

# SIMILIA

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## PRODUCT DEVELOPMENT

### Journey of itchgoes

**Ilma Hynson**

#### Abstract

Being a homoeopath and coming from the city, my main areas of treatment were general and treating children with autism spectrum disorder. However at the time I arrived in Yamba there seemed to be quite a few cases of mosquito borne viruses mainly Ross River and Barmah Forest. These viruses initiated an interest in mosquitoes and were the trigger to opening a Mosquito Borne Virus Clinic in Yamba (2005). The success achieved in the Mosquito Borne Virus Clinic, (which now includes the treatment of Dengue Fever) was the catalyst to starting my research. This article traces the journey from an idea to the development of a product.

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#### Inspired by Mosquitoes

When I first arrived in Yamba, I was totally unprepared for the mosquitoes and sand flies which enjoyed a feast on the fresh blood that had moved into town. I suppose I hadn't given too much thought to the environment I had moved into (across the road from Yuraygir National Park and surrounded by wetlands and mangroves) the ideal environment which is home to mosquitoes and sand flies (also known as midges).

My interest in Mosquito Borne Viruses reaffirmed the obvious, that everyone attending my Clinic had reached a point of overload and imbalance in their lives, resulting in a weakened immune system. Viruses are opportunists and will happily take residence in an out of balance immune system. As a result of the benefits being achieved in the Mosquito Borne Virus Clinic, I was motivated to start research to find a Homoeopathic topical product. This product would soothe the irritation of mosquito and sand fly bites.

## **Case appetizer to accompany the journey**

Acute case using topical product 3/9/2012

A case of tick bite poisoning, which was cured in three days by the addition of one other remedy taken orally and itches applied topically.

Monday morning 9am, a gentleman arrived at my Clinic. He had been bitten by a tick two days previous. By the time I saw this gentleman he had problems putting a sentence together.

He said he felt as though he wasn't in his body and was disconnected. He hadn't noticed the bite and swelling on his left tricep until his left arm pit started to throb. The arm became very painful, it was inflamed and itchy. He was now suffering with cellulitis which caused his arm to be three times its normal size. He had been to the hospital and he refused intravenous antibiotics. This man was in a state of shock, I gave him arnica 1M and went to get him a glass of water. On my return he was in floods of tears and unable to talk.

Rubrics used Robin Murthy Repertory (pages 342, 588, 597, 611):

Emergency, bites, animals and insects Calad, Hyper, Led

Generals, pulsation, Calad

Generals, pains, burning, externally Calad, Led

Generals swelling, Calad, Led

I prescribed the remedies in the product plus Hypericum 6c orally every half hour until symptoms lessen, then every two to three hours, again reducing the dose as symptoms reduced. I also asked him to use product topically on the area of the bite.

Wednesday morning, he arrived at the Clinic to show me his arm which was back to its normal size, very slight inflammation on the forearm and he now felt as though he was back in his body.

## **The journey from a thought to a product**

I chose to start with research in to the actual product and the many other issues involved in aiming to sell a homoeopathic topical product in retail outlets. The following is a guide to assist other Homoeopaths to attain their goal of producing a product.

## **Legal issues and protocol**

I first had to check with my Homoeopathic Insurance Provider to make sure I was covered to conduct trials with homoeopathic preparations. After answering a few questions and giving them a copy of the Disclaimer Form which I gave to all volunteers, an email arrived saying I could conduct the trials.

That box was now ticked. So how does one go about asking people to get bitten and stung for very little reward, other than a few complimentary bottles of a product? When the formula was found an advertisement in the local newspapers was the answer.

However there were a few pieces of jigsaw missing before I assembled my willing volunteers together.

### **Work within TGA guidelines (2009)**

I made contact with the TGA (Therapeutic Goods Administration) to inform them of what I intended to do then waited to be pointed in the right direction, which of course was crucial to the product being available to the public. My understanding of this legislation was that I had to meet the exemption criteria and comply with the labelling requirements.

*Schedule 5, Item 8 of the Therapeutic Goods Regulations (the Regulations), exempts certain homoeopathic medicines from the operation of Part 3-2 of the Act (Registration and listing of therapeutic goods), as follows.*

*The following medicines unless the indications proposed by the sponsor are in the treatment of a disease, condition, ailment or defect specified in Part 1 or 2 of Appendix 6 to the Therapeutic Goods Advertising Code:*

*(a) Homoeopathic preparations more dilute than a one thousand fold dilution of a mother tincture and which are not required to be sterile; and which do not include an ingredient of:*

*(i) Human origin; or*

*(ii) Animal origin, if the ingredient consists of, or is derived from, any of the following parts of cattle, sheep, goats or mule deer:*

*(A) Adrenal;*

*(B) Brain;*

*(C) Cerebrospinal fluid;*

*(D) Dura mater;*

*(E) Eye;*

*(F) Ileum;*

*(G) Lymph nodes;*

*(H) Pineal gland;*

*(I) Pituitary;*

*(J) Placenta;*

*(K) Proximal colon;*

*(L) Spinal cord;*

*(M) Spleen;*

(N) Tonsil;

*Schedule 7, Item 7 of the Regulations exempts 'homoeopathic preparations more dilute than a one thousand fold dilution of a mother tincture (a 3x potency) and that are not required to be sterile' from the operation of Part 3-3 of the Act (Manufacturing of therapeutic goods).*

### **TGA Guidelines of Labelling (2009)**

#### **Batch Number and Expiry Date**

The batch number and expiry date should be positioned together and situated preferably on the end or side panel of the package.

Ideally, the storage conditions should be located close to the batch number and expiry date, and preferably on the front or side panels as end panels are already filled with product / active ingredient names and / or batch expiry information

#### **Product Name and Strength**

Both the product name and the active ingredient names and strength should be prominently and equally displayed on the packet on at least three sides, including the two end panels. Strength and quantity should also be displayed. To assist in easy storage and reference the product and active ingredient names and strength / quantity should be displayed on end panels, with the first name alternating between the two end panels. To distinguish between the product name and the active ingredient name, the first letter of the product name should be in upper case and of the active ingredient name in lower case with a different colour for each. Fonts may be used to differentiate, but all fonts should be clearly legible.

There should be consistency in terminology to describe strength. All products in one product line should follow the same convention.

The use of colour and design should not unnecessarily clutter or obscure the message of the labels but make them clear and distinguishable.

Pictures or graphics should be meaningful, appropriate, and represent the use of a medicine.

Exceptions applicable to small containers up to 20 mL will apply to the bottle label:

See subclause 3(11) of the Therapeutic Goods Order (TGO 69). The carton label must still comply with all the requirements of subsections 3(2) and 3(3) of the TGO 69.

I complied with the TGA requirements as communicated to me and I was now able start the trials.

### **This advertisement appeared in our local paper**

**Wanted Volunteers**

**To trial a range of natural products**

**To sooth the itch**

## Of Mosquito and Sand fly bites

### To Register

Contact the Yamba Wellbeing Centre

Phone 6646 9452

4/5 Yamba St, Yamba NSW 2464

### Volunteers

Eighteen people volunteered all from the Clarence Valley. Fourteen females and four males, including a female pregnant nurse. The median age of the participants was forty two years.

### Remedy choice

The choice of remedies was based on the rubrics (symptoms) found in the Repertory. The remedies chosen to trial were the ones which contained the most skin irritation symptoms from insect bites and stings. I also included a couple of remedies that I felt were relevant (eg) Formica rufa (made from ants that has a lot of skin irritations) and Culex musca (made from the mosquito with skin irritation symptoms).

Skin Insect Bites												
Symptoms												
Mosquitoes	Calad		Led	Staph								
Mosquitoes bite burn / it	Calad											
Insect bite	Calad	Apis	Led				Hyper	lach			Caust	Urt u
Snake bite	Calad	Apis	Led					lach	Pyrogen	Viper		
Bite itching	Calad	Apis				Rhus tox						
Itching < night		Apis	Led			Rhus tox						
Bite burning	Calad	Apis		Staph	Canth	Rhus tox						
Bite stinging		Apis		Staph								
Erupt itch night						Rhus tox						
Eruption itching	Calad		Led	Staph	Canth	Rhus tox					Caust	Sulph
Eruption Hard						Rhus tox					Caust	
Eruption elevated								lach				
Eruption red	Calad	Apis										
Area pale/ mottled			Led 30									
Skin swollen		Apis				Rhus tox						
Blisters					Canth 30	Rhus tox						
Blister red edge						Rhus tox						
Blisters itching					Canth 30							
<Heat						Rhus tox						
<Touch		Apis										
> Cold		Apis	Led		Canth							
Pain shooting							Hyper					
Septic			Led				Hyper	lach	Pyrogen			

The objective of the trials was to find the most effective topical remedy. Eight remedies were used in six different potencies, ranging from 3x to 30c. These remedies were Caladium, Culex musca, Cantharis, Formica rufa, Ledum, Apis mellifica, Staphisagria and Rhus toxicodendron.

## Volunteer guide lines

All participants attended an information session during which people had a chance to ask questions after which they signed the Consent Form, Volunteer Disclaimer form and completed their Health Check form.

All trial participants then received a Volunteer Kit. The kit included their first six remedies and the forms below. All was now in place to begin the trials.

### The Volunteer Kit contained:

1. Form Observational Week - example below
2. Project 2007 Remedy Instructions / Application – example below
3. Weekly Project Instructions – example bellow

### An example of Observation Week

***Please follow instructions below.***

***Please highlight or ✓ all appropriate words***

***Where it is printed 'Other' please name, describe or state details***

*Do not use topical insect repellents, or itch relief products on the skin during this first week. You can use plain unscented moisturiser or sunscreen.*

*I need to collect base information. I am requesting you to observe your body's reaction to being bitten, this is important for a comparison.*

<b>Day 1</b>	<b>Date</b>			
<b>Symptoms</b>				
<i>Insect</i>	<i>Mosquito</i>	<i>Sand fly</i>	<i>Other</i>	
<i>Itch</i>	<i>None</i>	<i>Slight</i>	<i>Intense</i>	
<i>Swelling</i>	<i>None</i>	<i>Slight</i>	<i>Intense</i>	
<i>Eruption</i>	<i>Red</i>	<i>White</i>	<i>Other</i>	
<i>Heat</i>	<i>None</i>	<i>Slight</i>	<i>Intense</i>	

*Please describe anything else you have noticed.*

*The above question was repeated over the 7 days of the Observation week and when the form was returned. The volunteer picked up their first week trial remedies and instructions.*

### An example of Project 2007 Remedy Instructions / Application

***Please follow instructions below:***

- *Apply one drop of the remedy to each insect bite and massage gently for a couple of seconds. This will be classed as one application.*
- *Wait two or three minutes between applications.*

- Note the average application to each bite old and new.
- If you experience any reaction to the remedy stop the remedy and contact your supervisor.
- Please describe other observations or give further comments at the end of each day. This information will be of great benefit to the project and is greatly appreciated.
- Use one remedy per day for six days as indicated.
- On the seventh day use remedies based on the effectiveness of the previous days. Make comments to your choice of potencies and state the remedy potencies you use.

Please return your completed information sheets and your remedies to your Supervisor:

Date Returned 2007/08

**An example of Weekly Project Instructions -this format was repeated throughout the trials**

**Project Instructions**

Number                      Date / /2007

Abbreviation for Remedy is Rx and Potency is the number after the remedy name  
Please highlight or ✓ all appropriate words.

Where it is printed 'Other' please name, describe or state details

Stop application of the remedies when symptoms lessen and wait.  
Start the remedy again if symptoms return or change remedy as directed.

**Rx name and number Caladium 6c**

**Time first Rx applied \_\_\_\_\_**

**Day1 Symptoms**

<b>Insect</b>	Mosquito	Sand fly	Other
<b>Bite</b>	Red	White	Other
<b>Itch</b>	None	Slight	Intense
<b>Heat</b>	None	Slight	Intense
<b>Swelling</b>	None	Slight	Intense

**What changes did you first notice after applying the Rx**

<b>Bite</b>	No change	Decreased	Other
<b>Itch</b>	No change	Decreased	Stopped
<b>Heat</b>	No change	Decreased	Stopped
<b>Swelling</b>	No change	Decreased	Stopped

**How long did the changes last between applications**

2mins	5mins	10mins	1hr	3hr	6hr
9hr	12hr	1day	Other		

**What was the average application of the remedy to the bites Old ... New...**

**Please give further comments:**

**This question was repeated for 7 days and all weeks finished with the question below.**

**End of Week**

**What were the most significant changes you noticed?**

<b>Bite relief</b>	<i>Quick</i>	<i>Slow</i>	<i>No Change</i>
<b>Itch relief</b>	<i>Quick</i>	<i>Slow</i>	<i>No Change</i>
<b>Heat reduced</b>	<i>Quick</i>	<i>Slow</i>	<i>No Change</i>
<b>Swelling reduced</b>	<i>Quick</i>	<i>Slow</i>	<i>No Change</i>

*Please describe other observations that you have noticed and include any changes in your emotions or thoughts that you may consider as being relevant to this project. Your constructive criticism will be considered a great value to this project.*

### **Eureka! Trial results complete**

In December 2009 the trial was completed. A thank you note went out to the volunteers who persisted in getting bitten and stung. From the results it became clear that the 30c potency in all the remedies did not work as effectively in a topical application as the lower potencies. The results below indicate the top four most effective remedies and potencies from the trial.

Trial Results	2007/ 2008											
	Remedy	%	%	Remedy	%	%	Remedy	%	%	Remedy	%	%
Potency		9c	12c		9c	3x		12c	6c		6x	9c
Mosquitoes	Calad	87%	93%	Led	93%	87%	Culex	93%	83%	Rhus tox	83%	83%
Sand flies	Calad	93%	93%	Led	93%	87%	Culex	93%	83%	Rhus tox	87%	71%
itching / stinging	Calad	93%	93%	Led	87%	83%	Culex	87%	83%	Rhus tox	93%	93%
Bite	Calad	83%	88%	Led	93%	88%	Culex	87%	87%	Rhus tox	83%	87%
Itch	Calad	83%	100%	Led	83%	83%	Culex	93%	71%	Rhus tox	93%	83%
Heat	Calad	66%	87%	Led	71%	75%	Culex	66%	66%	Rhus tox	66%	66%
Swelling	Calad	83%	93%	Led	93%	93%	Culex	71%	83%	Rhus tox	87%	93%
<b>Overall percentages</b>		<b>84%</b>	<b>92%</b>		<b>92%</b>	<b>85%</b>		<b>85%</b>	<b>79%</b>		<b>84%</b>	<b>82%</b>

As is shown in the table Caladium 12c and Ledum 9c were the leading remedies in the trial both these remedies were effective for over 90% of people. These two remedies were therefore the formula choice for my new product.

### **Final Steps to Retail Shelves**

#### **Product name**

During those two years I was also having talks with friends and colleagues regarding names for the product and packaging design. I visited our local supermarkets and assessed which products stood out on the shelves, what colours were being used, what looked attractive and considered the trends at the time. When the name *itchgoes* was decided for the product and the graphics were in place I then went out onto the streets with a clipboard and asked people ‘what is the first thing you think of

if you came across a product called *itchgoes*? The results of this little survey convinced me the name was correct.

### **Trademark**

Trademarking the product was quite an easy procedure though lengthy as there was a waiting period where any objections to the name could be made. Fortunately this did not happen and *itchgoes* got intellectual property rights in 2010.

### **Expiry date**

John Morgan from Helios UK and Michael Dong from Similimum NZ were both very helpful in assisting me in calculating the ratios of alcohol and the product expiry dates.

### **Design and Packaging**

My graphic designer worked according to my design and specifications and a company in Brisbane manufactured the packaging. After lots of searching I realised that one couldn't get glass bottles manufactured in Australia. However there are distributors who import glass bottles from various countries and it was only a matter of time before I found a distributor selling at an affordable price for the quantity I wished to purchase.

### **End of a Journey**

The journey from a thought to a product took two years. When I set off on this journey it never occurred to me how many steps would be involved in reaching my objective. I couldn't have completed this journey without the supportive volunteers who remained with me, believing as I did that the product would benefit many skin irritations resulting from mosquito and sand fly bites. *itchgoes* has now been on the market for seven years and is healing far more than insect bites and stings. I am so often in awe at the power of homoeopathy and I am grateful to *itchgoes* for revealing more than I ever knew about the remedies Caladium and Ledum.

My *itchgoes* journey was a thought that became a reality I trust that this article encourages other homoeopaths to make their thoughts reality.



**Ilma Hynson** started her career in England in 1987, studying at the Northern College of Homoeopathy in Newcastle on Tyne. She completed her studies in 1993 with the qualification of Homoeopath Licentiate and became a registered Homoeopath in 1996.

In 1998 she found her way to our Australian shores and settled in Sydney where she lived for seven years. In 2005 ilma made a lifestyle change and moved to the Northern Rivers area of NSW, making her home in Yamba. ilma's vision to have a practice in Yamba came to fruition when she encouraged three other health professionals to become part of a Centre for Holistic Health. The idea became a reality when in March 2006 the Yamba Wellbeing Centre opened its doors to the people of Yamba.