The signatories to this document hereby agree to adhere to the Guidelines as set out below:

GUIDELINES APPLICABLE TO OFFERS OF- AND ACTUAL SALE OF DATA RELATING TO MEDICINES IN SOUTH AFRICA

Preamble

Data is an important commodity in all sectors and of particular importance in the healthcare sector, as it assists in healthcare planning, determining current patterns of treatment and medicines utilisation, as well as health outcomes and quality of care.

South Africa currently has no legislation specifically dealing with data protection. The general right to privacy contained in the South African Constitution of 1996 and the protections implied in the Promotion of Access to Information Act of 2000 are, however, applicable to situations of data collection, manipulation and sale.

The sale of data might, however, also be used in a manner inconsistent with patient interest and access to healthcare and the availability of treatment options. Recent documents have attempted to address these concerns, in, amongst others prohibiting perverse incentives in the healthcare sector, requiring that medicine formularies and treatment guidelines should be based on evidence and the promulgation of new anti-corruption legislation.

These guidelines are issued to determine acceptable parameters in connection with the sale and offers of sale of data in the healthcare industry.

1. Purpose

The objectives of these guidelines are -

1.1 To promote ethics in the healthcare industry and in particular the pharmaceutical- and related industries by providing a common framework for all involved in the particular transactions envisaged by these guidelines.
1.2 To eliminate the potential for perverse practices.
1.3 To provide for incidental matters incidental to the above objectives.

2. Application

2.1 These guidelines shall apply to actual and potential sales or offers of sale, and will therefore apply to sellers and potential sellers and/or - purchasers regardless of the imminence or realisation of the transaction of sale.

2.2 Further, these Guidelines will apply to situations, as described in 2.1. and that involve the following individuals and groups, irrespective of their legal status:

2.2.2 Professional providers of healthcare, including but not limited to medical practitioners and other persons registered with the HPCSA, pharmacists, pharmacy assistance and pharmacy groups and owners, registered by the Pharmacy Council, nurses, allied health professionals, etc.
2.2.3 The providers, wholesalers, importers and manufacturers of medical supplies, including medicines and medical devices.

2.2.4 Institutional providers of healthcare, including but not limited to hospitals, clinics, step-down facilities, etc.
2.2.5 Managed care- and similar organisations and/or their constituent members.
2.2.6 Independent practitioners' organisations and other healthcare provider groupings and/or their constituent members.
2.2.7 Medical schemes and medical scheme administrators.
2.2.8 (Electronic) claim and data processing institutions and warehouses.
2.2.9 Other healthcare funding institutions, e.g. those relating to motor-vehicle accidents, life, funeral or disability insurance, etc.
2.2.10 Independent third party data/information brokers appointed by any of the above acting as agents between the parties.

2.3 This list is not exhaustive and spirit of the guidelines will dictate its application.

2.4 The guidelines do not apply to situations where data-agreements are incorporated in logistics fees.

3. Interpretation

3.1 Any person applying these regulations must interpret its provisions-

3.1.1 to give effect to its objectives;
3.1.2 in compliance with the Constitution;
3.1.3 in compliance with the Code of marketing practice published in terms of the Medicines and Related Substances Act of 1965
3.1.4 In compliance with the Promotion of Access to Information Act
3.1.5 The HPCSA policy on perverse incentives and any other similar policy document from professional councils and
3.1.6 Any other relevant legislation in the RSA.

4. Guidelines on the sale of data

Whilst recognising the potential commercial value of data relating to medicines prescription, dispensing and reimbursement, the following principles should guide the offer, sale and purchase of such data:

4.1 The data must be relevant and of demonstrable commercial value to the buyer, in that it may assist in the understanding of –
(a) The treatment of a condition, especially in view of the requirement that all conditions would need to be coded from 2005 using the ICD10 system.
(b) The prescribing, dispensing or reimbursement rates of healthcare professionals, providers and/or funders.
(c) Market potential for the sale and utilisation of pharmaceutical products;
(d) The distribution of products within the- or a particular market

4.2 Data offered or sold shall be correct and verifiable and this shall include that -
(a) The methodology used to collect the data is scientific, verifiable, accurately recorded and readily available;
(b) Records of and/or actual proof of the original documentation sources from which the data is drawn, compiled and/or collated are kept and are available on request.
(c) The coverage of the data to be specified by the seller (percentage of national scripts processed or percentage of medical aid members covered In conjunction with the coverage would be geographical spread of the data ie. whether the data is from one region only or evenly distributed nationally) in order to facilitate objective decision-making on the value and reliability of the data.

4.3 Agreements relating to the sale of data should not be subjected to other conditions over which the seller has no authority, or which does not relate to the merits or price of the medicine, including –

(a) The procurement and supply of medicines (e.g. whether product is kept on stock, payment, etc.)
(b) The inclusion or exclusion of a product from a formulary
(c) Medicines regulatory affairs (registration, labelling, marketing, etc.) as governed by the MCC, Department of Health or any other applicable regulatory authority.

4.4 The seller must have the authority to sell the data, including permission as required by shareholders and suppliers (i.e. doctors, pharmacies, hospitals, wholesalers, distributors etc.) to transact on their behalf and the seller must have legal ownership of the data.

4.5 The rates (prices) and scales, if applicable, at which data is sold should be transparent and should be available on request.

5 Undue influence

5.1 Purchaser will not use data in any attempt to place any undue influence on a prescriber, dispenser or reimburser of the products.

5.2 The seller or any of its members, affiliates or constituents will not use the sale of any data or patterns emerging from data, or use volumes or similar factors to set or vary the price of such sale, in contravention of the principles set out in this guideline. The principles include, but are not limited to the following situations:

5.2.1 Selling data or offering of data for sale in contravention of the provisions of the Policy Statement on Perverse Incentives of the Health Professions Council of 2001.
5.2.2 Subjecting the inclusion of a product on a formulary or treatment guideline to the purchase of data by the manufacturer of that product.
5.2.3 Setting a formulary or treatment guideline for utilisation in the medical schemes environment in contravention of the requirements set in regulations 15, 15H and 15I to the Medical Schemes Regulations.
5.2.4 Incentivising or using, or attempting to use data to enforce or motivate alterations to patterns of scripting, dispensing or reimbursement on the basis of the willingness or unwillingness of a potential purchaser to buy the data.
5.2.5 Offering constituent members any incentive directly related to the scripting, dispensing or reimbursement of any product of the purchaser.
5.2.6 Setting any condition that may constitute an (attempted) act of corruption, - bribery or - fraud.
5.2.7 Setting any condition that leads to behaviour that is not in the interest of any patient or patient group.
5.2.8 Setting any condition that affects the access of marketers to potential or existing markets or clients, including access to healthcare facilities and/or events.
5.2.9 Using the sale of data as a mechanism to make up for, or justify the offer of data on the basis of the new transparent pricing system, including any now defunct- discounting, - rebate or - bonusing system.

6 Use of data by purchaser

6.1 The purchaser will not use the data bought to –
6.1.1 Compete with the seller in the field of data provision or
6.1.2 Re-sell such data, unless expressly authorised to do so by the seller or the agreement.

6.2 The intellectual property rights of the seller in the data sold are recognised, and the rights awarded in terms of the relevant provisions of the Promotion of Access to Information Act and the provisions of the Pricing Regulations of 2004, as it pertains to the information that may be requested by the Director-General from time to time.

7 All agreements in writing

All agreements of data sale shall be reduced to writing and should be transparent in view of ensuring compliance with these guidelines and applicable legislation.

Signed at _____ on this _____day of _____ 2_____.

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