HEALTH CANADA: Natural Health PRODUCTS REGULATIONS
SITE LICENSING

PRESENTED BY

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bjective:

he objective of this presentation is to rovide attendees with some essential nformation on HC Natural Health roducts regulations and site licensing rocess

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Background

All NHPs sold in Canada are subject to the *Natural Health Products Regulations*, which came into force on January 1, 2004.

To get product and site licenses, specific labelling and packaging requirements must be met, GMPs must be followed, and proper safety and efficacy evidence must be provided.

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What are natural health products?

Natural health products (NHPs) are naturally occurring substances that are used to restore or maintain good health. They are often made from plants, but can also be made from animals, microorganisms and marine sources. They come in a wide variety of forms like tablets, capsules, tinctures, solutions, creams, ointments and drops.

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HPs (complementary or alternative edicines, include:

- Vitamins and minerals
- Herbal remedies
- Traditional and Homeopathic medicines
- Probiotics
- Other products like amino acids and essential fatty acids

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HPs are used and marketed for a umber of health reasons, like the revention or treatment of an illness or ondition, the reduction of health risks, or he maintenance of good health. They nust be safe to be used as over-the-ounter products.

roducts needing a prescription are egulated as drugs.

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e there risks to using NHPs?

hile NHPs are generally safe, they are not free. Risks include:

- Manufacturing problems (Such as contamination, or incorrect ingredients)
- Unproven claims, which can lead people to use the wrong products for serious conditions

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e there risks to using NHPs?

- Not enough information for people to make an informed choice (like incorrect instructions or no warnings that a product may not be suitable for certain groups)
- Interaction with others prescription drugs
- Unwanted side effects

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HPs Marketing authorization?

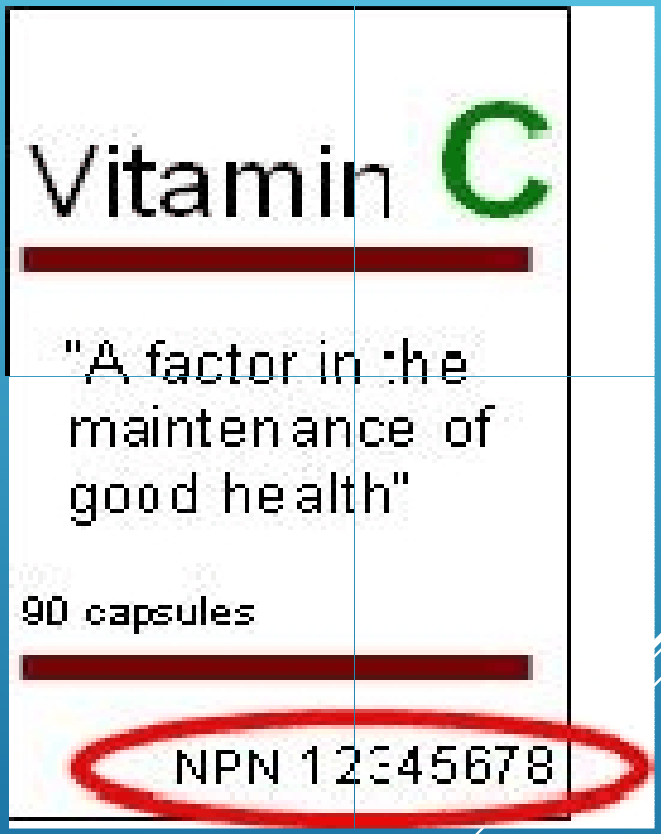
be licensed in Canada, NHPs must e safe, effective, of high quality and arry detailed label information

eople can identify products that have een licensed for sale in Canada by oking for the eight-digit Natural oduct Number (NPN) on the label.

NPN means that the product has een authorized for sale in Canada and safe and effective

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C Approval: NPN



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C Licensing Requirements:

- Product licensing
- Evidence requirements for safety and efficacy
- Site licensing
- Good Manufacturing Practices

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roduct licensing

ll NHPs must have a product license efore they can be sold in Canada.

o get a license, applicants must give etailed information about the product o Health Canada, including: medicinal ngredients, source, dose, potency, non-nedicinal ingredients and ecommended use(s).

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dence requirements for safety and efficacy

e safety and efficacy of NHPs and their alth claims must be supported by pper evidence so that consumers and C know the products are safe and fective.

e type and amount of supporting idence required depends on the pposed health claim of the product d its overall risks.

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e licensing

Canadian manufacturers, packagers, belers, and importers of NHPs must have e licenses.

get a license, sites must maintain oper distribution records, have proper ocedures for product recalls and for the ndling, storage and delivery of their oducts, and demonstrate that they eet GMPs requirements.

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hat is a Site Licence?

e Regulations requires a manufacturer, ackager, labeler, and importer of NHPs hold a valid site licence.

site licence issued by the NHPD gives e licensee authorization to conduct ese activities.

ese activities must be carried out ccording to the GMPs outlined under e Regulations.

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ood Manufacturing Practices (GMPs)

Good Manufacturing Practices for HPs cover:

roduct specifications, premises, quipment, personnel, sanitation rogram, operations, quality ssurance, stability, records, batch amples, and recall reporting

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rpose of the Site Licence Regulations

To ensure that HC is aware of all sites that are manufacturing, packaging, labelling, and importing NHPs in Canada.

To set the requirement that businesses assure HC that they are meeting the regulatory requirements related to GMP

To ensure that all NHPs are safe, of good quality, and are produced & stored in sites that comply with the GMP Regulations.

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Who Requires a Site Licence?

site licence is required for the physical te in Canada where any persons or usinesses wish to manufacture, ackage, label, and/or import a NHP or sale.

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lotes on Importing NHPs:

Any business or individual that brings into Canada a NHP for the purpose of sale is considered to be an importer.

Importers that ship a product directly to the retailer without first storing the product require a site licence

Retailers selling products that they themselves have imported are considered importers

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plying for a Site Licence

plicants must provide evidence of GMP mpliance in the form of one of the following:

- Audit Report from a NHPD recognized third party
- Quality Assurance Report (QAR) Form
- Drug Establishment Licence (DEL):
- Certificate of Compliance (CoC) or inspection eport issued by a Regulatory Authority from a country for which HC presently has a mutual ecognition agreement (MRA)
- GMP Certificate from a Qualified Authority

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Submission Management

creening & Assessment of the Application

- Applications meeting administrative requirements will be assigned a file number and a submission number.
- The NHPD aims to complete a site licence application within 45 days from the date of receipt to the date of issuance of the site licence or refusal.

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ficiencies in the Application

eficiencies in the application can range
om minor and easily correctable to
ajor or critical,
ere are four types of deficiencies:

- Administrative deficiencies
- Minor deficiencies
- Major deficiencies
- Critical deficiencies

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te Licence Issuance:

he NHPD will only issue or amend a site cence when the applicant has ubmitted a complete submission with ll the required supporting information o assess whether the site is fully ompliant with the Regulations.

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efusal to Issue a Site Licence:

he NHPD may refuse to issue or amend
a site licence when the site is not
compliant with the GMP requirements

- When the application is deficient,
- When the applicant does not provide additional information on request, or
- When the information submitted is false or misleading.

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oducts Manufactured, Packaged and belled at Foreign Sites

anadian importers must be licensed nd the onus is on them to provide vidence that imported products come om sites that meet Canadian GMPs or quivalent standards.

nporters may submit either an Audit eport from third party or a QAR or any the following of for their foreign sites:

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Foreign Site Reference Number (FSRN) Authorization Form:

A FSRN authorization form signed and dated by the Senior Official indicated for that company.

FSRN's are issued to sites that have demonstrated compliance to GMPs Regulations via the FSRN application process.

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Certificate of Compliance (CoC)

r inspection report (including orrective actions taken) issued by a egulatory Authority from a country for hich the HC Inspectorate presently as a mutual recognition agreement MRA) related to GMP.

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Good Manufacturing Practices
ertificate or inspection report (including
e corrective actions taken) from a
ualified Authority.
qualified authority is an authority
ember of the Pharmaceutical
spection Cooperation Scheme (PIC/S)
the United States Food and Drug
dministration (USFDA).

ence Expiry and Renewal

e site licence must be renewed as lows:

- Every year, for the first three years
- Every two years, when the licensee has eld the licence for three years from the ate of issuance but less than nine years.
- Every three years, when the licensee as held the licence for nine years from e date of issuance or more.

cence Amendment

n amendment is required when:

- Adding a new activity.
- Adding a new building
- Changing from manufacturing, packaging, labelling, or importing a non-sterile dosage form to sterile dosage form.
- Adding a new foreign site.

ence Suspension and Cancellation

C may suspend a site licence when:

- The licensee is found to have contravened the Regulations
- When licensee make a false or misleading statement in the application
- When HC has enough evidence to believe that it is necessary to suspend the licence to prevent consumers injury .

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To Conclude:

site wishing to obtain a SL must demonstrate
at requirements for GMP have been met.

To demonstrate GMP compliance, the site will need to provide evidence that its buildings, equipment, procedures and proposed practices meet the requirements

A Canadian importer must provide satisfactory evidence that the foreign site meets the Canadian GMP requirements required by the Canadian regulations

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For Any Questions Please Contact:

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