NEW HEP C TREATMENTS

~ STEPS IN THE NEW HEP C DRUG DEVELOPMENT AND APPROVAL PROCESS IN CANADA AND BC ~

NEW DRUGS IN THE APPROVAL PIPELINE AS OF SEPTEMBER 2017*

§ LINK ICON INDICATES DRUGS TAKEN IN COMBINATION

DRUG NAMES GROUPED BY COMPANY

ABBVIE

- **HOLKIRA PAK** - NS5A INHIBITOR | NS3/4A PROTEASE INHIBITOR | NON-NUCLEOSIDE NS5B POLYMERASE INHIBITOR
- **TECHNIVIE** - NS5A INHIBITOR | NS3/4A PROTEASE INHIBITOR
- **MAVIRET** - NS3/4A PROTEASE INHIBITOR | NS5A INHIBITOR

BRISTOL-MYERS SQUIBB

- **SUNVEPRA** - NS3/4A PROTEASE INHIBITOR
- **DAKLINZA** - NS5A INHIBITOR

GILEAD

- **SOVALDI** - NUCLEOTIDE NS5B POLYMERASE INHIBITOR
- **HARVONI** - NS5A INHIBITOR | NUCLEOTIDE NS5B POLYMERASE INHIBITOR
- **EPCLUSA** - NUCLEOTIDE NS5B POLYMERASE INHIBITOR | NS5A INHIBITOR
- **VOSEVI** - NUCLEOTIDE ANALOG NS5B POLYMERASE INHIBITOR/ PANGENOTYPIC NS5A INHIBITOR/NS3/4A PROTEASE INHIBITOR

JANSSEN

- **GALEXOS** - NS3/4A PROTEASE INHIBITOR
- § **GALEXOS/SOVALDI** - NS3/4A PROTEASE INHIBITOR | NUCLEOTIDE NS5B POLYMERASE INHIBITOR

MERCK

- **ZEPATIER** - NS3/4A PROTEASE INHIBITOR | NS5A INHIBITOR

*BE SURE TO CHECK THE TIP WEBSITE FOR THE PROGRESS OF THESE DRUGS: WWW.PACIFICHEPC.ORG/HEPCTIP
A TREATMENT MAY BE IN STEPS THREE, FOUR, AND FIVE AT THE SAME TIME. PLEASE SEE WWW.PACIFICHEPC.ORG/HEPCTIP/HEP-C-DRUG-PIPELINE FOR MORE INFORMATION

DRUG PIPELINE

STEPS IN THE DRUG APPROVAL PROCESS

STEP ONE

STEP ONE - TESTING

- Scientists develop chemical compounds/drugs.
- Initial testing takes place in labs/animals.
- The drug company applies for permission (to the Therapeutic Products Directorate (TPD) - an office of Health Canada), to start clinical trials with people.
- If the application is approved by TPD, the drug moves to STEP TWO.

STEP TWO

STEP TWO - CLINICAL TRIALS/NEW DRUG SUBMISSION (TO THERAPEUTIC PRODUCTS DIRECTORATE)

- Clinical trials with people are started.
- Clinical trials often take 1-3 years to conduct, in order to properly research and analyze how the drug works in people.
- If a clinical trial shows the drug works well and that the benefits of the drug outweigh risks or bad side effects, the drug company can file a 'New Drug' Submission with TPD.
- The New Drug Submission is then reviewed by TPD, for drug safety, how well the drug works (efficacy of the drug) and potential benefits and risks.

STEP THREE

STEP THREE - NOTICE OF COMPLIANCE + DRUG IDENTIFICATION NUMBER/NOC + DIN

- At this stage, the TPD looks at all the information about the new drug submitted by the drug company/sponsor of the clinical trial.
- If the New Drug Submission is considered beneficial, the drug is issued a 'Notice of Compliance' (NOC) and a 'Drug Identification Number' (DIN).
- The 'NOC' and 'DIN' allow the drug to be sold in Canada, with official approval.
- If a drug has an 'NOC' a doctor may prescribe the drug – but at this stage the new drug is still not available on public drug plans, like BC PharmaCare. Private insurers each decide company coverage of the new drug (ie. what percentage of the drug costs they will cover).
- If the New Drug Submission doesn't have enough evidence, or the risks outweigh the benefits, the government doesn't approve the drug. The company/sponsor can then provide more information/data, or appeal the decision.
- Average time for TPD to review a drug = 18 MONTHS.

STEP FOUR

STEP FOUR- COMMON DRUG REVIEW BY CADTH AND PCPA PROCESS

- After a drug is issued a NOC, the drug sponsor/company submits an application to the Federal agency, **www.cadth.ca** Canadian Agency for Drugs and Technology in Health (CADTH). At this stage of the process, the government analyzes a drug for economic and health value, evaluating a drug in comparison to other available drugs.
- CADTH conducts the Common Drug Review (CDR). The CDR is an economic and pricing analyses conducted in order make recommendations to the provinces on how a drug should be listed on the provincial PharmaCare formulary. Private insurance companies also use the CDR recommendations to make decisions about how to cover the new drug.
- Note: A drug can be submitted for the CDR before the federal government issues a 'NOC' – but the feds have to be informed of this prior to the CDR.
- The CDR is conducted by experts who review clinical data, economic analyses and patient input. This committee is called the Canadian Drug Expert Committee (CDEC).
- CDEC consider two main questions:
  - How does the drug compare to similar drugs used for the condition?
  - Does the drug provide value for money?
- The Common Drug Review can take up to 7 MONTHS from time of submission.

STEP FIVE

STEP FIVE- PROVINCIAL REVIEW

- Once the CDR is completed, the BC Ministry of Health Services initiates its own drug review, to define how a treatment/drug will be listed on the provincial formulary for Pharmacare.
- The "Drug Review Resource Committee", which has teams of experts evaluate different aspects of a drug under review, does the provincial review. Both practitioners and patients are also asked for input via "Your Voice"
- Once the review is done, the Ministry of Health Services determines if and how a drug will be listed on the provincial formulary for PharmaCare.
- This stage of the process can take up to 1 YEAR to complete.

APPROVAL

STEP SIX- PHARMACARE AVAILABILITY

- After the Provincial drug review is complete, a drug is available to BC residents, as per Pharmacare eligibility requirements.
- Pharmacare defines how much the province will pay for a treatment, and when a person is eligible to receive these public benefits.