8, 20
	NT-248	Spectradox 50%	Local	Local	DOXYCYCLINE	Powder for use in drinking water / milk replace	er Dec 8, 20
	NT-249	Fluralaner 250 mg–Eva Pharma	Local	Local	Fluralaner	Chewable Tablet	Dec 8, 20
	NT-251	Fluralaner 1000 mg–Eva Pharma	Local	Local	Fluralaner	Chewable Tablet	Dec 8, 20
	NT-255	L-Spectin Forte	Local	Local	LINCOMYCIN-SPECTINOMYCIN	Water Soluble Powder	Dec 8, 20
	NT-256	Oxytetrex 50% Powder	Local	Local	OXYTETRACYCLINE	Powder for use in drinking water	Dec 8, 20
	NT-257	Respotulathril plus	F-toll	Local	Tulathromycin -KETOPROFEN	Solution for injection	Dec 8, 20
	NT-258	Marbofloxacin -Mapco	F-toll	Local	Marbofloxacin	Solution for injection	Dec 8, 20
+[]						Activate Windows 1-109/#55ettinbs to activa	te Windows!

Figure 2.24: Work-list page

The submission details page will contain more than one tab each containing different types of data regarding the application. These tabs are as follows:

#### **Product Details**

The Product Details page contains the submission details





user-170 USER Ο	ollapse sidebar t Deta	iils [ ElSamman's Demo for I	manual ]			المن من المناطق المفرية
Navigation	NT-340	Application Date Wednesday, February 1, 2023	Status Pending	Current Step Final Screening	Days Remaining 5 WDs	
<ul> <li>Worklist</li> <li>Notifications</li> </ul>	Similar Submiss	sions				*
Requests	Product	t Details	1.Product D	Details		
New Modification	Inquiry Requ	est Check List	1.1 Application 1	Гуре		
Draft	Namin	ng Files	Type Of Marektir	ng	Export	
	Soft Files	Check List	Line Extension Type Of Registra	tion	true Local	
	Hard Files	Check List	Accepted Name		ElSamman's Demo for manual	
	Modifie	cations	Company Name		vetopharm nerhado international for pharmaceuticals and chemicals	
	Final a	pproval	Contact Email Manufacturer Na	ame	registration@vetopharm-eg.com 15 MAY PHARMACEUTICAL (M.P.C)-EGYPT	
			Product Inform	ation		
			Dosage Form		Ampoule	
			Reference (for	each product)	2345235234	
			Reference Cou	ntry	TGA (Australia)	
			1. Ingredients			scree
			Active Ingredie	ent	HYDROCORTISONE	inrec
सा			Unit/Strength		12342134 billion	Activate Windows Go to Settings to activate Windows
ч. — — — — — — — — — — — — — — — — — — —			1. Salts			

Figure 2.25: Product details page





#### **Inquiry request Checklist**

Inquiry request Checklist contains the Inquiry documents uploaded by the company.

δντεs USER	Request Details [ ElSamman's Demo for manual ]	مَيْتَةَالْأَوْالْوَالْقُوْرَةِ ٢
Navigation	ID Application Date Status Current Step Days Remaining NT-340 Wednesday, February 1, 2023 Pending Final Screening 5 WDs	
<ul> <li>Worklist</li> <li>Notifications</li> </ul>	Similar Submissions	~
Requests	Product Details 2.Inquiry Request Check List	
New Modification Draft	Inquiry Request Check List Scientific reference/pharmacopeia for composition	
	Soft Files Check List View file	
	Hard Files Check List Receipt Number 345645634 Receipt Group	63456rtrtyery34634456346346
	Modifications  Registration certificate / Scientific approval  View file	
	Final approval	
		screente
ť[]	Timeline	Activate Windows Go to Settings to activate Windows.

Figure 2.26: Inquiry request Checklist

#### Naming files

This is the files that is submitted duing the naming process

user-170 USER	Request Details	الم
Navigation	ID Application Date Status Current Step Days Remaining NT-343 Wednesday, February 1, 2023 Pending Naming Manager Comment 3 WDs	
🗄 Worklist		
Notifications	Similar Active Ingredients Drugs (7)	~
Requests	Product Details 3.Naming Files	
New Modification	Inquiry Request Check List Commercial Record	
Draft Draft	Naming Files	
	Naming List	
	Soft Files Check List	
	Hard Files Check List	
	Modifications	
	Final approval	-
		screen
		R
-f[]		Activate Windows Go to Settings to activate Windows.

Figure 2.27: Naming files





#### Naming List

This is list of names submitted during the naming process

6VERS USER	Request Details				الم
Navigation	ID Application Date NT-343 Wednesday, February 1, 2023	Status Pending N	Current Step Days Remaining Jaming Manager Comment 3 WDs		
Notifications	Similar Active Ingredients Drugs (7)				~
Requests	Product Details	5.Namin	g List		
New Modification Draft	Inquiry Request Check List				
	Naming Files	Name Order	Proposed Name	Arabic Name	Voice Note
	Naming List	1	kaskhg-vetopharm nerhado international for pharmaceuticals and chemicals	يستبتصقبي	
	Soft Files Check List	2	asdfasdfsadf	شىرسېشېشېمىت	
	Hard Files Check List	3	asdfasdfdf	بيسيبليسيل	
	Final approval	4	sadfsaddfdf	يليسباسيبلسيي	
					. screen
+[]				Activate Wing Go to Settings to	dows activate Windows.

#### Figure 2.28: Naming List

#### Soft files checklist

The Soft files checklist are the documents uploaded by the company during the soft file process









#### Hard files Checklist

The Hard files checklist are the documents uploaded by the company during the hard file process

user-170 USER	Request Details [ Ethostatvest P	remix ]	مَنْ مَنْ الْمُوْاءِ الْمُؤْرِيةِ ٢
Navigation	ID Application Date NT-247 Thursday, December 8, 2022	Status Current Step Days Remaining Pending junior hf 10 Ds	
<ul> <li>Worklist</li> <li>Notifications</li> </ul>	Similar Submissions		~
Requests	Product Details	7.Hard Files Check List	
New Modification	Inquiry Request Check List	Certificate of Veterinary Products	
Draft	Naming Files	View fie	
	Soft Files Check List	Scientific Committee Approval	
	Hard Files Check List	Central Administration for Drug Control Report (NODCAR report)	
	Modifications	View file	
	Final approval	General Administration of Stability Report	
		Hard Files Fees Mandatory	
		View file	a sue
		Receipt Number 45745775545454555 Receipt Group	567456745457454574575rt
÷[]		Formulation Composition	Activate Windows Go to Settings to activate Windows.

Figure 2.30: Hard files checklist

#### Modifications

This list of modifications the company applied for regarding any of its submissions

буция User-170 USER	Request Details [ Ethostatvest	Premix ]	هيْنَةُ الْقَنَاءِ الْمُصْرَةِ ٢
Navigation	ID Application Date NT-247 Thursday, December 8, 2022	Status Current Step Days Remaining Pending Junior hf 10 Ds	
<ul><li>Worklist</li><li>Notifications</li></ul>	Similar Submissions		*
Requests	Product Details	4.Modifications	
<ul> <li>New Modification</li> <li>Draft</li> </ul>	Inquiry Request Check List	Change of Manufacturer / license holder -after scientific committee approval done 04/0	01/2023 Accepted V
	Soft Files Check List	Issues for scientific committee opinion 11/01/2023	Rejected v
	Hard Files Check List		helipted *
	Modifications		
	Final approval		
			Streents
÷	Timeline		Activate Windows Go to Settings to activate Windows.







#### 2.1.7 Final approval

In this section the company can find all the final approvals

δivess user-170 USER	Request Details [ bo-201 ]	الم
Navigation	ID Application Date Status Current Step Days Remaining NT-150 Thursday, November 17, 2022 Accepted Submission Accepted NA	
🔃 Worklist		
Notifications	Similar Submissions	~
Requests	Product Details 9.Final approval	
New Modification	Inquiry Request Check List Signed Certificate of Registration	
Draft	Naming Files	
	Soft Files Check List	
	Hard Files Check List	
	Modifications	
	Final approval	
		scroonrec
f[]	Timeline	Activate Windows Go to Settings to activate Windows.



The company can find the comments sent to them in the comments section showing the date of the comment and who sent it and in which step was it sent along with an attachment if any.

### 2.2 Re-uploading Documents

At any time during the process the submission can be sent back to the company to re-upload the unaccepted documents





user-170 Ocilian USER Collian	Request Details			مَنْ مَنْ الْمُوْالْوَلُوْمُوْلُوْ عَنْ الْمُوْالْوُلُوْمُوْ اللهُ الْمُوْلُولُوْمُ الْمُ
Navigation	Product Details	2.Inquiry Request Check List		Save
iii Worklist	Inquiry Request Check List	Scientific reference/pharmacopeia for compos	ition	
Notifications	Naming Files	View file		
Requests	Soft Files Check List	Inquiry Receipt (Fee = 1000) Test PDE.pdf	Re-upload	
New Modification Draft	Hard Files Check List	Receipt Number 6776996797	0% Receipt Group	678967967uiouyio
	Modifications	Extra Fees Receipt (Fee = 5000)		
	Final approval	Receipt Number 65747457756	Receipt Group	56756754756trurtu
		Products List		
		Test PDF.pdf	Re-upload	
		Registration certificate / Scientific approval		
		Manufacturer's factory license		Screen
		Test PDF.pdf	Re-upload	Preview
-{[]				Activate Windows Go to Settings to activate Windows.



The company will be able to open the submission from their work list "My Assigned Applications Tab" or from the notification they received to open the submission details page from which they will be able to access all their submission details and re-upload the required documents.

The company will then have to re-upload the required documents by opening the Checklist Tab on the navigation bar inside the details page and start re-uploading all the documents.

After uploading all the documents the user should make sure to press on the save button on the top right to confirm his new uploads.





user-170 USER	Request Details [ Metrobin ]			<b>۵</b>	المن المن المن المن المن المن المن المن
Navigation	Previous comment KINDLY Fix the rejected files				×
Notifications Requests B New Request	ID Application Date NT-31 Wednesday, February 1, 2023	Status Current Step Pending Company Update Request	Days Remaining NA	Take action	
New Modification Draft	Similar Submissions				~
	Comments				~
	Regulatory Manager HF Regulatory Manager Technical Committee Rep HF	Comments (I) V			
	Product Details	7.Hard Files Check List			Save
	Inquiry Request Check List	Certificate of Veterinary Products			
	Naming Files	Electronic Veterinary Registration System.pdf		Re-upload	Preview
	Soft Files Check List	Scientific Committee Approval			
Ĵ	Hard Files Check List	View file Control Administration for Drug Control	N Doport (NODCAD ropor	+)	

Figure 2.34: Take action enabled

The take action button on the top corner inside the details page will now be enabled.

Svans USER	Request Details [ Metrobin ]	مَنْ مَنْ الْدُرْ الْوَالْغِبْرَةِ ٢
Navigation Home Worklist Notifications	Preview Choose your next action	×
Requests	NT-31 Send Reply	
Draft	Similar : Extra attachment Upload Files	~
	Regulatory Regulatory Mar Write Your Comment	· · ·
	Technical Com       B       I       U	
		C Save
	Cancel Submit	
ť[]	Soft Filles Check List  Files Check List  View Tie  View Tie	

Figure 2.35: Taking action





δνεικ USER	Request Details			المنتة المقتلة المفترة
Navigation Home Vorklist Notifications Requests	ID Application Date NT-341 Wednesday, February 1, 2023 Similar Submissions	Status Current Step Days R Pending Company Step 3	ternshing WDs Take action	
<ul><li>New Request</li><li>New Modification</li></ul>				Save
Draft	Inquiry Request Check List	$\checkmark$	,	
		Your application has been saved		
		ок	Re-upload	Preview
		Extra Fees Receipt (Fee = 5000)	Receipt Group	678967967uiouyio
		View file Receipt Number 65747457756		56756754756trurtu
		Products List Test PDF.pdf	Re-upload	Preview
-[]-		Registration certificate / Scientific approval	100%	Go to Settings to activate Windows



The company is now able to press on the "Take Action Button" to Re-forward their submission again to the EDA; they will also be given an option to upload any extra attachment or send a comment if needed.

By pressing submit the application will be sent once again to the EDA to continue assessment.



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Page 26

## 2.3 Naming process

#### 2.3.1 Line extension

user-170 USER								) هَيْنَةُ الْأَقْرَاءِ الْمِعْيَرَ	EDA)
Navigation	Naming Proce	ss			<ul> <li>You need to</li> </ul>	o insert at least 1	generic or 5 trade names		
🗄 Worklist	Commercial Record*								
Notifications		file name	Upload	0%					
Requests									
🗐 New Request	Extra Attachments								
New Modification		file name	Upload						
Draft				0%					
	Naming Comment								
	B I <u>U</u> <del>S</del> <i>∎</i> ≡	~ )≡ ~ A ~ Ti ~ ¶ ~ ≡ ~				x² x2			
	× 0 b × 0 7	• Ξ Ξ Δ 🖩 -	~	5 C P .	~ <> 🕺 👁	- ⊖ ?			
					CH	ARS: 0 WORDS: 0			
	Old Trade Name*								
									e scr
	Drug Type	Drug Name	Arabic Drug Name	Name C	Order S	imilarity	Acceptance	Recording	eenrec
	New Trade Name	Drug Name	Arabic Drug Name	Nam			Activate Go to Sett	e Windows tings windows	

Figure 2.37: Line extension form

δites User Coll	apse sidebar					<b>\$</b>	مَنْ مَنْ الْمُوْلِقُولُ
Navigation	Naming Proc	ess	Observe Newsier Free	(	<ol> <li>You need to insert at least 1</li> <li>You have 4 trials left</li> </ol>	generic or 5 trade name	55
Worklist			Normal Form     O     Line Exten	sion Form			
Requests	Commercial Record*	file name	Upload	0%			
Draft	Extra Attachments	file name	Upload	0%			
	Naming Comment						
	B I U S F		C	с <i>р</i> .	x² x₂ 		
	Drug Type	Drug Name	Arabic Drug Name	Name Orde	CHARS: 0 WORDS: 0 er Similarity	Acceptance	Recording
ť[	Generic	Drug Name	Arabic Drug Name	Nam		Activ Go to	rate Windows Settings Windows.

#### 2.3.2 Normal name list

Figure 2.38: Normal name list form



r-170 R <b>O</b>						<b>*</b>	
n le klist	B I <u>U</u> S J S B È ∨ D T	$ \begin{array}{c c c c c c c c c c c c c c c c c c c $	I≣ ~ ǿ ~	♦ v € 5 C	x² x₂ ∑ ⊛ ⊕ ?		
fications Request	Drug Type	Drug Name	Arabic Drug Name	Name Order	CHARS: 0 WORDS: 0	Acceptance	Recording
t	Generic	Drug Name	Arabic Drug Name	Narr			<b>Q</b>
	Trade Name	Drug Name	Arabic Drug Name	Nam			Q
	Trade Name	Drug Name	Arabic Drug Name	Nam			Q
	Trade Name	Drug Name	Arabic Drug Name	Nam			Q
	Trade Name	Drug Name	Arabic Drug Name	Nam			Q
	Trade Name	Drug Name	Arabic Drug Name	Nam			Q
	Trade Name	Drug Name	Arabic Drug Name	Narr		Activa	

Figure 2.39: Normal name list form

Drug Ty Ins Generic							en la
ons Generic					CHARS: 0 WC	DRDS: 0	
Generic	/pe Dru	g Name	Arabic Drug Name	Name Order	Similarity	Acceptance	Recording
	as	dfsdf	شىشىيش	2			0
iest Compar	ny name position:	Beside drug name     Be	elow drug name				V
<b>-</b> Trade	e Name qu	vqwerasdf	مخالفمب	1	47%	Initial Acceptance	0
<b>—</b> Trade	e Name qv	vesdfasdf	ر <u>مشومت</u> ن	5	50%	Initial Acceptance	0
<b>-</b> Trade	e Name pa	ndol	مالخمائ	4	74%	Initial Rejection	9
<b>O</b> Trade	e Name as	dfsdfqwer	ستيبستنى	3	55%	Initial Acceptance	0
<b>O</b> Trade	e Name sd	fsadfsawerqewrttyrtuy	مىمىئتىنىمىئتى	6	51%	Initial Acceptance	<b>Q</b>
<b>O</b> Trade	e Name Dr	ug Name	Arabic Drug Name	Nam			Q
			Add Name Show Final Li	ist Submit			
						Activate Go to Set	e Windows tings to activate Windows

Figure 2.40: Normal name list form







## 2.4 Start soft file

Request Details [ElSamman's Demo for manual ]			الم
Application Date Wednesday, February 1, 2023	Status Current Step Pending Waiting To Start a Soft Files	Days Remaining 30 Ds S	tart Soft Files
missions			~
duct Details	1.Product Details		Save
equest Check List	1.1 Application Type		
aming Files	Type Of Marekting	Export	
	Line Extension	true	
iles Check List	Type Of Registration	Local	
Files Check List	Accepted Name	ElSamman's Demo for manual	
	Under-reg code	Vre356	
odifications	Still Under Construction	Yes	
	Company Name	vetopharm nerhado international for pharmaceuticals and chemicals	
	Contact Email	registration@vetopharm-eg.com	_
	Manufacturer Name	15 MAY PHARMACEUTICAL (M.P.C)-EGYPT	screenre
	Product Information	Ampeule	Activate Windows Go to Settings to activate Windows.
	Application Date Wednesday, February 1, 2023	Application Date     Status     Current Step       Wednesday, February 1, 2023     Pending     Weiting To Start a Soft Files       missions     I.Product Details       equest Check List     I.1 Application Type       riles Check List     Type Of Marekting       lies Check List     Under-reg code       still Under Construction     Company Name       company Name     Contact Email       Manufacturer Name     Product Information       Dosage Form     Dosage Form	Application Date       Sature       Current Step       Days Benahing       30 Ds       30 Ds         missions       I.Product Details       I.Product Details       11 Application Type         rning Files       1.1 Application Type       Type Of Marekting       Export       I.I.Product Details       I.Prophysical Context Step       I.Product Details       I.Product Information       I.Product Informa

Figure 2.41: Waiting to start soft file

To start Soft Files Process you will be asked to upload a checklist of files according to your registration type and submit it to the EDA

δNERS USER			الم
Navigation	Soft Files [ElSamman's Demo for manual]	1.1 Soft Files [ElSamman's Demo for manual]	
🔝 Worklist		Soft Files Receipt *	
Notifications		Test PDF.pdf Upload	Preview
Requests		234523345234523452345234545ty45ty45ty45ty41545	
New Modification			
Draft		Preliminary Scientific Data Report*	
		Test PDF.pdf Upload	Preview
		Size of Package Declaration	
		Test PDF.pdf Upload	Preview
		Additional Deference	
		Upload Files	
		Supporting Document	
		Test PDF,pdf	Preview Science
			nrec
-[]			Activate Windows Go to Settings to activate Windows.

Figure 2.42: Uploading the soft files





## 2.5 Start hard file

USER	Request Details [ElSamman's Demo for manual ]			
Navigation	Submission Accepted			
<ul><li>Worklist</li><li>Notifications</li></ul>	ID Application Date NT-340 Wednesday, February 1, 2023	Status Current Step Pending Waiting To Start Hard Files	Days Remaining 1095 Ds	
Requests	Start Hard Files			
New Modification				
Draft Draft	Similar Submissions			~
	Product Details	1.Product Details		Save
	Inquiry Request Check List	1.1 Application Type		
	Naming Files	Type Of Marekting	Export	
	Soft Files Check List	Line Extension Type Of Registration	true Local	
	Hard Files Check List	Accepted Name	ElSamman's Demo for manual	
		Under-reg code	Vre356	
	Modifications	Still Under Construction	Yes	Scree
		Company Name	chemicals	<b>B</b>
<b>77</b>		Contact Email	registration@vetopharm-eg.com	Activate Windows
< <u>`</u>		Manufacturer Name	15 MAY PHARMACEUTICAL (M.P.C)-EGYPT	Go to Settings to activate Windows.

Figure 2.43: Waiting to start hard file

To start Hard Files Process you will be asked to upload a checklist of files according to your registration type and submit it to the EDA

overs user-170 USER			مَنْ تَذَالَذُوْ الْمُوْلَةِ (٢) هَنْ تَذَالُدُوْ الْمُوْلَةِ (٢)
Navigation	Hard Files [ElSamman's Demo for manual]	1.1 Hard Files [ElSamman's Demo for manual]	
🗄 Worklist	2 Suppliers Details	Certificate of Veterinary Products*	
Notifications		file name Upload	
Requests		Scientific Committee Approval •	
New Modification		oprodultinos	
Draft		Central Administration for Drug Control Report (NODCAR report)*	
		file name Upload	
		0%	
		General Administration of Stability Report*	
		file name Upload	
		Hard Files Fees Mandatory*	
		file name Upload	
		Receipt Number *	e screen rec
		Formulation Composition*	Activate Windows
чU		file name Upload	

Figure 2.44: Uploading the hard files

			REVENCEDA LER
		Page 30	هيَتة الأقراء المضرِّية
блика <b>user-170</b> USER О			الم
Navigation Home Worklist Notifications Request New Request New Modification Draft	<ol> <li>Hard Files [ElSamman's Demo for manual]</li> <li>Suppliers Details</li> </ol>	Suppliers Details HYDROCORTISONE  Suppliers  suppliers  cretificate of Analysis of Active Raw Materials*  file name  file	
			Activate Windows
÷.		Everest Minds © everestminds.com	Go to Settings to activate Windows.



### 2.6 Modifications

SVERS USER					الفريق	المعنى مَيْتَةُ الْأَوْالِ
Navigation	Modifications:					
📃 Worklist	Submission_id*			<ul> <li>Modifications</li> <li>1. Reference change before Sc.</li> </ul>	Committee Approval	-
Notifications						
Requests New Request New Modification	Reference change before Sc. Committee Approval	1.1 Reference change	before Sc. Commi	ttee Approval		
Draft		Scientific reference/pharmacopeia for	composition*			
		file name		Upload		
					0%	
		Fees*				
		file name		Upload		
					0%	
		Receipt Number *	Receipt Group *			
		Signed Cover Letter*				
		file name		Upload	0%	8
सी		Reference Country *		~	Activate Win Go to Settings to	dows o activate Windows.
- 4 <u>0</u> -		Reference (for each product) *				

Figure 2.46: Applying for a modification

The user can apply for a modification through the modification section in the side navigation bar. Firstly the user should select the modification that he/she wish to request. Then the user should make sure that the submission ID is correct.

		Pag	e <b>31</b>		المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المرابع المم المرابع المم المم المم المم المم المم المم الم
GW88 User-170 USER O					المن من من المراطق المن المن المن المن المن المن المن المن
Navigation Home Worklist Notifications	Modifications:			todifications	ie Approval
Requests Request New Request New Modification Carlot Draft	Reference change bofore Sc. Committee Approval	I.1 Reference change bef Scientific reference/pharmacopeia for compos file name Fees* file name	2. Saft / Dosage Form chain 3. Product Cancellation at 4. Product Cancellation at 5. Name change before Sc 6. Name change after Sc 7. Reference change at the 9. Change of Manufacture 9. Change Agent Modifica 10. Request of Approval of 11. Salt change (addition – 12. Issues for scientific con 13. Manufacturing Site Ch 14. Stability Requests (inis) 15. Central Administration 16. Request of issue of re- 19. Change of Manufactur 20. Change Agent in case 21. Manufacturing Site Ch	espectionininities Approval regise before Sc. Committee Approval fore Sc. Committee Approval ter scientific committee approval Committee Approval Committee Approval other referential product after Sc. Commit (in finalizing registration steps with no reference omission – edition) after Sc. Committee - mittee opinion ange requests under registration after Applications to the steps for Drug Control Requests egistration status letter - postpone (Re- ref / license holder (in case of imported po- of imported products before Scientific C ange than mentioned in Central Adminisi	hittee Approval ttee approval done rence after Sc.Committee Approval Approval egistration Module) roducts) before Scientific Committee stration of Drug Control Approval
ŕŪ		Receipt Number * Rece Signed Cover Letter* file name Reference Country * Reference (for each product) *	ipt Group *	Upload 0%	Activate Windows Go to Settings to activate Windows.

Figure 2.47: Applying for a modification

For any modification request the following points should be considered:

- The user requesting the modification should enter the Submission request id to proceed with the request.
- Only One modification can be requested at the same time for each request.
- Once the user applies for a modification request, all due dates regarding this submission in the normal request are to be put on hold and no action can be taken on the submission until the end of the modification request.
- After approval of the request all the concerned users will be notified.
- A Modification history on each submission will be available for viewing inside the details page.
- Any modification will require a list of requirements to be filled or uploaded.
- Each modification request has its own workflow and action plan with its own outcomes.





## 2.7 Status List

This is a table for the each status in the system. This works as a guide to know exactly the status of the application.

Status Name	Description
Pending	This means the submission is under processes
Queue	This means your submission is inside a Queue and waiting for its turn for the EDA to start working on
Modification	This means your submission is under a modification process
Rejected/Cancelled	This means the submission is rejected or cancelled by the EDA
Accepted	This Means the submission has ended and you got your Certificate of Registration





#### 2.7.1 Screenshots for the status names



Figure 2.50: Accepted status

Note : Any Updates on the system resulting in a change in the user manual, an updated user manual will be sent