[AS REPORTED FROM THE SOCIAL SERVICES COMMITTEE]

House of Representatives, 13 November 1962

Words struck out by the Social Services Committee are shown in italics within bold round brackets, or with black rule at beginning and after last line of struck out matter; words inserted are shown in roman underlined with a double rule, or with double rule before first line and after last line of new matter.

Hon. Mr McKay

FOOD AND DRUGS AMENDMENT

ANALYSIS

A BILL INTITULED

An Act to amend the Food and Drugs Act 1947

BE IT ENACTED by the General Assembly of New Zealand in Parliament assembled, and by the authority of the same, as follows:

1. Short Title—This Act may be cited as the Food and Drugs Amendment Act 1962, and shall be read together with and deemed part of the Food and Drugs Act 1947 (hereinafter referred to as the principal Act).

2. Interpretation—(1) Section 2 of the principal Act is hereby amended by repealing the definition of the term "drug", and substituting the following definition:

" 'Drug' means—

"(a) Any substance or mixture of substances used or intended for use, whether internally or externally, for the purposes of the prevention, diagnosis, or treatment of any disease, ailment, disorder, deformity, defect, or injury of the human body:

"(b) Any substance or mixture of substances used or intended for use for the purpose of altering the nutrition or structure of the human body:

"(c) Any substance or mixture of substances used or intended for use for the purposes of influencing, inhibiting, or modifying any physiological process in human beings, or the desires or emotions connected with any such physiological process, or the desire for tobacco:

"(d) Any disinfectant, germicide, antiseptic, or preservative used for any purpose:

"(e) Any anaesthetic:

Struck Out

"(f) Any device or appliance used or intended for use for the purpose of producing the effect that would be produced by any drug within the meaning of any of the foregoing provisions of this definition:

"(g) Any laundry soap, any toilet soap, cream, or lotion, and any synthetic detergent:

"(h) Any cosmetic:

"(i) Any dentifrice:

"(j) Any chemical contraceptive:".

(2) Section 2 of the principal Act is hereby further amended by inserting, in their appropriate alphabetical order, the following definitions:

" 'Advertisement' means any words, whether written, printed, or spoken, and any pictorial representation or design or device, used to explain the use or notify the availability or promote the sale of any food or drug; and includes any trade circular, any label, and any advertisement in any trade journal:

" 'Cosmetic' means any substance or mixture of substances used or intended for use for the purposes of cleansing, beautifying, improving, or altering the hair, skin, or complexion of human beings; and includes any perfume, any deodorant, and any dusting powder:

" 'Dentifrice' means any substance or mixture of substances used or intended for use for the purpose of cleansing the mouths or teeth (natural or artificial) of human beings; and includes any denture fixative:

New

" 'Director-General' means the Director-General of Health appointed under the Health Act 1956:

" 'Local authority inspector' means any City Health Inspector, Borough Health Inspector, Town District Health Inspector, County Health Inspector, or Road District Health Inspector:

New

" 'New drug' means any substance or preparation within the meaning of paragraph (a) or paragraph (b) or paragraph (c) or paragraph (j) of the definition of the term 'drug' in this section which has not previously been used in New Zealand; but does not include any dangerous drug within the meaning of the Dangerous Drugs Act 1927 or any radioactive substance within the meaning of the Radioactive Substances Act 1949:".

(3) Section 2 of the principal Act is hereby further amended—

(a) By omitting from the definition of the term "food" the word "man", and substituting the words "human beings":

(b) By adding to the definition of the term "officer" the words "and, in relation to the powers conferred on a local authority inspector by this Act, includes a local authority inspector".

New

(4) The provisions of subsection (4) of section 29 of the principal Act shall apply to any drug which was not within the meaning of the definition repealed by subsection (1) of this section as if any regulations made under the principal Act and in force at the date of the passing of this Act had been gazetted on that date.

(5) Section 2 of the Medical Advertisements Act 1942 is hereby consequentially amended—

(a) By omitting from the definition of the term "cosmetic" the words "(not being a drug)":

(b) By omitting from the definition of the term "dentifrice" the words "(not being a drug)".

3. Advisory and technical committees—The principal Act is hereby amended by inserting, after section 5, the following section:

"5A. (1) The Minister of Health may from time to time appoint such advisory or technical committees as he thinks fit to advise him for any of the purposes of this Act, and may from time to time determine the functions of any such committee.

"(2) There may be paid out of money appropriated by Parliament for the purpose to the members of any committee appointed under this section remuneration by way of fees, salary, or allowances and travelling allowances and expenses in accordance with the Fees and Travelling Allowances Act 1951, and the provisions of that Act shall apply accordingly as if the committee were a statutory Board within the meaning of that Act.

"(3) Subject to the provisions of this Act and of any regulations made under this Act, every such commitee may regulate its own procedure."

4. Offences in relation to sales—Section 6 of the principal Act is hereby amended by inserting in subsection (3), after the word "age", the word "effects".

5. Offences in relation to advertisements—Section 9 of the principal Act is hereby amended—

(a) By omitting from subsection (1) the words "statement, design, or device", and substituting the word "advertisement":

(b) By omitting from subsection (2) the words " a statement, design, or device", and substituting the words "an advertisement".

6. Powers of entry and inspection—(1) Section 12 of the principal Act is hereby amended by inserting, after subsection (1), the following subsection:

"(1A) Any local authority inspector may in respect of any food exercise, within the district or districts in which he is employed, any of the powers conferred on an officer by paragraphs (a) to (d) of subsection (1) of this section."

(2) Section 12 of the principal Act is hereby further amended by omitting from subsection (3) the words "shall become the property of the Crown", and substituting the words "shall, if the seizure was made by an officer other than a local authority inspector, become the property of the Crown, or, if the seizure was made by a local authority inspector, become the property of the corporation of the local authority in whose district he was employed at the time of the seizure".

(3) Section 12 of the principal Act is hereby further amended by repealing subsection (4), and substituting the following subsection:

"(4) Nothing in subsection (3) of this section shall prevent—

"(a) The keeping by the Crown of any food or drug, or the keeping by the local authority of any food, seized under this section, for such period as may be necessary for its production in any proceedings under this Act; or

"(b) The release or return by any officer, whether a local authority inspector or not, of any food or drug seized under this section if he is satisfied that the food or drug is fit for sale or if any conditions or stipulations imposed by him for the purpose of making it fit for sale have been complied with to his satisfaction."

(4) Section 12 of the principal Act is hereby further amended by adding the following subsection:

"(6) It shall be the duty of every local authority to furnish to the Medical Officer of Health from time to time such reports relating to the exercise of the powers of local authority inspectors under this section as the Director-General (*of Health*) or the Medical Officer of Health may require."

7. Power to obtain particulars of certain ingredients—Section 13 of the principal Act is hereby amended by inserting, after subsection (2), the following subsections:

"(2A) For the purpose of enabling the making of regulations under this Act, the Director-General (*of Health*) may from time to time, by notice in writing to the manufacturer in New Zealand of any compounded food or drug which is sold under a trade name, or to the importer into New Zealand of any such food or drug, require such manufacturer or importer to state correctly in writing to the Director-General the nature of the ingredients of the food or drug and the proportions in which those ingredients are contained in it. For the purposes of this subsection, the term "manufacturer", in relation to a food or drug, means the person who, as owner, packs the food or drug for sale or causes it to be so packed.

New

"(2B) The disclosure of any information pursuant to subsection (2A) of this section shall not prejudice any application subsequently made for a patent."

8. Power to require name and address of seller—The principal Act is hereby further amended by inserting, after section 13, the following section:

"13A. (1) Any officer acting in the exercise of any of his powers under this Act may require any person who is in possession of any food or drug for sale, or for delivery upon sale, to state correctly his name and address and, so far as he is aware of them, the name and address of the person from whom he obtained the food or drug.

"(2) Every person commits an offence against this Act who refuses or neglects to comply with any requisition made pursuant to this section."

9. How samples to be taken—(1) Section 16 of the principal Act is hereby amended by omitting from subsection (4) the words "in an insured parcel by any railway, road, or air service", and substituting the words "by any railway service or in an insured parcel by any road or air service".

(2) The proviso to subsection (6) of section 16 of the principal Act (as enacted by section 12 of the Statutes Amendment Act 1951) is hereby amended—

(a) By inserting, after the words "bottled cream", the words "or packaged ice cream or any other frozen confection":

(b) By inserting, after the words "milk or cream", the words "or two packages which purport to contain similar ice cream or a similar frozen confection under the same brand or label".

10. Copy of Analyst's report on sample to be available—Section 17 of the principal Act is hereby amended—

(a) By inserting in subsection (3), after the words "Analyst's certificate" where they first occur, the words "or, if there is no such certificate, a copy of the report made by the Analyst in respect of the sample":

(b) By inserting in subsection (3), after the words "Analyst's certificate", where they last occur, the words "or report":

(c) By inserting in subsection (4), after the words "Analyst's certificate", the words "or report".

11. Statements by Director-General of Health—The principal Act is hereby further amended by inserting, after section 28, the following section:

"28A.(1) Notwithstanding anything in this Act, the Director-General (*of Health*) may from time to time, for the purpose of protecting the public, publish statements in respect of any food or drug, or in respect of any matter contained or implied in advertisements (either generally or in any particular advertisement or any class or classes of advertisements) relating to any food or drug.

"(2) Every statement published under this section shall be privileged unless the publication is proved to be made with malice."

12. Protection of persons acting under authority of Act—The principal Act is hereby further amended by inserting after section 28A (as inserted by section 11 of this Act), the following section:

"28B. A person who does any act in pursuance or intended pursuance of any of the provisions of this Act shall not be under any civil or criminal liability in respect thereof, whether on the ground of want of jurisdiction, or mistake of law or fact, or on any other ground, unless he has acted in bad faith or without reasonable care."

13. Regulations—(1) Section 29 of the principal Act is hereby amended by inserting in paragraph (d) of subsection (2), after the words "freedom from", the words "infection or".

(2) Section 29 of the principal Act is hereby further amended by inserting in subsection (2), after paragraph (d), the following paragraph:

"(dd) Prohibiting, restricting, or regulating the sale or supply for human consumption of unpasteurised milk (being milk within the meaning of the Milk Act 1944) that is infected or is suspected by any Medical Officer of Health, on reasonable grounds, of being infected:".

(3) Section 29 of the principal Act is hereby further amended by adding to paragraph (g) of subsection (2) the words "and requiring any matter to be printed, embossed, impressed, branded, stamped, or otherwise marked on any food or drug (whether sold in a package or otherwise) in such manner as may be prescribed in the regulations".

(4) Section 29 of the principal Act is hereby further amended by inserting, after paragraph (j) of subsection (2), the following paragraph:

"(jj) Requiring that any specified food or drug, or foods or drugs of any specified class or classes, shall be artificially coloured by the addition thereto of such colouring substance or substances as may be prescribed in the regulations, in such proportion or proportions as may be so prescribed:".

(5) Section 29 of the principal Act is hereby further amended by inserting, after subsection (2), the following subsection:

"(2A) Any regulation under this section may empower the Minister of Health to vary by notice in the *Gazette*, for such period (not exceeding twelve months) as may be prescribed in the regulation any limit imposed by any such regulations on the quantity or proportion of any agricultural chemical (within the meaning of the Agricultural Chemicals Act 1959) or other contaminating substance that may be contained in any food or drug."

New

14. New sections inserted—The principal Act is hereby further amended by inserting, after section 11, the following heading and sections:

"Special Provisions as to Drugs

"11A. **Duty of importer or manufacturer to report untoward effects of drug**—(1) If at any time the importer into New Zealand of any drug, or the manufacturer in New Zealand of any drug, has reason to believe that any substantial untoward effects have arisen from the use of the drug, whether in New Zealand or elsewhere, he shall forthwith notify the Director-General of the nature of those effects and the circumstances in which they have arisen, so far as they are known to him.

"(2) Subsection (1) of this section shall not apply in any case where particulars of such effects and circumstances as aforesaid have been published in the English language in any medical or pharmaceutical publication or periodical which in the ordinary course is circulated among or distributed to members of the medical and pharmaceutical professions in New Zealand.

"11B. **Distribution of new drugs restricted**—(1) Every person who proposes to import into or manufacture in New Zealand any new drug shall deposit with the Director-General a notice in writing setting out the information specified in subsection (3) of this section.

New

"(2) Except with the prior consent in writing of the Director-General, no person shall sell, or distribute by way of gift, loan, or sample or in any manner whatsoever, or advertise for sale, or advertise the availability of, any new drug until after the expiry of at least ninety days from the date of the deposit with the Director-General of such notice as aforesaid.

"(3) The notice required by subsection (1) of this section shall be in the true name of the person by whom the notice is deposited, and shall set out—

"(a) His address and, if he is not the manufacturer, the true name and address of the manufacturer:

"(b) The name under which the drug will be distributed:

"(c) A full statement of the ingredients, named by descriptive or non-proprietary names, including details of the quantities in which they are contained in the drug:

"(d) A description of the form or forms of the drug:

"(e) The proposed or recommended dosage and frequency of dose, and the manner in which the drug will be recommended to be administered, applied, or otherwise used:

"(f) The purposes for which the drug will be recommended to be used, and the claims to be made in respect of its usefulness:

"(g) Reports of any tests made to establish the safety of the drug for the purposes for which and in the manner in which it is intended to be used:

"(h) Reports of any tests made to control the strength, quality, purity, or safety of the drug:

"(i) The intended method of distribution of the drug in New Zealand:

"(j) A specimen of every label proposed to be used on packages containing the drug:

"(k) If the drug is to be manufactured, prepared, or packed in New Zealand, the name and address of the place or places where the manufacture, preparation, or packing is intended to be carried out.

"(4) For the purposes of section 27 of the Poisons Act 1960, every notice deposited with the Director-General under this section shall be deemed also to be a notice to the Registrar satisfying the requirements of subsections (1) and (2) of that section.

New

"(5) In any proceedings for an offence against this section the drug to which the proceedings relate shall be presumed to be a new drug until the contrary is proved.

"11C. **Distribution of changed drugs restricted**—(1) Where at any time after the commencement of this section a material change is made by the manufacturer of any drug, whether in New Zealand or elsewhere, in—

"(a) The purpose for which the drug is intended to be used, or the recommended dosage, or the recommended manner of administration; or

"(b) The labelling of the drug or of any package containing it; or

"(c) The pharmaceutical form of the drug; or

"(d) The strength, quality, or purity of the drug; or

"(e) The methods of manufacture, or the facilities for testing the strength, quality, purity, or safety of the drug—

the importer into New Zealand of the drug, or its manufacturer in New Zealand, shall deposit with the Director-General a notice in writing describing the change and giving particulars, so far as they are known to him, of any effect that the change might have on the safe consumption or use of the drug.

"(2) Except with the prior consent in writing of the Director-General, no person shall sell any drug in respect of which any such change as aforesaid has been made, or distribute it by way of gift, loan, or sample or in any manner whatsoever until after the expiry of at least ninety days from the date of the deposit with the Director-General of such notice as aforesaid.

"11D. **Further particulars**—(1) Within thirty days after the deposit of any notice under section 11B or section 11C of this Act the Director-General may by notice in writing given to the person in whose name the first-mentioned notice was deposited require him to supply such further information or particulars as the Director-General may require with respect to any matter set out in that notice.

"(2) Every person to whom notice is given under this section shall, within thirty days after the receipt by him of the notice, comply with the requirements set out therein, so far as he is able to do so.

New

"11E. **Exemption for investigation**—(1) Notwithstanding anything in section 11B or section 11C of this Act, but subject to the provisions of this section, any drug may be distributed by the importer or manufacturer, for the sole purpose of obtaining clinical and scientific information with respect to its safety, stability, appropriate dosage, or efficacy, to persons who are for the time being approved by the Director-General as being qualified, either generally or in relation to any particular drug or class of drugs or in any particular circumstances or class of circumstances, to use the drug for that purpose.

"(2) The distribution of any drug under this section shall be subject to the following conditions, namely:

"(a) That the Director-General shall be informed, before the drug is so distributed, of the identifying name or mark by which it may be recognised:

"(b) That every label on every package of the drug shall bear the words 'To be used by qualified investigators only':

"(c) That the importer or manufacturer shall, before so distributing the drug, take all reasonable steps to ensure that every person to whom it is supplied is approved under this section as a person qualified to carry out, and has available the necessary facilities for, the investigation to be conducted by him, and that the drug will be used solely by that person or under his direction for the purposes of such investigation:

"(d) That the importer or manufacturer shall keep complete and accurate records of all quantities of the drug so supplied and of the results of the investigation, and shall make copies of those records available to the Director-General when required to do so.

"11F. **Exemption for drug required by medical practitioner**—Nothing in section 11B or section 11C of this Act shall prevent the supply by any person to any medical practitioner, on his request, of any drug required by him for the treatment of a patient under his care, or the administration by any medical practitioner of any drug to any such patient.

New

"11G. **Offences**—Every person who contravenes or fails to comply with any of the provisions of sections 11A to 11E of this Act or any requirement thereunder commits an offence and is liable to a fine not exceeding five hundred pounds and, if the offence is a continuing one, to a further fine not exceeding fifty pounds for every day on which the offence has continued."

15. Medical appliances—The principal Act is hereby further amended by inserting, after section 31, the following section:

"31A. The provisions of this Act relating to drugs, so far as they are applicable, shall extend and apply to any device or contrivance sold for the purpose of producing the effect that would be produced by a drug within the meaning of any of the provisions of paragraphs (a) to (e) of the definition of the term 'drug' in section 2 of this Act."

WELLINGTON, NEW ZEALAND: Printed under authority of the New Zealand Government, by R. E. OWEN, Government Printer—1962